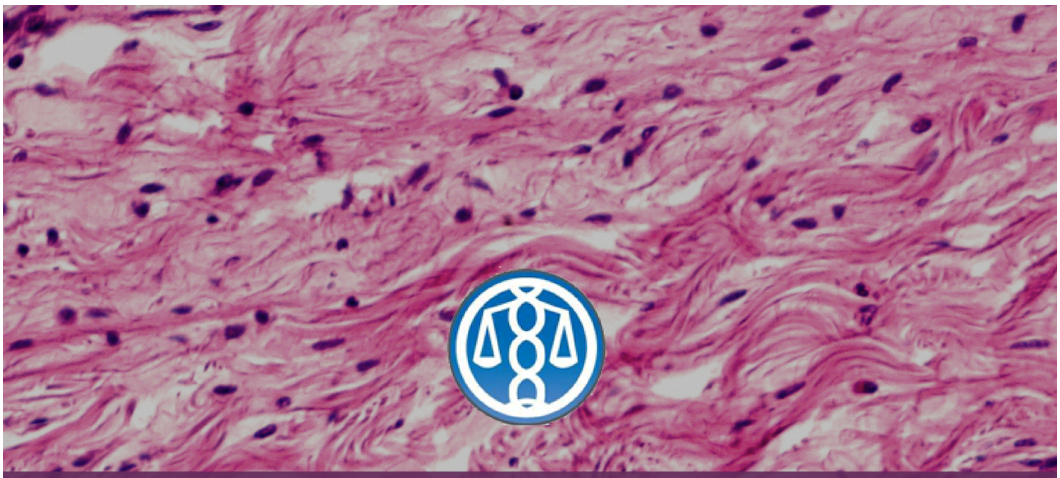
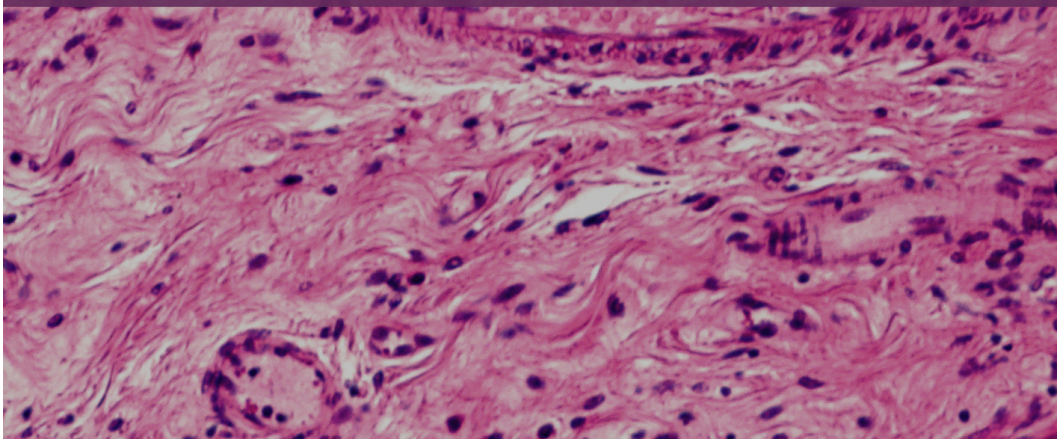


Centre for Law and Genetics
Occasional Paper No 10

MY WAY OR THE MTA

The Use of Material Transfer Agreements in Publicly Funded Research in Australia

JANE NIELSEN, DIANNE NICOL, TESS WHITTON AND DON CHALMERS



MY WAY OR THE MTA:
THE USE OF MATERIAL TRANSFER AGREEMENTS IN PUBLICLY FUNDED RESEARCH IN AUSTRALIA

Centre for Law and Genetics

University of Tasmania

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PREFACE

This Occasional Paper is the product of a four-year study investigating the use of material transfer agreements (MTAs) in Australian publicly-funded, biological research. The study commenced in 2014, and was inspired by similar studies, primarily conducted in overseas jurisdictions, which reported that MTAs have been having detrimental impacts on the progress of research. Our aim was to consider whether similar trends were evident in Australian research, and the implications of these practices on research. The study involved:

- interviews with technology transfer officers and scientists in universities and research institutes;
- a survey of scientists;
- review of existing literature and empirical research;
- review of the terms of standard and template MTAs which were either provided to us by interviewees or freely available online;
- analysis of publicly available data from websites and other sources; and
- case law and doctrinal analysis.

The study was funded by the Australian Research Council Discovery Grants Scheme (DP140100301).

We thank all participants in our study for giving their time so generously. As always, we were amazed by how willing people are to speak with us and contribute to our research. We also thank our research staff for the invaluable assistance they provided during the course of the project. In particular, we thank John Liddicoat, Bryanna Workman and Tracey Jacques for their help in transcribing, collating, researching, calculating, and grappling with data. This Occasional Paper would not have come to fruition without Bryanna Workman who worked tirelessly to format, edit and see it to publication.

In November 2016 collaborators and members of our expert advisory team met with the research team in Hobart for a two-day workshop to share research results and debate solutions to the MTA impasse.[1] We thank all participants for their collegiality and invaluable contributions.

[1] Participants included the research team and Dr John Liddicoat (Cambridge University, UK), Professor Tania Bubela (University of Alberta, Canada), Dr Joanne Kamens (Addgene), Dr Linda Kahl (Biobricks Foundation, US), Professor Charles Lawson (Griffith University, Australia), Dr Amber Johns (Garvan Institute of Medical Research, Australia), Ann Monotti (Monash University, Australia), Dr Julian Clark (Walter and

Study findings and conclusions were presented at various other fora, including: The European Policy in Intellectual Property (EPIP) Conference in 2014, 2015 and 2016; the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP) Congress in 2017; the Australasian Intellectual Property Academics Conference in 2014 and 2016; the Intellectual Property Research Institute of Australia (IPRIA) IP and Media Law Conference in 2015; and The Network for Bodies, Organs and Tissues (NBOT) Inaugural Annual Symposium in 2014.

Professor Nicol was invited to attend and present at a number of national and international workshops during the course of the study, including: the OECD Workshop, Gene Editing in an International Context: Scientific, Economic and Legal Issues across Sectors, Ottawa Canada, in 2016; The Future of Genomic Medicine Patents in Europe Workshop, Cambridge University in 2016; QUT Gene Patent Forum, Brisbane, Australia in 2016; The Workshop on Analysing Policy Impacts on Biotechnology Innovation Using Patent Data, Duke Sanford School of Public Policy, McGill University Faculty of Law and University of Alberta School of Public Health, Washington DC in 2014; and a seminar at Swinburne University, Melbourne, Australia.

The following peer reviewed articles and book chapters incorporate aspects of this study:

> Jane Nielsen, Tania Bubela, Don Chalmers, Amber Johns, Linda Kahl, Joanne Kamens, Charles Lawson, John Liddicoat, Rebekah McWhirter, Ann Monotti, James Scheibner, Tess Whitton, and Dianne Nicol, 'Provenance and Risk in Transfer of Biological Materials' (2018) *PLOS Biology* doi.org/10.1371/journal.pbio.2006031
>
> Rochelle Dreyfuss, Jane Nielsen and Dianne Nicol, 'Patenting Nature – A Comparative Perspective' (2018) *Journal of Law and the Biosciences* doi: 10.1093/jlb/lsy021
>
> Jane Nielsen and Dianne Nicol, 'Patent Law and the March of Technology: Did the Productivity Commission Get It Right?' (2017) 28(1) *Australian Intellectual Property Journal* 4

Eliza Hall Institute of Medical Research, Australia), Professor Clare Scott (Walter and Eliza Hall Institute of Medical Research, Australia), Dr Rebekah McWhirter (University of Tasmania, Australia) and Mr James Scheibner (University of Tasmania, Australia).

Dianne Nicol, 'Gene Patents' in Ian Freckleton and Kerry Petersen (eds), *Tensions and Traumas in Health Law* (The Federation Press, 2017) 401

Tess Whitton, Dianne Nicol and Don Chalmers, 'Human Embryos, Genome Editing and Future Directions' in Ian Freckleton and Kerry Petersen (eds), *Tensions and Traumas in Health Law* (The Federation Press, 2017) 384

Christine Critchley and Dianne Nicol, 'Commercialisation of Genomic Research: The Issue of Public Trust' in Ian Freckleton and Kerry Petersen (eds), *Tensions and Traumas in Health Law* (The Federation Press, 2017) 350

Jane Nielsen and Dianne Nicol, 'The Legal Vacuum Surrounding Access to Gene-Based Materials and Data' (2016) 24 *Journal of Law and Medicine* 72

Dianne Nicol, 'The Changing Role of IP in Genomics' (2016) July/August *Australasian Science*

Dianne Nicol, 'Myriad Genetics and the Remaining Uncertainty for Biotechnology Inventions' in Charles Lawson and Berris Charnley (eds), *Intellectual Property and Genetically Modified Organisms: A Convergence in Laws* (Ashgate, 2016) 123

Don Chalmers, Dianne Nicol, Pilar Nicolas and Nik Zeps, 'A Role for Research Ethics Committees in Exchanges of Biospecimens through Material Transfer Agreements' (2014) 11 *Journal of Bioethical Inquiry* 301-306

Dianne Nicol, Don Chalmers, Rebekah McWhirter and Joanne Dickinson, 'Impressions on the Body, Property and Research' in Imogen Goold, Kate Greasley, Jonathan Herring and Loane Skene (eds) *Persons, Parts and Property: How Should We Regulate Human Tissue in the 21st Century?* (Hart Publishing, 2014) 9

A version of Chapter Two has been submitted for publication and is currently under review. The status of this publication will be made available on our website.

The following submissions were made in response to calls for submissions to law reform inquiries:

Isabella Alexander, Catherine Bond, Kathy Bowrey, Robert Burrell, Michael Handler, Graham Greenleaf, Dianne Nicol, Jane Nielsen,

Kimberlee Weatherall, written submission to Productivity Commission Draft Report, *Intellectual Property Arrangements,* 3 June 2016

Dianne Nicol, Jane Nielsen, Don Chalmers and Tess Whitton, Centre for Law and Genetics Submission to the World Health Organisation (WHO), 'Blueprint on Draft R & D BluePrint MTA Tool', 16 June 2017

Jane Nielsen and Dianne Nicol, written submission to the Productivity Commission Issues Paper, *Intellectual Property Arrangements,* November 2015

All references to material contained in these articles has been footnoted throughout this Occasional Paper.

The authors have no conflicting interests.

To the best of the authors' knowledge, the literature relied upon in this Occasional Paper was current as at 21st December 2018.

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CHAPTER 1

INTRODUCTION AND BACKGROUND

1.1 INTRODUCTION

The sharing of scientific knowledge is a fundamental premise of scientific endeavor.[2] During the last four decades we have witnessed the increasing engagement of universities and public research institutes with industry, and the development of national biotechnology strategies aimed at commercialising research, coinciding with a move away from the scientific norm of free and open sharing.[3] University policies for

[2] See, eg, United Nations Educational, Scientific and Cultural Organisation, *Universal Declaration on Bioethics and Human Rights,* 33 C/22 (adopted 19 October 2005) art 15.

[3] Victor Rodriguez, 'Merton and Ziman's Mode of Science: The Case of Biological and Similar Material Transfer Agreements' (2007) 34 *Science and Public Policy* 355.

engagement with industry began to be directed towards protection of intellectual property rights and their transfer to industry through assignment, licensing and creation of spin out companies. This university engagement with industry resulted in the emergence of specialist technology transfer offices (TTOs) and the increasing formalisation of exchanges of biological materials.[4]

The Genome Era has been marked by an expansion of research collaborations into different institutes, different countries and multi-centre consortia. Somewhat paradoxically, despite the impetus to commercialise research gaining momentum, raw research data are increasingly shared amongst researchers and uploaded on open access sites to maximise their availability to other interested research groups.[5] This modern open access culture has been promoted by major research funders and aims to increase the volume and quality of research using existing and new datasets.

In the context of genomic research, a range of biological materials are transferred, including but not limited to whole living organisms, human and other tissue, reagents, cell lines, plasmids and vectors. The tradition of sharing these research tools is not new: customarily, biological materials were freely exchanged between researchers, frequently without any type of legal documentation.[6] Material transfer agreements (MTAs) began to enter the picture as the mandate of universities moved towards capturing the commercial potential of innovation.

An MTA can be defined as:

> *a contract that governs the transfer of tangible research materials between two organizations, a provider and a recipient, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider*

4 See, eg, Brady Huggett, 'Reinventing Tech Transfer: US University Technology Transfer Offices Are Adopting New Models in Search of Increased Return on Research Investment' (2014) 32 *Nature Biotechnology* 1184; Timothy Caulfield, Shawn HE Harmon and Yann Joly, 'Open Science Versus Commercialization: A Modern Research Conflict?' (2012) 4(2) *Genome Medicine* 17.

5 See, eg, Toronto International Data Release Workshop Authors, 'Prepublication Data Sharing' (2009) 461 *Nature* 168.

6 Alan B Bennett, Wendy D Streitz and Rafael A Gaecel, 'Specific Issues with Material Transfer Agreements', in Anatole Krattiger et al (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR and PIPRA, 2007) 697.

> *and the recipient with respect to the materials and any derivatives.*[7]

Much has been written about the probable impact of formalisation on scientific endeavor, and yet how these formalised MTAs operate in an era of open science remains unclear. In particular, it is not clear whether MTAs facilitate or stifle collaborative research in the emerging genomic research commons. As the formalisation of the transfer process proliferated, a body of literature started to emerge documenting the inevitable issues that accompany any cultural shift. There have been a number of studies conducted into the effects of MTAs, primarily in the United States of America (US). This scholarship suggested that MTAs could interfere with progress in genomics, particularly if they involve protracted negotiations and include the following types of terms: grant-back provisions providing for an option to license patent rights to subsequent discoveries; prohibitions on researchers from sharing with other institutions; and pre-publication review of research results.[8]

It is well documented that MTA negotiations may delay research and deter collaboration.[9] At worst, refusals to enter into MTAs may lead to project abandonment. Onerous terms could have a similar effect, particularly if they relate to reach-through rights or publication restrictions.[10] Obligations imposed on users to agree to such terms could be at odds with the expanding open data access and open science policies of public funders.[11] Innovation could also be impeded, particularly in the context of healthcare.[12] Potentially, then, MTAs could increase research transaction costs with a flow-on effect on research, commercial development and translation of research into products and treatments.

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7 International Society for Biological and Environmental Repositories, 'Best Practices for Repositories Collection, Storage, Retrieval, and Distribution of Biological Materials for Research (Third Revision)' (2012) 10(2) *Biopreservation and Biobanking* 79.

8 'Report of the NIH Working Group on Research Tools' (Report, NIH, 4 June 1998) 4 <https://www.mmrrc.org/about/NIH_research_tools_policy/>.

9 See further below at 1.3.1.

10 Arti K Rai and Rebecca S Eisenberg, 'Bayh Dole Reform and the Progress of Biomedicine' (2003) 66 *Law and Contemporary Problems* 289, 294–5; Victor Rodriguez, 'Material Transfer Agreements: A Review of Modes and Impacts' (2009) 27 *Prometheus: Critical Studies and Innovation* 141.

11 Caulfield, Harmon and Joly, above n 4, 6–9.

12 David C Mowery and Arvids A Ziedonis, 'Academic Patents and Materials Transfer Agreements: Substitutes or Complements?' (2007) 32 *The Journal of Technology Transfer* 157, 160–2; E Richard Gold et al, 'Are Patents Impeding Medical Care and Innovation?' (2010) 7(1) *PLoS Medicine* e1000208 <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000208>.

MTAs are in common use in Australia and other countries. There has been no major study in this country to understand whether MTAs promote, impede or delay collaborative research. The aim of this study is to build on this empirical foundation and assess the status of the MTA landscape in Australia.

Our study involved investigation of the role of MTAs in exchanges of biomedical materials involving publicly funded universities and other research institutions in Australia. Australia has a rich tradition of biomedical research, particularly research emanating from public funding.[13] At the time we conducted the study, there were 43 accredited universities, a small number of which are engaged in very limited amounts of research, but most of which have significant research programs. A number of research institutes are also engaged in health and medical research. Some of these research institutes are associated with universities, and some are independent; some are publicly funded and some are privately funded.

This study was undertaken in light of the detailed exploration of these issues overseas, and in light of the fact that it is likely that the number of MTAs in circulation has proliferated in Australia, just as it has elsewhere. The study had both empirical and doctrinal components. There were three empirical components of the project, involving: interviews with individuals involved in the process of negotiating and transacting formalised exchanges of materials through MTAs (most, but not all of whom were located in TTOs); interviews with and surveys of the researchers who generate and use those materials; and analysis of the terms of the MTAs themselves. For the doctrinal component of the project, we briefly consider how the major legal institutions of contract law, intellectual property law, property law, privacy law and other aspects of the law might govern the content and use of MTAs. This analysis is necessarily accompanied by reference to national and institutional intellectual property and research ethics obligations, and other policies and guidelines. This integrated analysis permits options for best practice governance of MTAs to be carefully evaluated. The limited academic literature on MTAs highlights the need for this research to understand and promote effective, efficient and ethical exchanges of materials.

[13] See, eg, Warwick Anderson, 'Healthy, Wealthy and Affordable', (Speech delivered at the QIMR Berghofer Medical Research Institute Derrick-Mackerras Lecture, 21 October 2014) <https://www.nhmrc.gov.au/media/newsletters/ceo/2014/healthy-wealthy-and-affordable>.

1.2 KEY DRIVERS FOR THE USE OF MTAS

A major explanation for the growth in the use of MTAs has been posited to be the protection of opportunities for commercialisation,[14] and clarification of the arrangements between the parties with respect to present and future IP rights.[15] The trend towards formalisation of materials exchanges can also be attributed, to some extent, to concerns about the biosafety of biological materials and the development of biosafety principles.[16] Laying the ground rules for indemnification from liability in the event of misuse or accidents involving a research material has frequently been cited as a basis for formalising material transfers.

As we know, for many researchers, free and open sharing has been a practice norm for many years. Nonetheless, these open transfers have been governed by the understanding that contribution through provision of a sample would be attributed in some way to the supplier of that sample according to their degree of input. This usually entails acknowledgement or the provision of authorship rights. MTAs evolved in part as a vehicle to cement this right to attribution in an era where research metrics are increasingly important in maintaining research performance and securing competitive funding. Contrary to principles of academic freedom, however, it is not uncommon for clauses in MTAs to impose requirements for pre-publication review, restrictions on disclosure, and limitations on field of use.

The expansion of formalisation can also be traced to concerns about the provenance of tissue, as illustrated by various policy statements in the context of biobanks (collections of human tissue available for research). The Organisation for Economic Co-operation and Development (OECD) developed best practice guidelines for biobanks in 2009 and recommended that the 'terms of access for researchers to specimens and samples collected from participants, should be set out in a material transfer agreement or other agreement appropriate for that purpose' to enable the tracking of data and sample usage.[17] Similarly, the

[14] Wendy D Streitz and Alan B Bennett, 'Material Transfer Agreements: A University Perspective' (2003) 113 *Plant Physiology* 10, 10.

[15] Zhen Lei, Rakhi Juneja and Brian D Wright, 'Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research' (2009) 27 *Nature Biotechnology* 36.

[16] Jacqueline Peel, *The Precautionary Principle in Practice: Environmental Decision-Making and Scientific Uncertainty* (Federation Press, 2005).

[17] Organisation for Economic Co-operation and Development, *OECD Guidelines on Human Biobanks and Genetic Research Databases* (OECD Publishing, 2009) 7.6.

International Society for Biological and Environmental Repositories (ISBER), in promoting uniform best practice standards, proposed standardisation of common terms and the types of considerations that MTAs 'should address'.[18] ISBER devoted a session to MTAs at an international summit on biobanks in Sweden in 2012. In Australia, the National Health and Medical Research Council (NHMRC) has stated that MTAs 'are an important mechanism for ensuring traceability of biospecimens and data, and transparency and accountability on the part of biobanks and their users'.[19]

1.3 DOCUMENTED STICKING POINTS IN MTA NEGOTIATIONS

A considerable amount of anecdotal evidence during the early 2000s hinted that transfers of tangible research materials were potentially posing more problems for scientific advancement than hold-ups involving patents, with delays due to glitches in the negotiating process being a major problem.[20] The issue of delay has been posited to be more pronounced where universities are receiving materials from commercial entities.[21] A series of empirical studies followed, which demonstrated that some exchanges of tangible materials were prone to denials of access or protracted negotiations.

1.3.1 Withholding and Delaying Access

There is some data on withholding of materials. A survey conducted by Campbell et al in 2002 found the prevalence of withholding of information, data and materials to be significant, with 35 per cent of geneticists reporting having a request for biomaterials denied.[22] Amongst doctoral and postdoctoral researchers, Vogeli et al observed almost a

[18] International Society for Biological and Environmental Repositories, above n 7, M2.610.

[19] 'Biobanks Information Paper' (Information Paper No E110, National Health and Medical Research Council, 2010).

[20] Rebecca Eisenberg, 'Bargaining over the Transfer of Research Tools: Is this Market Failing or Emerging?' in Rochelle Dreyfuss, Dianne L Zimmerman and Harry First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (Oxford University Press, 2001) 223.

[21] Streitz and Bennett, above n 14; Amrita Mishra and Tania Bubela, 'Legal Agreements and the Governance of Research Commons: Lessons from Materials Sharing in Mouse Genomics' (2014) 18(4) *OMICS* 254.

[22] Eric Campbell et al, 'Data Withholding in Academic Genetics: Evidence from a National Survey' (2002) 287 *Journal of the American Medical Association* 473, 473, 476–8.

quarter having a request for information, data or materials refused.[23] In a subsequent, influential study, Walsh, Cho and Cohen found that 19 per cent of their respondents had a request for a material from another academic researcher refused and that 33 per cent of requests to industry researchers were not fulfilled.[24] At least eight per cent reported a (usually temporary) cessation in a research project due to an inability to access a material.[25] Twenty per cent of respondents reported that their most recent request for a material was not granted.[26] Walsh, Cho and Cohen subsequently concluded that their evidence supported the conclusion that requests for materials had become increasingly likely to be met with a refusal since the study by Campbell et al.[27]

Data on whether the use of MTAs provokes delays in the transfer of materials is more equivocal. Respondents in a survey conducted by Henry et al reported that because MTAs usually protect 'non-valuable' materials, they generally proceed with less negotiation, and correspondingly take less time than more complex agreements such as patent licence agreements.[28] In contrast, Monotti undertook a survey of health science-related researchers at Monash University in Australia and found that a significant number of respondents considered delays in obtaining research materials to be the main source of frustration or the main adverse effect in transactions involving the exchange of materials.[29] This factor was the primary source of discontent amongst respondents.[30] Although respondents were not specifically asked whether this

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[23] Christine Vogeli et al, 'Data Withholding and the Next Generation of Scientists: Results of a National Survey' (2006) 81(2) *Academic Medicine* 128, 128, 131, 133–2; See also David Blumenthal et al, 'Data Withholding in Genetics and the Other Life Sciences: Prevalences and Predictors' (2006) 81(2) *Academic Medicine* 137.

[24] John P Walsh, Charlene Cho and Wesley M Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research' (2007) 36 *Research Policy* 1184, 1191.

[25] Ibid 1193; John P Walsh, Charlene Cho and Wesley M Cohen, 'Patents, Material Transfers and Access to Research Inputs in Biomedical Research' (Final Report, National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions, 20 September 2005) <http://www2.druid.dk/conferences/viewpaper.php?id=776&cf=8>.

[26] Walsh, Cho and Cohen, 'Patents, Material Transfers and Access to Research Inputs', above n 25, 38.

[27] Walsh, Cho and Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research', above n 24, 1193; Walsh, Cho and Cohen, 'Patents, Material Transfers and Access to Research Inputs', above n 25, 15.

[28] Michelle R Henry et al, 'A Pilot Survey on the Licensing of DNA Inventions' (2003) 31 *Journal of Law, Medicine and Ethics* 442, 446.

[29] Ann L Monotti, 'Access to Tangible Research Materials in Biomedical Research (7 May 2012)' (2006) 14 *Journal of Law and Medicine* 86.

[30] Ibid 100.

frustration or adverse effect related to an MTA, Monotti seems to infer that a considerable number of them answered in this way due to an accompanying MTA.

A study of the American Association for the Advancement of Science (AAAS) reported high use of MTAs in transferring technology,[31] with the procurement of MTAs accounting for more 'difficulties' in transferring patented technologies than any other factor.[32] Settlement times for MTAs (whether involving patented technologies or not) were significant. Forty per cent of transfers involving MTAs took between two and six months, while 32 per cent occurred within one to two months.[33] Transfers were more likely to be conducted within this timeframe where a transfer was academic to academic (46 per cent). The time frame was more likely to be two to six months where industry was involved (48 per cent of total transfers).[34]

In addition to reporting on withholding materials, Walsh, Cho and Cohen made some notable observations about delays caused by the MTA process. In their study, 11 per cent of requests for materials occasioned a delay of more than one month (in receiving material).[35] Admittedly, the requirement to enter into an MTA was not the only reason why these difficulties were being encountered, in that only around 42 per cent of requests for a material were actually accompanied by an MTA.[36] In fact, Walsh, Cho and Cohen observed that more disagreement was likely to be encountered where a transfer was *not* accompanied by an MTA, which seemed to indicate that there would have been reluctance to transfer these particular materials in any event. Negotiations were required in only 40 per cent of instances where an MTA accompanied the transfer, and just 26 per cent required any significant negotiation of MTA terms, or negotiation lasting for longer than one month.[37]

Relevantly, Walsh, Cho and Cohen also explored the impact of TTO involvement in the MTA negotiation process. Generally speaking, TTOs were not always involved in transfers of materials, but were more likely

31 Stephen A Hansen, Michael R Kisielewski and Jana L Asher, *Intellectual Property Experiences in the United States Scientific Community* (American Association for the Advancement of Science, 2007) 20–1.

32 Ibid 24–5.

33 Ibid 22–3.

34 Ibid.

35 Walsh, Cho and Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research', above n 24, 1193.

36 Ibid 1192–3.

37 Ibid 1193.

to be where industry was involved in the transfer, or where the other party attempted to impose terms that might be considered problematic.[38] Walsh, Cho and Cohen found that requests for materials were more likely to be refused where a TTO was involved in the MTA negotiation process,[39] and significantly more likely to be delayed.[40] This may reflect the fact that TTO personnel see more complicated transfers,[41] although it might be possible to surmise that they are implicated in these delays.

Finally, Mishra and Bubela reported friction between researchers operating in the pre-competitive space and TTO personnel, particularly with regard to extended and delayed negotiations. Examples provided by respondents suggested that delays of six to eighteen months were not uncommon.[42]

One of the aims of the present study was to assess the extent to which delays are actually occurring in MTA negotiations in Australia, and what might be the root causes of these delays.

1.3.2 The Link between Withholding and Delays and MTAs

The evidence that MTAs can have a significant impact on the progress of materials exchange is mounting. There has been considerable speculation as to why MTAs might generate delays, in turn stifling the open movement of biological research materials and hindering the development of an open research commons.[43] A number of scholars whose work has been discussed have offered reasons for this trend. It has been noted above that transactions for the exchange of materials might be problematic, even where they are exchanged without an MTA. Difficulties tracking use of materials and greater competition between institutions for public and industry funding might feed into decisions to resist sharing materials.[44] This funding environment might diminish the

38 Ibid 1194.

39 Ibid 1195.

40 Ibid 1194.

41 Ibid.

42 Mishra and Bubela, above n 21.

43 Charlotte Hess and Elinor Ostrom, 'Introduction: An Overview of the Knowledge Commons' in Charlotte Hess and Elinor Ostrom (eds) *Understanding Knowledge as a Commons: From Theory to Practice* (MIT Press, 2006).

44 Walsh, Cho and Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research', above n 24, 1196–7; Campbell et al, above n 22, 479.

'cooperative character' of research and related efficiency mechanisms,[45] and fuel risk averse behaviour (this factor is expanded on below). Increased commercial activity by publicly funded institutions might also be a relevant factor.[46]

What role, then, does the negotiation of MTAs play in slowing down the pace of exchange (and, by implication, the pace of research)? The factors outlined above might point to the desirability of having MTAs in place to govern the exchange of materials. Looked at this way, there is a possibility that MTAs might promote the exchange of materials and the development of an open research commons. Walsh, Cho and Cohen have found that scientists who are prepared to sign MTAs are more likely to receive requested materials.[47] But at what point do MTAs generate more problems than they solve? The evidence to date demonstrates that delays in MTA processes are seemingly inevitable. Can these delays be attributed not simply to the incorporation of MTAs into the transfer process, but to inefficiencies in the way in which the MTA process is conducted?

Although the studies examined in this section have contributed important findings on whether the use of MTAs hinders the transfer of materials, they have offered limited insight into what it is about the MTA process that creates inefficiencies. This study attempts to bridge that gap by examining the characteristics of institutional processes engaged in the use of MTAs, and how these characteristics might fuel a culture of delay.

1.3.3 The Role of Provenance and Risk

Guaranteeing a material has a clear 'chain of custody' is important for both suppliers and users.[48] The existence of an MTA documenting the various paths travelled by a material gives parties a clear, retrospective line of sight as to whether the material can be legally transferred for a specified purpose. Establishing a clean chain of custody for the material involves determining: origin and ownership; encumbrances imposed by

[45] Wesley M Cohen and John P Walsh, 'Real Impediments to Academic Biomedical Research' (2007) 8 *Innovation Policy and Economy* 1, 20.

[46] Walsh, Cho and Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research', above n 24, 1196–7.

[47] Cohen and Walsh, above n 45, 16; Walsh, Cho and Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research', above n 24, 1195.

[48] Alex Edwards et al, 'A Trust Approach for Sharing Research Reagents' (2017) 9 *Science Translational Medicine* eaai9055 <http://stm.sciencemag.org/content/9/392/eaai9055.full?ijkey=uMGKxsCEiOb5s&keytype=ref&siteid=scitransmed>.

previous agreements (including funding agreements); other rights or obligations; and, specifically for human tissue, obligations imposed through ethics approvals and conditions under which consent was obtained. From the researcher perspective, materials should ideally be transferred without any obligations attached that could impact on the research purpose for which they are transferred. Realistically, however, many materials are shared multiple times, and the potential for conflicting legal obligations is real.[49] In this sense, MTAs undoubtedly serve a useful record-keeping purpose and provide some comfort to both suppliers and users.

Negotiation over terms dealing with perceived risks can delay the transfer of materials, despite the very low prospect of such risks actually eventuating. Even short delays constitute significant impediments in research fields where funding imposes time constraints and technology quickly evolves.[50] There is no doubt that there is a culture of risk aversion on the part of many institutional administrators. As a consequence, they tend to want to control for every eventuality and nuance that may arise in the future, during the process of negotiating MTAs.[51] There are likely to be particular concerns in relation to *liability or legal risks*. These might include issues related to the safety of the material, such as liability for contaminated material and appropriate use of materials.[52]

Concerns that might arise around legal risks might also encompass inappropriate use (such as use outside the scope of consent for human tissue) or use that infringes the intellectual property of third parties. Other concerns might emerge in relation to *reputational risks*, leading suppliers of materials to insist on the inclusion of rights to be acknowledged or attributed, or to vet materials prior to publication.[53] The final category of risk is the *loss of control* over either the material or commercial opportunities arising from use of the material. This can manifest in suppliers of materials prohibiting or limiting on-transfer of the material, or requiring destruction or return of materials at the end of the research project. This loss of control is particularly evident in

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49 Streitz and Bennett, above n 14.

50 Walsh, Cho and Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research', above n 24; Walsh, Cho and Cohen, 'Patents, Material Transfers and Access to Research Inputs', above n 25.

51 Tania Bubela, Jenilee Guebert and Amrita Mishra, 'Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation' (2015) 13(2) *PLoS Biology* e1002060 <http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002060> 8.

52 Ibid.

53 Ibid.

behaviour that reflects a 'fear of missing out'. In other words, where there is a desire to protect against a perceived risk that windfalls from future (speculative) commercial outcomes resulting from use of the material will be lost.[54]

These factors, or possibly a combination of them, create a real possibility that institutions will engage in risk averse behaviour. Beyond refusing access to materials, this includes the imposition of terms aimed at avoiding risk or capturing downstream benefit. The importance placed on these perceived risks and benefits has led to the dedication of resources to personnel involved in the transfer of materials, and to increased bureaucratisation within public institutions.[55] This in turn sets up an important precondition for disputes and delays during the exchange process. There is no doubt that although parties might be more willing to hand over materials with an MTA in place, insistence by either party on the inclusion of restrictive terms in MTAs can result in an unwillingness to proceed with the exchange.[56]

Together, these risks drive TTOs to expend time and effort tailoring bespoke MTAs to suit what they perceive to be the best interests of their institution, without necessarily considering the broader research environment. Mantras of 'keeping it simple' and 'realistically balancing risk against benefit', hold little traction for negotiators who have limited experience in gauging the magnitude of particular risks or benefits to their institution, and are concerned that their institutional interests will be compromised.

The reality is that very few MTAs between academic and other research institutions are likely to be monitored, let alone enforced.[57] Few materials are valuable enough to warrant ongoing scrutiny to ensure sustained compliance with the terms of a written agreement. Even if terms are breached, the likelihood that a risk averse institution would embark on the highly risky course of litigation is remote.[58] Despite this, the number of MTAs in circulation has proliferated massively and the time taken to negotiate their terms has inevitably had an impact on scientific progress (although actually quantifying that delay and resultant opportunity cost is difficult). It remains the case that the main concern of

54 Katherine Ku and James Henderson, 'The MTA – Rip It Up and Start Again?' (2007) 25(7) *Nature Biotechnology* 721.

55 Streitz and Bennett, above n 14, 10–11. As Streitz and Bennett point out, significant resources are dedicated to MTAs in the private sector: at 11.

56 Cohen and Walsh, above n 45, 17.

57 Bubela, Guebert and Mishra, above n 51.

58 Ibid.

scientists is delay to their research.[59] That said, most scientists appear to recognise the need for some form of formal transfer mechanism to document the source of the material and ensure proper attribution.[60] As a consequence, there is, in general, decreasing resistance to the use of formalised MTAs in some form. Ironically, however, those same factors that motivate the use of MTAs have often been reported to be sticking points in the negotiation of these instruments, leading to delays and research holdups.

1.4 FINDING THE ANSWER: SUGGESTED RESPONSES TO A FLAWED PROCESS

1.4.1 The MTA Process

Perhaps the most fundamental step in improving the process of material transfer for research purposes is the implementation of standard form agreements.[61] Proposals to standardise MTAs are not new. The National Institutes of Health (NIH) endorsed a Uniform Biological Materials Transfer Agreement (UBMTA) for all transfers of biological materials. The Association of University Technology Managers (AUTM) subsequently became the repository for signed UBMTA Master Agreements. There is an absence of similar work or developments in Australia. In 1997, the Director of the NIH established a working group to examine the competing interests of intellectual property rights holders, who often require restrictions on sharing biological materials to facilitate product development, and users of those materials, who need freedom to explore future research and development opportunities. The working group recognised that these needs can be in tension. As a result of the working group's findings, the NIH published guidelines in 1999 on sharing of biomedical research resources for recipients of research grants and contracts.[62] The guidelines rely on the UBMTA as the primary instrument for streamlining the transfer of materials.

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[59] John P Walsh, Charlene Cho, and Wesley M Cohen, 'View from the Bench: Patents and Material Transfers' (2005) 309 *Science* 2002; Monotti, above n 29; Bubela, Guebert and Mishra, above n 51.

[60] Bubela, Guebert and Mishra, above n 51.

[61] Bubela, Guebert and Mishra, above n 51; Ku and Henderson, above n 54; Monotti, above n 29.

[62] National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (US Department of Health and Human Services, 25 May 1999)

The intention behind the UBMTA was to simplify the process of exchange between universities and research institutes, so that transfer takes place pursuant to an implementing letter designed to record the transfer and stipulate the terms of transfer as being in accordance with the UBMTA. There has been some success in terms of the number of signatories to the UBMTA, particularly in the US, but also in a number of other countries. The US AUTM and NIH have also been instrumental in developing further templates and guidelines, including a standard-form Simple Letter of Agreement.

The 1999 NIH Sharing Policy states that materials developed using NIH federal funding should be freely transferred between researchers using 'either no formal agreement, a cover letter, the Simple Letter Agreement of the Uniform Biological Materials Transfer Agreement (UBMTA), or the UBMTA itself'.[63] The Jackson Laboratory (JAX), Bar Harbour, Maine, exemplifies best practice in the use of the Simple Letter of Agreement.[64] JAX 'provides mice to academic and not-for-profit researchers with the simple notification that the mice are to be used solely for research purposes and are not to be sold or transferred to third parties without permission'.[65] Despite this progress, however, it still seems to be the case that many parties are unable to resist the temptation to tweak agreements, with the result that TTOs and business managers receiving them are compelled to carefully examine them for discrepancies, variations or anything perceived to disadvantage the interests of their institution.[66]

This problem is well illustrated in the work of Tania Bubela and her colleagues relating to material transfers involving the International Knockout Mouse Consortium (IKMC) and International Mouse Phenotyping Consortium (IMPC).[67] An MTA modelled on the UBMTA had

<https://grants.nih.gov/grants/intell-property_64FR72090.pdf> ('1999 NIH Sharing Policy'); Eisenberg, above n 20.

63 National Institutes of Health, above n 62.

64 Paul N Schofield et al, 'Post-publication sharing of data and tools' (2009) 461 *Nature* 171.

65 Tania Bubela et al, 'Governance of Biomedical Research Commons to Advance Clinical Translation: Lessons from the Mouse Model Community' in Katherine J Strandburg, Brett M Frischmann and Michael J Madison (eds), *Governing Medical Knowledge Commons* (Cambridge University Press, 2017) 222. This chapter was part of the Cambridge Series on Governing Knowledge Commons; Ibid.

66 Philip Mirowski, 'Livin' with the MTA' (2008) 46 *Minerva* 317; Bubela, Guebert and Mishra, above n 51; Tania M Bubela and Timothy Caulfield, 'Role and Reality: Technology Transfer at Canadian Universities' (2010) 28 *Trends in Biotechnology* 447; Nielsen, Nicol and Whitton, above n 60.

67 Bubela et al, above n 65; Schofield et al, above n 64.

been used successfully in the North American operations of the IKMC, established in 2007 to produce a set of mouse embryonic stem cell lines from which individual genes have been disabled ('knocked out'), and to make the lines freely available for research purposes. Subsequently, the IMPC was established in 2011 to characterise the phenotypes of knockout mouse strains. In 2013–14, Bubela and colleagues undertook a study to examine the MTAs and other legal instruments used by eleven repositories established for deposit and distribution of these cell lines and mouse strains.[68]

In the US, the Knockout Mouse Project (KOMP) repository, housed at the University of California, Davis, extended the UBMTA to include distribution to for-profit partners, thereby facilitating distribution of its mouse model resources. However, the European repositories in the project utilised more restrictive terms for deposit and distribution, which flowed, in part, from concerns about use, appropriate attribution of the source of material, or distribution of profits from commercial exploitation. Such 'attribution stacking', or insistence on terms that require attribution of the contributor in derivative products, may flow through to impede distribution, as may the inclusion of reach-through rights and restrictions on use of materials. Although these departures did not lead to systemic failure in these arrangements, Bubela and her colleagues found that they did constitute hindrances that led to frustration and delays. In addition, the restrictions limited distribution to for-profit partners, which has long-term implications for the sustainability of publicly resourced biorepositories.[69]

Aside from continued support for the adoption of the UBMTA or other simple standard form MTAs, it has been argued that certain terms should be eliminated altogether from all MTAs between research institutions.[70] Reach-through rights and terms permitting on-licensing are included in this class.[71] These terms are viewed as particularly problematic and likely to hold up the negotiation process, yet in a vast majority of cases they will never be enforced. While it may be unrealistic to expect commercial partners to forego these clauses, the situation is quite different where the exchange is primarily for research purposes.[72] Universities and

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68 Bubela et al, above n 65.

69 Amrita Mishra, Paul N Schofield and Tania Bubela, 'Sustaining Large-Scale Infrastructure To Promote Pre-Competitive Biomedical Research: Lessons from Mouse Genomics' (2015) 33(2) *New Biotechnology* 280.

70 National Institutes of Health, above n 62; Bubela, Guebert and Mishra, above n 51; Ku and Henderson, above n 54.

71 Tania Bubela et al, above n 65; Bubela, Guebert and Mishra, above n 51.

72 Bubela, Guebert and Mishra, above n 51; Ku and Henderson, above n 54.

research institutes rarely benefit from seeking rights to modified or derivative materials and negotiators should refrain from insisting on their inclusion when transferring to other research-focused institutions.

Although a handful of Australian organisations are included in the 650 signatories to the UBMTA program to date, there has not been widespread adoption of it in Australia. As part of the empirical component of our study, we sought the views of interviewees and survey respondents on whether standardisation is a feasible response to problems with the MTA process.

1.4.2 Reform of TTO Practices

The second category of options to improve research related material transfers focuses on improving the practices of TTOs. Proposals range from refining understanding of the role of TTOs,[73] to simplifying the procedures and practices around execution of MTAs. Effectively managed repositories of materials demonstrate that transfer procedures can be streamlined when there is no room for negotiation of standard MTA terms. Another effective strategy is to reduce the number of MTAs required for a particular research project. Circumventing the need for the highest-level research manager within an institution to sign off on every MTA executed by their institution, often in the absence of any working knowledge of the project in question, should also increase the speed and efficiency of transfer. However, the experience of researchers engaged in the IKMC and IMPC suggests that these good intentions do not always come to fruition. Success requires buy-in from all interested parties, both researchers and administrators.

Aside from the standardisation option, the extent to which reform of TTO practices could be an effective response to deficiencies in MTA processes was also explored with interviewees and survey respondents.

1.4.3 Abandoning the MTA Process: The Implications of Informality

As noted earlier in this Chapter, Walsh, Cho and Cohen found that researchers are more likely to have requests for materials met where they are prepared to enter into an MTA.[74] This does not necessarily mean, however, that researchers embrace the process of entering into MTAs as useful and a preferable alternative to not having MTAs in place. It might simply mean researchers accept the inevitability of the MTA

[73] Schofield et al, above n 64.

[74] Cohen and Walsh, above n 45, 16; Walsh, Cho and Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research', above n 24, 1195.

process, and that institutional insistence on formal agreements has embedded a culture of acceptance among the scientific research fraternity: no MTA means no material.

On the face of it, informal transfers would appear to be the logical response to inefficiency (and a natural extension of the concept of simplicity). If a system whereby materials were transferred without agreements succeeded in the past, why has a Mertonian culture of open and informal sharing not reclaimed its foothold now? Interviewees and survey respondents in this study were asked for their views on informal transfers, and the legal implications of these types of transfers were explored in the doctrinal component of this study.

1.5 DATA TRANSFER

Perhaps equally perplexing is the question as to why transfers of data (whether raw or annotated, or comprised in datasets) do not always require accompanying written agreements. This trend is not so surprising when considered in the context of the benefits likely to be attained if data is shared. The exchange of data appears to be one area where a push for 'openness' has gained increasing traction over time, and the movement toward building a sustainable data commons has achieved critical mass.[75] Practices of data withholding attract criticism, and funding bodies increasingly insist on open data policies as conditions of funding. In this way, data sharing has taken a somewhat different path to sharing of materials. Misappropriation of data could in some circumstances have more significant ethics ramifications than misappropriation of tangible materials, particularly if it raises privacy concerns. However, there is arguably less potential for data to be used in ways that go beyond the contemplation of the parties involved in its generation and use. A piece of tissue could be used in any number of ways, whereas data extracted from the tissue has more limited uses. Some of the uses to which material is put could have significant and unforeseeable economic value, whereas data is more restricted in its application.

Nonetheless, data withholding is not uncommon,[76] and may have detrimental effects on scientific progress. Even data associated with tangible materials is not always freely transferred, and it is very difficult

[75] Patricia A Deverka et al, 'Creating a Data Resource: What Will It Take To Build a Medical Information Commons?' (2017) 9(84) *Genome Medicine* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5610432/>.

[76] See, eg, Christine Vogeli et al, above n 23.

for one party to compel another party to provide access to this data.[77] Issues associated with privacy and data re-identification further complicate matters.[78] Given the potential for problems associated with transferring data, protection in the form of written agreements is arguably beneficial to researchers both supplying and receiving, just as it is for materials. Issues associated with data transfers were explored with interviewees and survey respondents in this study. One particular question we explored was whether formal data transfer practices are developing in line with formal material transfer practices.

1.6 THE SPECIAL CASE OF HUMAN TISSUE AND WHY FORMALITY IS NECESSARY

There are some areas of materials exchange where the need for complexity in written MTAs is not disputed. Materials that are close to clinical application comprise one category that this tenet might apply to. Human tissue samples are another. Human tissue is a special subset of materials where issues associated with consent, ethics approvals, ownership, privacy and identifiability come to the fore.[79] When tissue and associated data are collected for research, an essential part of the consent process requires that donors be given information and assurances that their tissue will be used in accordance with national ethical guidelines. It is a universal ethical principle that donors should be asked for consent to the collection and use of their biospecimens and data, as specified in articles 8, 16, and 17 of the UNESCO *International Declaration on Human Genetic Data*.[80] This consent must be given freely and after sufficient information has been provided to the donor. On this

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77 Jane Nielsen and Dianne Nicol, 'The Legal Vacuum Surrounding Access to Gene-Based Materials and Data' (2016) 24 *Journal of Law and Medicine* 72.

78 Melissa Gymrek et al, 'Identifying Personal Genomes by Surname Inference' (2013) 339 *Science* 321; Erika Check Hayden, 'Privacy Protections: The Genome hacker' (2013) 497(7448) *Nature* 172; Margaret Otlowski and Dianne Nicol, 'The Regulatory Framework for Genetic Privacy in Australia' in Terry Sheung-Hung Kaan and Calvin Wai-Loon Ho (eds) *Genetic Privacy: An Evaluation of the Ethical and Legal Landscape* (World Scientific, 2013) 283.

79 See, eg, Jane Kaye et al, 'Trends and Challenges in Biobanking' in Ian Freckleton and Kerry Petersen (eds), *Tensions and Traumas in Health Law* (Federation Press, 2017) 415; E Richard Gold and Dianne Nicol, 'Beyond Open Source: Patents, Biobanks and Sharing' in G Pascuzzi, U Izzo and M Macilotti (eds) *Comparative Issues in the Governance of Research Biobanks: Property, Privacy, Intellectual Property, and the Role of Technology* (Springer, 2013) 191.

80 United Nations Educational, Scientific and Cultural Organisation, *International Declaration on Human Genetic Data,* 32 C/22 (adopted 16 October 2003).

basis, if transfer of tissue and data is anticipated at the time of collection, consent should have been given with the full knowledge of this possibility.

These very real concerns warrant careful attention to terms of transfer where human tissue is transferred for research purposes, and suggest that transfer without adequate protections in place will often be contrary to the conditions under which tissue samples were provided. The issues are compounded by the fact that once source tissue is altered it may be transformed into an entirely different product.[81] The issues associated with transfers of human materials were explored with interviewees and survey respondents in this study, and were a particular focus of doctrinal analysis.

1.7 CONCLUSION

This Occasional Paper is organised as follows:

Chapter Two presents the results of interviews with personnel from universities and research institutes involved in technology transfer and specifically transfers of tangible materials.

Chapter Three provides detailed analysis of a survey of research scientists, as well as interviews with scientists. This material is intended to provide a counterpoint to the evidence presented in Chapter Two.

Chapter Four contains analysis of MTAs gathered from interviewees and other sources, with a view to undertaking comparison between theory and reality.

Chapter Five examines the MTA process and TTO practices in light of legal and ethical obligations. Data transfers and human tissue transfers are considered separately. It concludes by assessing the viability of standardisation of MTAs and offering some recommendations for promoting the simplification of MTAs.

[81] Nicholas Tonti-Filippini and Nikolajs Zeps, 'Trade in Human Tissue Products' (2011) 194(5) *Medical Journal of Australia* 263.

CHAPTER 2

'TECH TRANSFER' PERSONNEL: INTERVIEWS

2.1 INTRODUCTION

One of the key components of this mixed-methods study was a set of semi-structured interviews with personnel from technology transfer offices (TTOs) in universities and research institutes in Australia. The purpose of this component of the study was to identify how commonly material transfer agreements (MTAs) are used in Australia and to identify and assess the strengths and weaknesses of MTAs in facilitating exchange of research materials between organisations within Australia and between Australian and overseas organisations.

2.2 METHODOLOGY

A list of Australia's 43 universities was compiled using data from an Australian Government website.[82] After reviewing university websites, four universities without wet sciences were removed. We attempted to

[82] Australian Trade and Investment Commission, *List of Australian Universities* (9 July 2018) Study in Australia <https://www.studyinaustralia.gov.au/ArticleDocuments/3425/List%20of%20Australian%20Universities.rtf.aspx>.

contact all 39 remaining universities. All universities were contacted via telephone or email.

In Australia, the term 'TTO' is not widely recognised and applied across universities. As such, we spoke to the research office or commercialisation/innovation office and asked individuals to recommend personnel within their institution for interview. In other words, we asked participants to self-identify whether they were involved in implementing MTAs and whether they would be an appropriate respondent.

A similar process was undertaken in respect of research institutes. We obtained a list of Approved Administering Research Institutes for 2014 and 2015.[83] We removed universities from this list, and used the list and our knowledge of medical research institutes to select institutes engaging in research with a human medical focus.

In total, 40 interviews were conducted with representatives from 24 universities and seven research institutes. In the case of five institutions, we conducted more than one interview in order to obtain a complete picture of biological material transfers within those institutions. All universities implemented MTAs for biological or biomedical-related research, and for all but two of the 25 universities, this was their predominant area of transfer. If there were personnel in charge of different types of transfers, we spoke to those dealing predominantly with biological and medical-research transfers.

In some cases, more than one representative from an organisation was present. Thus, in total, we interviewed 42 personnel from publicly funded institutions involved in the transfer of materials both to and from other universities, research institutes, and commercial entities. A number also transferred materials from intermediary distributors such as Addgene and the Jackson Laboratory. Participants were selected using purposive and critical case sampling techniques, and we continued to conduct interviews until thematic saturation was reached. Our reviews of existing literature and previous studies in the area provided an invaluable backdrop against which to construct an effective conceptual framework for iterative data analysis. Employing nVivo software, de-identified transcripts were coded and analysed inductively using thematic and

[83] National Health and Medical Research Council, *NHMRC Administering Institutions* (9 July 2018) <https://www.nhmrc.gov.au/grants-funding/administering-grants/administering-institutions>.

latent content analysis techniques,[84] with findings from interviews being progressively used to inform subsequent interviews.

We recognise there are limitations in this particular methodology that relate primarily to the sample size. However, our sample certainly captured a significant proportion of the Australian universities and major research institutes involved in biomedical research. A limitation of the university-TTO surveys is that some interviewees commented on all MTAs, regardless of whether they were biological/bio-medical. For the two cases mentioned above, the main materials transferred were in the agricultural, plant-based or environmental areas. Three other interviewees indicated that up to half of the transfers conducted involved materials that were not biological. These universities all executed 50 or fewer MTAs per year (one conducted less than ten, one conducted between 11-20 and the remaining three conducted between 21-30).

The subjective selection of themes and evidence to support our findings is also acknowledged, although findings were validated using accepted practices and interviews were conducted well beyond saturation point. The real benefit of conducting semi-structured interviews is that it permitted an in-depth exploration not only as to whether difficulties (including refusals to supply materials and delays) might be occurring, but also why they are occurring. Qualitative evidence lends itself to inductive formation of concepts as opposed to generalisable hypotheses.[85]

Another limitation is the fact that, at any point in time, the approach of an institution to negotiating MTAs is coloured by the individuals employed to undertake these tasks. We recognise that different individuals may give different answers to many of the questions we asked.

2.3 RESULTS

In undertaking analysis of interview results, we grouped institutions according to the number of MTAs processed annually by the institution, based on figures provided during interviews and in some cases, subsequent to interviews. This grouping was undertaken in order to

[84] Maria J Mayan, *Essentials of Qualitative Inquiry* (Left Coast Press, 2009).

[85] Jane Ritchie et al, 'Designing and Selecting Samples' in Jane Ritchie et al (eds), *Qualitative Research Practice: A Guide for Social Science Students and Researchers* (Sage Publications, 2nd ed, 2014).

provide some context for analysis, and also because we embarked on the study with a view that institutions with greater experience of transfers of materials using MTAs were likely to offer different insights to those engaging in fewer MTA transfers.

As we have indicated in our methodology section, the vast majority of MTAs entered into by interviewees involve transfers of biological materials. These materials include tissue and blood samples, DNA sequences, cell lines, reagents, vectors, plasmids, chemical compounds, antibodies and animals, primarily genetically engineered mice. Nineteen universities and all seven research institutes enter into MTAs for transfers of human tissue, although some of these university interviewees indicated that they conduct very few.

Some initial results are contained in Tables 1 and 2, which form the basis for the discussion that follows in Parts 2.3.1 through to 2.3.6.

	Number of MTAs per year						
	<10	11-20	21-30	31-50	51-100	101-300	301+
Number of institutions	6	4	5	4	5	4	3
Informal transfers	Yes = 4 No = 2	Yes = 3 No = 1	Yes = 2 No = 2 Uncertain = 1	Yes = 3 No = 1	Yes = 5	Yes = 4 (although in decreasing numbers)	Yes = 2 (although very few) Uncertain = 1 (unlikely)

Table 1: Number of formal MTAs and informal transfers per year

	Number of MTAs per year						
	Less than 10	11-20	21-30	31-50	51-100	101-300	301+
No of Institutions	6	4	5	4	5	4	3
Average time taken to sign-off	7 days to 'months'	Couple of days (1) to 3 months	1-2 days to 2 weeks	'Instant' to 2 weeks	1-2 days to several weeks	1-2 days to 1 month	1-2 days to a couple of months
Delegated sign-off	VC, DVC, PVC, Company Secretary	DVC, PVC, Industry Engagement Officer	DVC, Research Office	DVC, Office of Innovation, TTO Office, COO	Director of Research, Commercialisation or Legal	HOS or Department, Director or Deputy Director of Faculty Office, Head of Business Development, TTO Officer	Commercialisation unit staff, Head of Business Development, IP and Contracts officer, Research program director
Path to sign-off	No defined path or multiple parties involved	Multiple parties involved	Usually through research or commercialisation offices, then legal	Research or commercialisation offices. Often different pathway depending on whether simple or complex (legal will review)	Research or commercialisation offices. Often different pathway depending on whether simple or complex (legal will review)	Dealt with by TTOs, either located in Faculties or university-wide. Legal review if very complex	Commercialisation unit or research office. Delegated sign-off at lower level
Main purpose of MTAs	Protection, indemnification, IP, clarification, publication	Decrease risk, protection, indemnification, clarification, IP	Protection, control, provenance, IP, clarification, IP, publication, collaboration	Certainty, provenance, decrease risk, indemnification, publication,	Certainty, indemnification, protection, IP, publication	Certainty, decrease risk, boundaries, clarification, provenance, IP, indemnification	Provenance, collaboration, legal certainty, publication, decrease risks, less about protecting value

Table 2: Processes to MTA sign-off by level of institutional activity

2.3.1 Prevalence of MTAs: Are Informal Transfers Nothing but a Fading Memory?

While recent empirical evidence has pointed to a dramatic rise in the number of MTAs being executed, it is difficult to ascertain whether this correlates with a decrease in transfers undertaken without a formal agreement in place. While it might seem logical to conclude that it does, we were interested to interrogate this issue in interviews with our TTO personnel.

There was significant variance between institutions as to the number of MTAs entered into per year. The lowest number of MTAs encountered by an interviewee was one, and this MTA had caused sufficient difficulty that its negotiation was still ongoing. Six institutions in all indicated that they generally entered into fewer than 10 MTAs per year. At the other end of the scale, several institutions routinely executed in excess of 300 MTAs annually. In the remaining categories, institutions were fairly evenly split. A considerable number of interviewees indicated that the number of MTAs they were required to navigate per year had increased greatly over the previous decade.

We asked interviewees whether the figures they provided captured all transfers, or whether it was likely some transfers were occurring without an MTA in place. The answers provided are depicted in Table 1.

Strikingly, interviewees from institutions engaged in a larger volume of transactions were also more cognisant of the fact that scientists within their institution continued to engage in transfers of materials without an MTA in place ('informal transfers'). Although claiming that the number of transactions taking place without an MTA was likely decreasing, these interviewees did acknowledge informal transfers still occurred. In contrast, more interviewees from institutions engaging in lower numbers of transfers (with a correspondingly longer time to sign-off), stated that it was very unlikely that transfers without an MTA were taking place. Given that earlier studies have shown that at least some researchers will engage in informal transfers in response to frustrations with MTA processes, it would be surprising if it were indeed the case that no, or very few informal transfers were occurring. Rather, we posit that the institutions with the most inefficient formal transfer processes are perhaps most likely to encounter informal transfers. However, it is impossible to verify this assertion, because there is no record of the informal transfers.

2.3.2 Attitudes Towards MTAs: What is Their Primary Purpose?

Purpose Behind MTAs

All TTO interviewees were asked what they considered to be the main purpose(s) of MTAs. The answers provide insight into why MTAs might be subject to more convoluted procedures in some institutions than others. It is possible to discern subtle differences in the language used to describe the purpose of MTAs: the purpose ascribed to MTAs differed somewhat depending on the volume of MTAs transacted by institutions.

The level of institutional MTA activity also had an effect on the language used to describe the purpose of MTAs. For institutions with the highest levels of MTA activity, interviewees more commonly described the purpose of MTAs as being facilitative: to increase certainty and record provenance; to foster collaboration; and to clarify the terms of the exchange. For example, an interviewee from one university commented:

> *It is really just to keep the research effort in locomotion. That is what it seems to me in a general sense. They really do facilitate, or just add a bit of comfort to the relationship, especially where you do not know the other party. So it just provides a level of comfort and on it goes.*

In respect of those institutions that entered into fewer MTAs, interviewees tended to use terms such as 'protection', 'indemnification' and 'control of IP' far more frequently, especially when describing the predominant purpose of MTAs. But many terms were commonly used across all categories (examples include 'clarification', 'decrease risk', and 'publication').

There was also a correlation between turnaround time and views on the purpose of MTAs, as illustrated in Table 2. Interviewees from institutions with more efficient turnaround times more commonly used terms such as 'maintaining integrity of title', 'formalisation', 'acknowledgement' or 'recognition' and 'collaboration'. A number of interviewees who had estimated longer turnaround times were at pains to emphasise that 'locking down IP' was a fundamental basis for formal MTAs. A similar trend was evident when terms connoting purpose are examined in light of institutional structures. There is a clear link between volume of transactions, institutional processes and path to sign-off.

Thus, we conclude that there is a correlation between high volume of transactions, efficiency in institutional structures, fast turnaround times and recognition that MTAs are rarely useful for protecting commercial

outcomes arising from the use of materials. Institutions in this category appear to be less likely to become caught up in arguing over contentious terms in MTAs than other institutions. Rather:

> *[w]e see MTAs very often as being the beginning of major collaboration. It's setting the scene for attribution or contribution. But it is legal clarity that's very important. It's like when you're buying and selling properties and you move on, you've got to know, either you own it or you don't and there's no room for squatters in this.*

Indemnification

Indemnification against risks associated with the use of a material was frequently cited as being a purpose of MTAs. Table 3 highlights the frequency with which indemnification or clarification of use was provided as a basis for MTAs.

	Number of MTAs per year							Total
	<10	11-20	21-30	31-50	51-100	101-300	301+	
Number of Institutions	6	4	5	4	5	4	3	31
Indemnification = *primary* purpose	2 (33%)	2 (50%)			1 (20%)			5 (16%)
Indemnification = *a* purpose	1 (17%)	2 (50%)	1 (20%)	1 (25%)	2 (40%)	3 (75%)	3 (100%)	13 (42%)
Clarify uses of material	1 (17%)	1 (25%)	4 (80%)	3 (75%)	3 (60%)	2 (50%)	2 (66%)	16 (52%)

Table 3: Indemnification as a basis for MTAs

In total, 58 per cent of interviewees stated that indemnification, or warranties against improper use, were an important aspect of MTAs. Related to this, 52 per cent of interviewees commented that MTAs are an important tool to clarify appropriate uses of a material. While clarification of the restrictions around use may have a proprietary basis, or be necessary in order to comply with ethics requirements, in some instances it was evident that it indicated a strategy to mitigate risk arising from improper use of a material. Safety concerns were paramount for some interviewees.

Acknowledgement and Publication

Likewise, there was significant institutional alignment in the desire to obtain certainty that the role of researchers in developing materials would be acknowledged. As Table 4 demonstrates, a considerable number of interviewees (54 per cent) viewed the inclusion of terms requiring attribution or publication rights to be a critical aspect of MTA negotiations. The role of researchers in developing or collecting materials was seen as being incredibly important, and for those institutions supplying materials, some acknowledgement of this was frequently required. This result correlates nicely with the concept of open science. Researchers (and institutions) are prepared to share research materials provided there is some reward for doing so.

This data also supports the concept of MTAs being an important vehicle for collaboration, in that many research materials are provided to collaborators, and many collaborations emerge from the provision of materials to others. Although many comments relating to publication revolved around receiving appropriate recognition for the development of a transferred material, approximately an equal number centred on the progression of research relationships through sharing materials. Indeed, collaboration was an important theme in the context of MTA purpose, in and of itself, particularly for those interviewees involved in a higher volume of transfers. Eighteen interviewees (58 per cent) articulated 'collaboration' to be a purpose of MTAs (see Table 4).

This collaborative attribute of MTAs was universally accepted by interviewees in the 301+ category and the 51-100 category, but less so in other categories. But many more interviewees across all categories intimated that it is an important aspect of MTAs, despite the fact they did not refer to it as a 'purpose' of MTAs. What this may indicate is that staff from TTOs do not see MTAs as a catalyst for collaboration; rather, they assume that collaboration will probably occur independently of MTAs, and that the function of MTAs is better described as recording the transfer of materials and providing clarity around transfers associated with collaborative relationships. In support of this, many interviewees (68 per cent in total) had been involved in large collaborative arrangements involving multiple institutions.

	Number of MTAs per year							Total
	<10	11-20	21-30	31-50	51-100	101-300	301+	
Number of Institutions	6	4	5	4	5	4	3	31
Publication = *primary* purpose	1 (17%)			1 (25%)				2 (6%)
Publication = *a* purpose	1 (17%)	1 (25%)	4 (80%)	2 (50%)	4 (80%)	1 (25%)	2 (66%)	15 (48%)
Publication not mentioned	4 (66%)	3 (75%)	1 (20%)	1 (25%)	1 (20%)	3 (75%)	1 (33%)	14 (45%)
MTAs are about 'collaboration'	3 (50%)		3 (60%)	3 (75%)	5 (100%)	1 (25%)	3 (100%)	18 (58%)
Indicated involvement in large collaborative arrangements	3 (50%)	1 (25%)	3 (60%)	3 (75%)	4 (80%)	4 (100%)	3 (100%)	21 (68%)

Table 4: Publication as a basis for MTAs

IP as a Driver: Collecting on Commercial Success

The perceived importance of protection of IP as a basis for MTAs was not exclusive to interviewees engaging in fewer transactions. It was mentioned by many interviewees across most categories. However, interviewees from institutions undertaking fewer transactions had a greater tendency to specifically articulate IP concerns. It was frequently cited by interviewees in these categories as a *primary* purpose for using MTAs. One interviewee whose university executes in the vicinity of 11-20 MTAs per year stated that an MTA:

> *is really to lock down intellectual property, or your original thought that's gone into development of the technology. So, if you have provided a lot of time and effort and creative ability into creating the technology then you would want to have some security. If you collaborate or give it away that it will be property acknowledged and if money is to be made from it then you want some sort of reward for your efforts.*

Table 5 demonstrates perceptions as to the importance placed on IP as a driver of MTAs by the various groups of interviewees. While these numbers are based on our interpretation of comments made by interviewees, it is possible to discern their views on IP protection as a purpose of MTAs from these comments.

	Number of MTAs per year							Total
	<10	11-20	21-30	31-50	51-100	101-300	301+	
Number of Institutions	6	4	5	4	5	4	3	31
IP = *primary* purpose	2 (33%)	3 (75%)	3 (60%)					8 (26%)
IP = *a* purpose	2 (33%)	1 (25%)	2 (40%)	2 (50%)	4 (80%)	3 (75%)		14 (45%)
IP not mentioned	2 (33%)			1 (25%)		1 (25%)	2 (66%)	6 (19%)
IP not relevant				1 (25%)	1 (20%)		1 (33%)	3 (10%)

Table 5: Intellectual property as a basis for MTAs

It should be pointed out that not every interviewee who considered IP to be an important purpose behind MTAs was concerned to attempt to extract the most favourable IP position they could for their institution. For example, one interviewee, whose institution fell within the 11-20 range, stated that they considered clarification of the situation in relation to IP ownership to be an important purpose behind MTAs. This institution did not claim reach-through rights to IP generated using their materials, nor did they tolerate the inclusion of reach-through terms in incoming agreements. The important aspect to them was certainty in the IP position. There were other interviewees who took a less pragmatic approach and had a policy of attempting to claim rights to future IP in every transaction they encountered.

Several interviewees whose institutions conducted the highest number of transactions (and had, on average, the shortest turnaround times), explicitly pointed out that MTAs are rarely, if ever about protecting IP. They were also (generally) realistic about the prospect of a commercial outcome from research and, accordingly, preferred that provision be made for dealing with IP only if and when it became an issue. While MTAs 'permitted a conversation' about IP, there was little to be gained by protracted negotiations at an early stage to attempt to embed obligations in relation to IP in an MTA. Responses from these interviewees were typified by one respondent's comment that the chance of a commercial outcome is 'one in a million'.

The reality is that the prospect of commercial success is very slight. As one interviewee from a university with a significant material sharing culture commented:

> *Many organisations think materials are valuable and need protecting. Some organisations think they're going to make money out of this. They're not. We make more money for the university by enhancing the university's grant money and helping the researchers do more collaboration, and hence get more research dollars than we do through our commercialisation income. And yet a lot of people still think, 'oh, we're going to make a bucket load of money out of this'. Well you're not.*

A similar point was made by another interviewee whose institution conducted in excess of 100 MTA transactions per year, and who had considerable experience in MTA negotiations:

> *not so much here but certainly in the last university that I worked for where people would argue endlessly [about] who's*

> *going to own the IP, meanwhile the research in the background: the researcher's got their head on their desk and they're sort of mumbling to themselves, 'there's not going to be any IP, there's not going to be any IP, I'm only using it as screen, there's no IP, there's no IP!' But you know, people seem to. We try and take those kind of – [if] the researcher tells us 'there isn't any IP, I'm not using it to generate any IP', I'm not going to argue IP clauses, it's just not relevant.*

Of course, dealings with commercial entities present added complexities, although many interviewees were circumspect about the commercial imperatives of the private sector. Nevertheless, the difficulties associated with determining the IP position at the time of negotiation were referred to by a number of interviewees, and are captured by the following statement made by an interviewee with experience dealing with companies:

> *So I'd be quite happy with companies if they signed up to say 'In the event that we make a [lot] of cash from this, we'll make a substantial ex gratia payment to you,' rather than trying to figure out what kind of royalty we're on. That's where I think the MTA landscape becomes complex, is where people put a high monetary value on either the material or with what you're going to do with the material. Then they get into this 'trying to plot the future' when you don't really have any idea.*

More respondents were concerned to highlight the importance attached to IP protection rather than ownership of derivatives, modifications or progeny, although the attempted imposition of terms relating to these materials was not uncommon.

Risk Minimisation

Use of terms such as 'protection', 'indemnification' and 'control of IP' hints at a degree of risk aversion amongst those interviewees who ascribed these purposes to MTAs. It is difficult to overstate the importance attached to MTAs by many interviewees as a method of protecting against risk, whether this be through the use of warranties and indemnification clauses, or via clauses ensuring interviewees could overcome the 'fear of missing out' evident in many MTA negotiations. As neatly put by one interviewee:

> *I see the main purpose [of MTAs] as managing the risks for the university. It's understanding what we're getting and what we're giving away, whatever it is, and also managing our intellectual property.*

It is difficult to refute this argument, as these are all important motivations behind MTAs. Difficulties occur when these risks are overestimated and negotiations are complicated accordingly. This issue is explored further in Chapter Five.[86]

2.3.3 Practice and Efficiency: Delays and Culture

Overview of TTO Interview Findings

Results taken from our TTO interviews are summarised in Table 2. They reveal an established culture of materials exchange within and between universities and research institutes in Australia. Our results demonstrate considerable variance between institutions in relation to the volume of transactions undertaken. Numbers are based on interviewees' best estimates as to the annual volume of transactions undertaken. A number of universities, in particular, executed very few MTAs, with ten executing less than 20 per annum. In contrast, every research institute executed at least 30 MTAs per year.

A vast majority of university-based TTO interviewees indicated that they transfer more materials into their institutions than out. In fact, very few execute a significant number of outgoing MTAs. Only two university interviewees indicated that they transferred out more than a few materials per year: one university interviewee falling into the 30-50 MTAs per year category said that just under half of their transactions involved outgoing materials. Another university interviewee falling within the 300+ category stated that around one third of MTAs executed per year involved outgoing materials. In contrast, all of the seven research institutes transferred considerable numbers of materials out.

Given the preponderance of incoming MTAs in the university sector, it might be expected that delays caused by MTA negotiations would be minimal, on the basis that most suppliers of materials will insist on using their own MTA. If every party receiving a material was willing to use the supplier's MTA there is every reason to believe the result would be a streamlining of processes. However, the evidence points to timeframes for execution of anything from one to two days to 'months'. This suggests that institutions (generally universities) exhibit a high degree of caution when conducting MTA negotiations – it is probably the case that they often see new agreements, necessitating the need for review.

In generating and analysing data, themes began to emerge. We used 'numbers of MTAs entered into by an institution per year' as a proxy to

[86] See 5.2.

measure the extent to which levels of 'experience' in administering MTAs impacted on the efficiency with which they were executed (see Table 2). We were particularly interested in exploring the factors associated with delay reported in previous studies. We anticipated continuing evidence of delay within Australian institutional transfers resulting from the MTA negotiation and execution process.

Levels of 'Experience' and Length of MTA Negotiations

Our results in relation to time taken to execute MTAs confirmed that greater experience with negotiating MTAs leads to reduced delays. Generally speaking, those institutions entering into larger numbers of MTAs had more streamlined procedures for negotiating them. As a rule, those institutions also managed sign-off on MTAs more rapidly. The critical point at which marked efficiencies are seen is where the number of transactions per year was at least 21. Institutions undertaking less than 20 transactions per year indicated that, on the whole, they had more transactions tending toward the longer time periods they had provided. For example, of the six institutions who had ten transactions per year or fewer, only one estimated that MTAs might take as little as seven to ten days to sign-off. Even for this interviewee this was unusually quick, and the process was ordinarily in the order of one month. The remainder reported that MTAs usually took considerably longer: between two and four weeks for two interviewees but at least a month for the other three.

For institutions conducting in excess of 301 MTAs per year, interviewees indicated that a vast majority could be executed within a day. Although some (opposing) parties slowed the process down by wanting to negotiate terms, this was something these interviewees tried to avoid: as one interviewee put it, 'researchers cannot afford a delay lasting months in a three-year research program'. This interviewee attributed a desire to negotiate on the part of other parties despite the low likelihood of commercial prospects to 'some of it [being] inexperience but some of it [is] a cultural thing.' This points to inexperience being one underlying factor in delays in MTA negotiations.

What Constitutes 'Delay' in Negotiations?

The TTO interviews suggest that delays in MTA negotiations involving Australian universities and research-focused institutions are not overly protracted in that the 'average' time from request to sign-off is around two weeks. We have no reason to believe that interviewees underestimated the time taken to conclude MTAs. Although some isolated negotiations become drawn out, these instances are relatively unusual and a majority of transactions were described as fairly

straightforward. Given this, it is perhaps surprising that simple transactions can take as long as two weeks to conclude.

Admittedly, a number of interviewees did provide evidence that some transactions were concluded very quickly ('instant' to 'one or two days'). These often involved requests for materials from non-profit intermediaries such as Addgene and the Jackson Laboratories. These requests for materials were concluded quickly because intermediaries require execution of a standard form contract.

However, it became clear that transactions involving other institutions or commercial parties usually took far longer. As previously noted, those institutions with smaller workflows of MTAs tended to take longer, on average, to conclude them. A relevant factor is that TTO officers in these categories tended to view transactions with these parties as requiring tailored agreement, primarily to protect their institution. On the whole, interviewees who entered into 21-30 or fewer transactions per year were less likely to indicate that MTAs took a day or two to conclude. More commonly, negotiations in which they were involved took at least two weeks. Some of the interviewees in categories with a lower volume of transactions acknowledged that the time frames they were dealing with were problematic, with one accepting that a two to three month negotiating period could be frustrating for researchers. Another stated that sign-off could be achieved within three weeks if negotiations were very focused, but would otherwise be longer. One explicitly recognised the understandable concern of researchers about these delays:

> *I am personally lucky because these researchers and I have established a good relationship because I have been here at the University for quite a while now. But I do share their frustrations and I understand. … I'm sorry to say this but in terms of priorities, MTAs are not something we attach a high priority to.*

However, other interviewees in these 'lower' categories felt longer time periods for negotiating MTAs were entirely reasonable. When asked the average time between receiving a request to execute an MTA and signing-off, one interviewee answered:

> *Not very long usually. We have a bit more of a longer signing process with the international agreements and that has a tendency to throw out all our agreements a little bit. But if we're using our template then that's quite quick. … I would hope a month. That's with scanned copies of the agreement.*

Table 2 clearly shows that as the volume of MTA transactions conducted by interviewees increased, the average period of time taken to negotiate

MTAs decreased. More complex negotiations generally took at least two weeks to conclude, but only two interviewees who conduct 31 MTAs or more per year (both falling within the 31-50 category) provided two weeks as the *minimum* period of time necessary to conduct MTA negotiations (encompassing sign-off by both parties). Every other interviewee falling within these categories at the higher end of the scale stated that many transactions involve a very quick turnaround time of one to several days. Notably, most of these institutions transferred materials in as well as out, indicating that they probably accept the MTAs provided by suppliers fairly regularly. Non-standard MTAs do, however, generally take longer to finalise:

> *If they are non-standard the normal turnaround time would be ten working days. … That is a bit dependent on factors like workload of legal department, availability of the scientists of both sides, legal department on the other side, time difference and these typical things.*

Despite this, another interviewee indicated that his specialist unit took 'a day or two' even if the MTA was required to be reviewed by his university's legal team. This, of course, does not tell the whole story on time taken to execution, as it does not incorporate sign-off by both parties.

In contrast with US studies, our results indicate that, although MTAs are used relatively frequently, negotiations lasting more than a month are uncommon. Although some outliers might take 'a couple of months' or in one case, 'one and a half years', it was clear that these are exceptional cases. A resounding comment from many interviewees was that the time taken to negotiate MTAs is variable, and largely depends on the willingness of the party with whom they are negotiating to conclude a negotiation quickly. This proved a source of frustration for many.

Institutional Processes and Impact on Negotiation Times

Despite the fact MTAs are becoming commonplace, structures through which they pass in different institutions are far from uniform. Our data demonstrates that while most institutions have a TTO or at least a designated technology transfer officer or equivalent, the scope of TTO responsibility varies considerably. Interviewees from a number of universities reported having one person responsible for MTAs. Others dealing with a greater volume of transactions often had several dedicated staff. The level of responsibility for execution of MTAs varied. Institutions executing fewer MTAs were far more likely to require sign-

off by a senior executive such as the Vice Chancellor, Deputy Vice Chancellor-Research or other senior executive member.

A distinct trend was evident within institutions with higher levels of MTA activity for the sign-off process to be expedited, generally through delegation to heads of school, or directors of faculties or research programs. As one interviewee whose university engages in over 300 MTA transactions per year observed:

> *in terms of legal sign-off our senior business development managers and senior management like myself have delegated sign-off, so they'll be negotiated typically by one of our associate level staff with … a couple of years' experience, but if they've got any issues they'll come to one of the senior people. … To be honest, for outgoing ones there are very few issues that are significant, it's more for the incoming ones where we come across some issues.*

Another university TTO officer whose university deals with around 40 MTAs per year commented that:

> *sign-off for MTAs technically comes through to the DVCR but she delegates that to the Deans of the Colleges. … [A]ctually we're just looking at those delegations because we think they might [still] be at too high a level.*

This particular interviewee, as head of his university's TTO, felt that it was more efficient if he did not see every MTA:

> *[Given] the volume of MTAs and their increasing volume and the standardisation of practice, providing we can put the stage gate in and that it's reviewed by someone that knows what to do then who signs it is of less importance.*

A clear correlation was observed between delegated sign-off procedures and decreased sign-off time. In addition, institutional administrative structures with the highest level of efficiency (in terms of MTA turnaround time), were those that had simplified the process of materials transfer. Although formal agreements were still put in place, the processes for communicating with scientists, negotiating, and signing-off on MTAs was significantly more straightforward than in institutions where a more protracted process was in place. More meticulous

processes were reserved for complex transactions,[87] whereby legal personnel often became involved.

The Evidence from TTOs on Specific MTA Holdups

Our evidence appears to indicate that the typical time taken to negotiate and sign-off on MTAs varies widely, and ranges from one or two days to 'months'. Involvement in a greater volume of transactions seems to equate with more efficiency in signing-off on MTAs. We sought specific evidence on this question, and asked TTO interviewees what they had encountered in terms of 'sticking points' in MTA negotiations. Results from this series of questions are represented in Table 6.

[87] Jane Nielsen et al, 'Provenance and Risk in Transfer of Biological Materials' (2018) *PLoS Biology* (forthcoming).

	Number of MTAs per year							Total Number of Institutions
	Less than 10	11-20	21-30	31-50	51-100	101-300	301+	
No. of institutions	**6**	**4**	**5**	**4**	**5**	**4**	**3**	**31**
Time/delay	4 (66%)	3 (75%)	1 (20%)	4 (100%)	3 (60%)	2 (50%)	2 (66%)	**19 (61%)**
Inflexibility	2 (33%)		2 (40%)	2 (50%)	4 (80%)	3 (75%)	1 (33%)	**14 (45%)**
Particular Parties	3 (50%)	2 (50%)	2 (40%)	3 (75%)	5 (100%)	3 (75%)	2 (66%)	**20 (65%)**
Overvaluation of material	1 (17%)	1 (25%)		1 (25%)		1 (25%)	1 (33%)	**5 (16%)**
IP	2 (33%)	2 (50%)	4 (80%)	2 (50%)	3 (60%)	3 (75%)	3 (100%)	**19 (61%)**
Indemnification		1 (25%)		2 (50%)	4 (80%)	4 (100%)		**11 (35%)**
Publication	2 (33%)	1 (25%)	2 (40%)	3 (75%)	4 (80%)	4 (100%)	1 (33%)	**17 (55%)**
Inexperience	2 (33%)	1 (25%)	2 (40%)	1 (25%)	1 (20%)			**7 (23%)**
Culture or individual	1 (17%)	3 (75%)	3 (60%)	4 (100%)	5 (100%)	4 (100%)	3 (100%)	**23 (74%)**
Jurisdiction – International MTAs	1 (17%)	1 (25%)	1 (20%)	2 (50%)	3 (60%)	2 (50%)		**10 (32%)**

Table 6: Identification of 'sticking points' from negotiation to execution by level of institutional MTA activity

As Table 6 illustrates, a large number of interviewees acknowledged that delay was a negative aspect of MTA negotiations (61 per cent of total interviewees). Interviewees who engaged in at least 31 transactions per year were more likely to view delays as an impediment in MTA transactions. This is not surprising given that their own processes were likely to be efficient, and delays on the part of other parties were no doubt a source of frustration. The remaining questions interrogated the extent to which particular aspects of MTAs were 'sticking points' in negotiations, some of these invariably feeding into the delays complained of by interviewees.

Inexperience was cited as a problem less frequently than we might have anticipated (23 per cent in total), and paradoxically, only by interviewees from institutions undertaking fewer transfers. While it may not be a major issue, it is almost certainly a factor playing out in negotiations. It was also likely accounted for in other comments made, particularly those relating to culture and the impact of individuals on MTA negotiations. Cultural idiosyncrasies and characteristics of particular individuals within organisations accounted for a great many perceived problems with MTA processes (74 per cent across all groups of interviewees). This was the most common sticking point identified by interviewees, particularly those undertaking 51 or more transactions per year. It highlights the fact that negative perceptions of the MTA process are very much driven by individual characteristics and culture within institutions, and the lack of homogeneity this produces. Inflexibility in conducting negotiations was also seen as challenging (for 45 per cent of institutions), especially by those interviewees who conducted in excess of 51 transactions per year.

Sixty-five per cent of interviewees considered that particular parties or groups of institutions (such as commercial parties or international institutions) presented problems. Interviewees' views were very variable across categories of interviewees, although it is possible to discern some patterns. Table 7 captures the range of parties identified as presenting obstacles in some circumstances. It demonstrates that parties conducting fewer MTA transactions appear to have different views on particular parties as being problematic, compared to those conducting higher numbers of MTA transactions. *Commercial parties* were mentioned by interviewees in every group except those conducting 301 or more transactions per year. But commercial parties were mentioned less frequently by interviewees conducting 31 or more MTAs than those falling into lower volume categories. This 'higher' volume group is seemingly more accepting of the demands made by commercial parties, and many commented that while commercial parties have certain requirements, these are rarely an issue of concern. Of course, it may also

be indicative of their greater bargaining power given that they are invariably more experienced negotiators. Problems encountered in dealing with companies often centred around the seeking of rights, particularly to future IP, although one interviewee in the 101-300 category commented that:

> *nine years ago we used to get a lot of the, particularly the smaller biotechs who would try and retain IP, and that's almost completely gone, you know, I think I've seen it once in the last couple of years*

Universities featured prominently in comments made by interviewees across all levels of transfer activity as constituting problematic negotiators. This reflects the fact that they are probably the group most frequently party to MTA transactions, and also reinforces the importance of institutional culture.

Exchanges with *international institutions*, especially *US universities* were mentioned by a considerable number of interviewees as being potentially problematic. Interviewees from 29 Australian institutions (94 per cent of interviewees) undertake transfers to international jurisdictions, whether this be supply or receipt of material, involving universities and research institutes, commercial entities, intermediaries and repositories. Issues generally arose on several grounds. Probably the primary issue is the insistence of US institutions on the inclusion of terms requiring disputes to be resolved under the law of the state in which the institution is based (32 per cent of interviewees mentioned this point). Generally, more 'experienced' interviewees indicated that this issue was not difficult to overcome when dealing with institutions, and requests to leave the question of jurisdiction silent were often accepted. Other interviewees were content to capitulate to this requirement, while others negotiated outcomes whereby jurisdiction relevant to the supplying institution governed disputes, or where jurisdiction of the party who received the complaint was adopted. Different considerations applied with commercial entities: where materials were received from companies it was generally accepted that there was no scope for negotiation on terms governing jurisdiction (including leaving jurisdiction silent).

US institutions also tend to require quite onerous indemnification clauses in line with US legislative requirements. Some agreements require providers of materials to 'hold harmless' recipients from any liability arising from the use of a material. These clauses could be watered down in some instances, and were not regarded as an insurmountable problem by more experienced interviewees. US institutions were also noted for

putting requirements into agreements that imposed restrictions on future use of materials. The inclusion of terms requiring reach-through rights was also mentioned.

Another matter of concern in relation to US universities is their tendency to want to depart from the standard terms of the UBMTA, with the result that every agreement needed to be carefully checked, as it could not be assumed that terms were uniform across agreements. When asked whether they came across the UBMTA often, one interviewee in the 101-300 category observed:

> *Ah yes, and the worst thing about it is that … a lot of US places use it, and the worst thing they can do is take the UBMTA and add their own words. So you can't just look at it and go, 'yeah, that's the UBMTA', you still have to read it very thoroughly and check.*

	Number of MTAs per year						
	Less than 10	**11-20**	**21-30**	**31-50**	**51-100**	**101-300**	**301+**
Number of institutions	6	4	5	4	5	4	3
Particular parties identified as being 'problematic' in MTA transactions	• International institutions • US universities • 'Bigger' Australian universities • Commercial parties • Big pharma	• Universities • CSIRO • Inexperienced parties • Commercial parties • Smaller companies	• Universities • Larger universities • Biotechnology companies • Big pharma	• Big Australian universities • Smaller Australian universities • Certain Australian institutions • Inexperienced parties • US universities • Big pharma	• Universities • Australian universities • US universities • EU universities • Overseas institutions • Commercial parties • Small companies • Large companies • Big pharma	• Universities • Research institutes • US institutions • Individuals within institutions • Companies • US companies • Big pharma	• Australian institutions, universities and hospitals • US universities • French hospitals

Table 7: Parties identified by TTOs as being problematic in MTA negotiations

It seems, however, that it isn't just the UBMTA that US institutions tinker with. This same interviewee outlined that their institution had recently begun to include a cover letter with their MTA explaining that they were not prepared to change their standard MTA. This had the effect of cutting their workload by half because prior to this

> *pretty much every single American university wanted their own wording … and it didn't actually change the gist of the agreement, they just prefer their own words. Some states like Texas … have state law requirements that they have to put in and they'll still write to us and change it because I don't want to block anything, but the changing things just for the sake of changing things was just getting a bit ridiculous.*

Some interviewees, particularly those who conducted higher volumes of transactions, perceived this 'tendency to change' issue to be less problematic, but nonetheless it invariably delayed transfers and increased workload. Other issues with international transfers generally included longer response times given the time difference and geographical separation, issues at times with materials clearing customs, and issues surrounding local legislative requirements. It should be noted that some interviewees across each category of institution considered there to be no real issue dealing with international parties, or no issues that differed from local transfers, or no issues that could not be overcome.

Interviewees across the board considered the seeking of rights over IP, derivatives and modifications to be sticking points, particularly those engaged in a higher volume of transactions (61 per cent of total interviewees). This issue arose primarily in respect of transactions involving *universities and research institutes*. Although commercial rights were often sought by commercial parties, this was accepted to some degree as part of the process of doing business with them. This is consistent with findings by Walsh, Cho and Cohen that the inclusion of terms seeking reach-through rights is not limited to commercial parties.[88] Publication, too, proved to be a sticking point for many, with a considerable number of interviewees expressing frustration at attempted restrictions on publication (55 per cent in total).

Seeking indemnification for the use of materials was also a dominant issue for interviewees undertaking between 51 and 300 transactions per year, although it factored very little for interviewees in other categories.

[88] John P Walsh, Charlene Cho and Wesley M Cohen, 'Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research' (2007) 36 *Research Policy* 1184.

Comments by these interviewees indicated that they are forced to contend with risk averse parties (particularly within smaller universities) seeking indemnification despite the fact the risks from using particular materials are very low. Risk aversion remains a prominent feature of many MTA negotiations, particularly amongst parties with less 'efficient' MTA processes, and lower MTA volume.

The Case of Multi-Institutional Collaborations

The high prevalence of multi-institutional collaborations was pointed out earlier in this Chapter. These arrangements are important conduits for the sharing of research materials in Australian biomedical research, as they promote sharing and collaborative research efforts. Despite the fact the initial negotiation of multi-institutional agreements presents challenges, these challenges were not considered to be especially insurmountable by most interviewees. Generally, interviewees indicated that MTAs in these instances are embedded within larger agreements, although several interviewees said they were party to collaborative arrangements where separate MTAs were negotiated. This appeared to be contingent on particular collaboration and the materials involved. As with any negotiation though, one interviewee observed:

> *Look, there's an exponential effect, the more parties involved in an overall collaboration the harder it gets. It gets hard quickly. It's all about everyone wanting to be able to do what they want with outcomes and using material and MTAs are a key part of that. … [O]ften the material will come later or we'll sign that later but when we know there's going to be some issues or potential issues with how the material's going to be used [and] ultimately the IP that comes out of it, there may not even be an MTA, … [it] may be embedded in the agreement itself.*

Although the initial time outlay can be significant, these multi-institutional arrangements can have the ultimate effect of expediting the transfer of materials and facilitating the free flow of information.

Specific Types of Materials: The Problems with Human Tissue Samples

We alluded earlier to the fact that a considerable number of our interviewees transferred human tissue under MTAs. It became evident that there are specific issues associated with the transfer of human tissue. Most notably, ensuring adequate consents (and ethics approvals) are in place at the time of transfer is critical, which could at times be a time-consuming process (one interviewee estimated the time it

sometimes took as being 12-18 months). Depending on the consents in place, obstacles that could arise subsequently included clarifying the scope of consent, obtaining re-consent if the original consent was not broad enough, and sorting out consent if the original donor is no longer alive. This was particularly the case with samples obtained some time ago when broad consents were rarely obtained. In short, bespoke MTAs are always required where human tissue is concerned, with clear provisions as to scope of consent, and future transfer and future use of the material concerned.

2.3.4 Is Standardisation the Solution?

Standardisation has long been mooted as a solution to the delays and other obstacles brought about by the use of MTAs. If standard agreements are produced and adhered to, in theory there would be nothing inhibiting a rapid transfer process. Of all our interviewees, there were few who did not advocate a system of standardisation, whether this be use of standards developed in-house, or an industry wide-standard. What became clear, however, is that what constitutes an acceptable standard means different things to different parties.

Individual Institutional Standards

Many of our interviewees indicated that they had standards in place at their institutions. We refer to these institutional standard-form MTAs as templates in this Chapter and particularly in our terms analysis in Chapter 4, to distinguish them from standards like the UBMTA, which are more broadly adopted by a number of institutions. As will become evident, there is some variation in the practices employed by institutions transferring biological materials regarding the use of template agreements. Institutions that execute less than 30 transactions per year are far less likely to have institutional template agreements than others executing larger numbers of transactions. Of the 15 interviewees executing 30 MTAs or less per year, seven had template agreements. This relatively low number likely indicates that these institutions transfer relatively few materials out, and that spending time drafting template agreements is not warranted.

On the other hand, every interviewee who executed in excess of 30 MTAs per year had at least one institutional template agreement at their disposal. As to whether they were prepared to make changes to these templates, most interviewees who addressed this question said that they would consider changes if requested. Several interviewees who conducted higher volumes of MTA transactions stated that they were always reluctant to change terms in their template agreement, and that

their agreements contain a cover letter stating that changes to the template agreement are not permitted. Nevertheless, in the interests of reaching agreement requests for changes were entertained in some instances.

These comments were reinforced to some degree when interviewees were asked whether there was capacity to negotiate changes to MTAs provided by other parties. Of the ten interviewees who conduct 20 or less transactions per year, just three considered that requests for changes to MTAs are usually entertained. Of the remaining eight interviewees in this category, six stated they had been unable to negotiate changes to agreements. One interviewee did not offer a response to this question, which may suggest they had not been in a position where they had needed to request changes to an incoming MTA. The remaining twenty interviewees *all* stated that negotiating changes to the MTAs of other parties was feasible. Several qualified their comments by articulating that embarking on such negotiations could be tricky, but there was no outright bar to negotiating changes into MTAs.

An Australian Standard?

All but three of our interviewees supported the introduction of an Australian standard MTA, although a number of interviewees doubted that attempts to introduce such a standard would be successful. The reasons for their scepticism varied. Several interviewees felt that an Australian standard would be unlikely to be universally adopted, and some commented that it would be useful only in the simplest of transfers. Others felt that an industry standard MTA would need to be useful in a global context given the number of international transactions in which they are involved. One (who executes 21-30 MTAs per year) questioned whether there was sufficient 'baseline activity' in Australia to justify the effort required to implement a standard agreement, although our evidence on the volume of transactions conducted would suggest that there is.

Others pointed to problems with the UBMTA as evidence of the fact that universality in standardisation is a difficult thing to achieve. As outlined above, transactions with US institutions could be difficult not only because the UBMTA was seen by some as 'US-centric' in that it contains 'US language', but also because it was rare for the UBMTA to be adopted and used in its pure form. More often than not this standard had been tweaked by the US institution using it, so that the terms of every agreement still required scrutiny.

Nevertheless, there was broad consensus that standardisation as a concept was worth striving for, regardless of the fact that changes to standard or template agreements are viewed as inevitable much of the time. As one very experienced interviewee put it, '[i]t's absolutely impossible to have a legal template that never needs to be changed.' Another commented '[w]e love the one size fits all concept, a bit like the paper free office, it's never actually materialised.' The fact that changes are unavoidable is supported by the comments reported above by interviewees who were prepared to change their template agreements if necessary. Does this support a conclusion that an industry standard is an overly ambitious prospect?

What it probably highlights instead is that trust plays a more important part than any other single factor in the negotiation of agreements. There is no doubt that MTAs requiring negotiation take significantly longer to conclude than simple agreements without contentious terms. MTAs that result from repeat transactions and MTAs with collaborators are bound to be quicker and easier to conclude, and this was reinforced a number of times by many interviewees.

What Would an Australian Standard MTA Look Like?

Even if an Australian standard could be developed, given divergences between institutional practices, it is not altogether clear what it would look like. We asked interviewees to articulate what terms they would like to see included in a standard MTA, and what terms they would like to see excluded. Answers given were diverse and depended on many factors: whether the institution involved generally transferred materials in or out, the purpose for which materials were used, and the levels of risk aversion evident in respect of the particular institution involved. Interviewees' views on what a standard agreement should look like were also influenced by their assessment as to what purpose MTAs should serve and, as we have highlighted, there was considerable variance between what interviewees perceived to be the main purpose of an MTA.

There was some consensus that many MTAs bear common characteristics, and a significant number of interviewees considered that they would like to see a standard MTA include terms that are commonly seen in MTAs, but 'better defined or better delineated'. Put another way:

> *What I think you would have to do if you were going to develop a standard template, is take the most commonly used type of terms as your baseline, so you're talking about probably non-contentious, non-high risk, non-commercially valuable materials to be used for non-commercially facing research I*

> *suppose is where I'm going with that. … So a pure academic collaboration type use. It's only really when you're talking about MTAs they should only become complicated if there are genuine commercial considerations.*

A common refrain was that clarifying some basic definitions, such as what the materials in question are, and what derivatives and progeny are, would be beneficial. Tidying up the terms around ownership and permitted uses of a material (and progeny) was also frequently mentioned, usually in the context that inclusion would be beneficial. Several very experienced interviewees stated that they would be prepared to adopt a very lenient, simple MTA if it would ease the process of transfer.

Proscriptive terms on publications and terms requiring vetting of publications were viewed negatively by many interviewees. On the other hand, a considerable number stated that they would want to see terms that ensure proper attribution or acknowledgement. A number expressed a preference for terms setting out their rights in relation to IP ownership, progeny, modifications or derivatives. Around the same number stated unequivocally that such terms should be excluded from a standard MTA. Perhaps the answer lies in the inclusion of a generalist provision, which would seem to align with the views of parties on both sides of this debate. As stated by one interviewee, the solution may be:

> *a generalist provision that says 'ownership of the actual materials and any modifications to the materials themselves based on the type of thing would be owned by the provider but the outcomes or the results of the individual experiments are to be owned by the end user' but then anything which is not, … has the scope to be determined at a later point and that would be determined based on the inventive contributions or things like that. Probably it's a much fairer playing field where you could be okay upfront.*

The inclusion of terms providing indemnities and warranties was also contentious. Some interviewees felt their inclusion in a standard MTA to be critical, while others were equally adamant they had no place in a standard agreement. Even if agreement could be reached as to whether these contentious terms should be included in a standard agreement, their composition would need to be carefully considered. Overcoming institutional self-interest would be key to reaching agreement on a set of terms that might comprise a baseline Australian standard.

2.3.5 So Are MTAs Worth it?

An overarching theme that emerged during our interviews was that interviewees generally considered MTAs to be worth the effort of negotiating them. We asked every interviewee to weigh up the costs of negotiating MTAs against the benefits, and assess whether or not the benefits outweighed the costs. These costs can be significant, for smaller institutions without streamlined processes for negotiating MTAs, but particularly for larger institutions undertaking higher volumes of MTA transactions. One interviewee from a 'high volume' university estimated the cost per MTA to be approximately $2,000, based on the fact that one FTE member of staff was engaged to handle MTAs as his/her sole responsibility. Nevertheless, this interviewee felt that although MTAs are 'a bit of work', they are effective at establishing boundaries around a material. This sentiment was fairly universal among our interviewees. Just two interviewees outwardly disagreed, with one referring to MTAs as 'a necessary evil.' In all, 29 interviewees considered that the benefits of MTAs outweigh the costs, as demonstrated by Table 8.

	Number of MTAs per year							Total
	<10	11-20	21-30	31-50	51-100	101-300	300+	
Number of Institutions	6	4	5	4	5	4	3	31
Had given notice under an MTA for breach of a term	1 (16%)					1 (25%)	3 (100%)	5 (16%)
Institution would be willing to litigate the terms of an MTA						1 (25%)		1 (3%)
The benefits of MTAs exceed the costs	5 (83%)	4 (100%)	5 (100%)	3 (75%)	5 (100%)	4 (100%)	3 (100%)	29 (94%)

Table 8: Interviewee perceptions of costs versus benefits of MTAs

In terms of the benefits that MTAs reap, many interviewees returned to the points they raised when asked to articulate the primary purpose or

utility of MTAs. A number stated that MTAs provide a level of comfort, usually because they clearly delineate the uses to which a particular material may be put. They constitute part of the due diligence required around materials and assist in tracking ownership and provenance. They are 'good housekeeping' and 'set out the rights' of each party. One interviewee commented that they are part of the commercialisation process. Several interviewees pointed out that MTAs are effective at increasing the research profile of the institution, by distributing materials developed by researchers. One high volume interviewee referred to MTAs as 'a petri dish for a lot of things … [in that] you can potentially grow some work out of this.' As MTAs document research collaborations, they underscore many research and potentially development opportunities. Another commented:

> *we understand why people need them. … [I]f we're getting materials from someone it's usually in a collaboration anyway but there's nothing like having the fall back I suppose and if a rogue researcher goes and does something inappropriate then both sides need some sort of protection and understanding. I think they're worth it.*

These positive views about MTAs persisted despite the fact that MTAs are very rarely (if ever) enforced. This is also demonstrated by Table 8. When specifically asked whether their institution had ever given notice under the terms of an MTA, just five interviewees responded that they had. More often than not, these situations were brought about by inadvertent transfer, or as one interviewee put it, the 'wandering material and wandering researcher phenomenon', where a researcher moves or passes a material on to another researcher. Where this occurred, they had all sought to reach rapid agreement and put an MTA in place post-transfer. Generally, this could be done amicably. An interviewee in the 300+ category said that they usually issue notifications on the basis of advice from researchers alerted to publications which make it clear a material has been used improperly.

Most interviewees acknowledged that it was virtually impossible for them to monitor the use of a material once it had been transferred to another party. Some interviewees had seen commercial parties implement measures to monitor the use of materials (such as asking for a monthly report on the use of a material), but it was not something institutional representatives were in a position to do due to the impracticality of implementing and following up on such measures. Two more interviewees stated that they would notify another party of the breach of the terms of an MTA if it became necessary, and two further interviewees had received notification from another party.

Just one interviewee overtly stated that his institution would be willing to litigate a breach of the terms of an MTA, and that would only occur if the transferred material was being put to a commercial use. Several other interviewees made more equivocal comments to the effect that it was possible their institution would consider litigation in this instance. Generally, however, it was clear that there would be very few instances in which a publicly-funded institution would litigate on the basis of a breach of an MTA. This result is unsurprising when considered in the context that most materials are unlikely to reap a commercial return. One interviewee summed up the role of MTAs nicely when he commented:

> *an MTA's almost an honour code between universities in some respects: although they may not enforce it, they could if they had to and that's the threat that hangs over the academic to enforce a little bit of discipline of what they do with the reagents that don't really belong to them.*

2.3.6 How Does Data Fare?

Given the ease of sharing data, is it more or less likely that people would have a formal agreement in place? It would be easy to assume that Data Transfer Agreements (DTAs) or Data Sharing Agreements (DSAs) are more commonplace that MTAs, because genomic data is rapidly becoming more valuable and easier to transfer (on the whole)[89] than tangible materials.

The mechanics of data transfer were something we addressed in our interviews. A number of interviewees were not aware of whether their researchers transferred data or not, suggesting that data is probably still transferred more often than not without an agreement in place. Others openly acknowledged that informal transfers of data probably occurred frequently:

> *Interviewer: So do you think that data is ever transferred without an agreement?*
>
> *Interviewee: Oh yeah.*
>
> *Interviewer: More commonly or less commonly than materials?*

[89] Some datasets are very difficult to transfer given the size of the files concerned. A number of interviewees commented that it is easier to transfer data on a portable storage device rather than send it electronically. Therefore, it cannot unequivocally be claimed that data is easy to appropriate or to transfer.

> *Interviewee: Probably more commonly, because all the researchers collaborate with a whole range of people and internationally, and I would say I've got two collaboration agreements I've been asked to do this year. … So they don't feel a need to put a collaboration agreement in place until it gets to a certain critical point where they think they're going to get something.*

For some interviewees, this was less cause for concern than informal material transfers. For others, there was recognition that potentially valuable data required as much protection as materials as one interviewee from a high volume research institute pointed out:

> *I guess the only difference is that you're not going to injure yourself with some data, so I guess … the liability is less, but for the researcher, certainly someone can steal your information and do something with it.*

Consequently, there seems to be an evolving tendency to protect exchanges of data by ensuring an agreement is in place, as illustrated by Table 9. Table 9 clearly demonstrates that a greater proportion of interviewees in higher volume categories use formal agreements to transfer data. Sixty per cent of total interviewees use formal agreements of some description to transfer data.

	Number of MTAs per year							Total
	<10	11-20	21-30	31-50	51-100	101-300	300+	
Number of Institutions	6	4	5	4	5	4	3	31
Conduct Formal Transfers of Data	1 (17%)	1 (25%)	2 (40%)	4 (100%)	4 (80%)	4 (100%)	2 (67%)	18 (58%)
Use MTA	1 (17%)		1 (20%)	2 (50%)	1 (20%)	2 (50%)	1 (33%)	8 (26%)
Use Separate Agreement (DTA or DSA)			1 (20%)	2 (50%)	3 (60%)	1 (25%)	1 (33%)	8 (26%)
Other*		1 (25%)				1 (25%)		2 (6%)

Table 9: Modes of transferring data

Of these interviewees, a surprisingly significant number said that they adapted MTAs to accommodate data transfers. In fact, an equivalent number of interviewees used MTAs as opposed to DTAs or DSAs. It is particularly interesting to note that even institutions experienced in transfers of materials had not necessarily developed a template specific to transfers of data. Some considered this to be sensible given similarities between the processes involved in transfers of materials and data.

Likewise, another interviewee who did use a dedicated DTA stated that:

> *They wouldn't have a lot of the material specific clauses but it would be the name you know, we own the data, we've given you licence to use it for these purposes, don't publish anything without letting us know, that kind of stuff.*

Another stated of their DTA:

* Transfers of data are provided for under another agreement, such as a large collaborative agreement or a Confidential Disclosure Agreement.

> *There are some quirks in them but yes, because it's still about use, ownership, exploitation, rights. The issues are there whether they're tweaked for a particular application or not.*

Others considered the use of MTAs to transfer data to be problematic given the differences between transfers of materials and data: one interviewee commented that they are seeing increasing numbers of data transfers, and there were likely to be better ways of doing these transfers than through the use of MTAs. Another commented that although there are similarities between the two processes, there are specific differences when transferring data:

> *The definition of the material is usually changed and obviously some of the other things within it because it's data and not an actual sample. So there will be some changes but generally the position will be quite similar.*

One interviewee commented on the use of MTAs to govern data transfers:

> *Sometimes I've pointed out that there are more specific data sharing agreements around but then you might get another institution that is willing to provide a starter that we've asked for and that institution insists on it being provided to us under an MTA. So you know, I use my great persuasive skills to try and talk them into a data-use agreement but that's not the way they want to go. So I see it happen and sometimes you can sort of retrofit it a bit to make it suitable.*

One interviewee indicated that the only mechanism through which data is transferred by researchers within her institution is a large collaboration agreement. In reality, it is likely that data is exchanged via collaborative agreements on a regular basis in many institutions despite the fact that this was not specifically reported. It is possible to infer from comments made by interviewees that a good number of collaboration agreements include the transfer of data and materials within their terms.

2.4 CONCLUSION

There is no doubt that the use of MTAs is firmly embedded in the management of materials transfer. Many institutions now have well developed systems for effecting formal processes, and the volume of formal transfers greatly outweighs the prevalence of transfers that take place without an agreement in place. Notwithstanding, there may be

implications from a legal perspective in respect of those transfers that do take place informally, whether these be transfers of materials or data. This issue is considered in more detail in Chapter Five.

Invariably, this process of formalisation has not come without cost. Problems with the use of MTAs that have been well documented over the last two decades, continue to be prevalent and produce frustration, particularly amongst those with an inclination to exert control over the use of materials beyond a level that might be considered prudent. MTA negotiations tend to become overly complicated and protracted as parties argue over the specifics of individual agreements. Whether this can be attributed to the use of MTAs, the form of MTAs or the processes accompanying the negotiation and execution of MTAs is an open question. Some level of engagement with MTAs is required. There is no doubt, however, that there is scope for significant streamlining of MTA processes as an initial step in addressing the problems identified in this chapter. This was well put by one experienced interviewee from a research institute, whose observation holds significant traction:

> *The problem with any of these systems is that they're only as good as the people in them. … So don't blame it on the MTAs – [an] over-zealous lawyer or gate keeper somewhere, for whatever reason they've got a different threshold. … But the fundamental concept is spot on, and it is required.*

CHAPTER 3

SCIENTISTS: INTERVIEWS AND SURVEY DATA

3.1 INTRODUCTION

We have seen in Chapter 2 of this Occasional Paper that technology transfer offices (TTOs) in universities and other research organisations have as their *raison d'etre* the facilitation of research, and the translation of research findings into tangible benefits for society as a whole. Inevitably there will be tensions in these two functions. Effective translation of research findings could, at least in some circumstances, lead to blockages and delays in research efforts. One major concern is that the need to maintain exclusivity to secure return on the large investment required for effective translation impedes the process of material and data sharing for research purposes. The process of formalised sharing could, in and of itself, exacerbate the problem if it is managed inefficiently or with excessive bureaucracy.

We have seen in Chapter 1 of this Occasional paper that there are some notable examples of circumstances where the capacity for researchers to use essential research materials has been impeded both by outright refusals to provide access and by restrictive terms in patent licences or material transfer agreements (MTAs). At worst, refusals to enter into MTAs may lead to project abandonment. Onerous terms could have a similar effect, particularly if they include reach-through rights or publication restrictions.[90] Obligations imposed on users to agree to such terms could be at odds with the expanding open data access and open science policies of public funders that we are seeing across the fields of biotechnology and genomics. Innovation could also be impeded, particularly in the context of healthcare.[91] Potentially, then, MTAs could increase research transaction costs with a flow-on effect on research, commercial development and translation of research to products and treatments.

This chapter explores the extent to which these concerns are becoming manifested in the Australian research sector, with a particular focus on biomedicine. This research serves as a counterpoint to the analysis of practices of intermediaries, including TTOs and others, in the exchange of materials that was reported in Chapter 2. Here we explore with researchers who are both generators and users of biological materials their views of the ways in which their institutions engage with the transfer process. This chapter thus provides guidance on whether systemic issues remain with regard to the ways in which materials are transferred in Australia, or whether problems that may have existed in the past have been rectified as those involved in the transfer process have become more skilled in their work.

Mixed methods were used in this component of the overarching study, including both a survey instrument and interviews. It was originally planned that the only component of this part of the study would be interviews. However, a disappointing response rate encouraged us to employ the survey option for exploring the views of a range of scientists on the material transfer process.

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90 Arti K Rai and Rebecca S Eisenberg, 'Bayh Dole Reform and the Progress of Biomedicine' (2003) 66 *Law and Contemporary Problems* 289; Victor Rodriguez, 'Material Transfer Agreements: A Review of Modes and Impacts' (2009) 27 *Prometheus: Critical Studies and Innovation* 141.

91 David C Mowery and Arvids A Ziedonis, 'Academic Patents and Materials Transfer Agreements: Substitutes or Complements?' (2007) 32 *The Journal Of Technology Transfer* 157; E Richard Gold et al, 'Are Patents Impeding Medical Care and Innovation?' (2010) 7(1) *PLoS Medicine* e1000208.

3.2 METHODOLOGY FOR THE SCIENTIST SURVEY

The intention behind the survey component of this aspect of the project was to get the view of a broadly representative sample of genomic researchers in Australia on their experiences with the material transfer process. Publications were used as a proxy for involvement in the relevant research field. The Scopus database was mined for this purpose.

3.2.1 Participant Selection

Potential participants were selected based on having published in relevant journal articles and having an affiliation with Australian universities and research institutions.

Searches were undertaken on Scopus using the search terms 'Australia', 'genetics', 'human' and 'not agriculture'. To limit the number of journal articles retrieved, only those published from 2014 onwards were considered. In this way, researchers who are currently active in the field were more likely to be identified than those who left the field some years ago. We worked through journal articles in reverse chronological order (beginning with most recently published), and identified first, second and last authors. Contact details were then obtained for these authors where possible, via internet searches, institution websites and phone calls. Authors were removed from the list where we were unable to ascertain contact details. Authors were also removed where it was clear that they represented bodies or consortia from a peripheral or unrelated field, or were otherwise involved in research that was unlikely to be relevant to the research inquiry. We continued to add the names of scientists to the compilation until a total of 900 scientists meeting the search criteria were collated. At this point, we began to increasingly observe repeated names on our list, indicating that the list was reasonably comprehensive.

The survey was delivered on Survey Monkey. The survey asked a series of initial questions about the research profile of the scientist and their institution. It then asked a series of questions designed to ascertain the degree to which scientists were transferring materials subject to MTAs, both incoming and outgoing. Finally, a number of questions asked respondents about difficulties they may have encountered in relation to the use of MTAs when transferring materials. A print version of the online survey is provided in Appendix 1.

Emails were sent on 18 August 2016 to all scientists on the list directing them to the survey on Survey Monkey and requesting that they participate. In total, 887 invitations were sent out to the selected participants. A reminder was sent on 5 September 2016. The survey was

open to participation for one month following the initial invitation request, which was sent via email. Thirty-nine (4.4 per cent) emails bounced and 330 (37.2 per cent) remained unopened. Four hundred and ninety-six (55 per cent) recipients opened the email, and 128 clicked through the survey (14.4 per cent). Twenty-two (2.5 per cent) recipients elected to opt out of the survey. A total of 122 responses were received, including 111 (12.5 per cent) complete responses, and 11 (0.1 per cent) partial responses. Although low, the response rate is not atypical when compared with other surveys in the biomedical field.

3.2.2 Demographics

One hundred and nine survey respondents self-identified their affiliations, as shown in Table 10.

As evidenced by Table 10, a majority of respondents identified themselves as working for a research institute. A considerable number indicated that they worked for a university. Just one respondent answered that they were affiliated with a clinical room, and three with a hospital. No respondents self-identified as working for a Cooperative Research Centre (CRC). Because the survey permitted respondents to identify more than one research environment, some respondents were classified as having selected a 'Dual Classification'. Where respondents had provided additional information which permitted us to establish their primary research environment, we used this information to allocate them to that category. In addition, some respondents elected 'Other' for this question but then clarified that their primary research environment fell into one of the specified categories. In these instances, respondents were reallocated into the specified category.

As Table 10 demonstrates, respondents from a range of appointment types answered the survey. Just over half of our respondents (52.2 per cent) were employed at professorial level. A considerable number (27.5 per cent) had research appointments as postdoctoral or research fellows. Approximately 15 per cent of respondents were unable to identify their appointment type within the options provided. Respondents were involved in a range of research fields, the most common being cancer, genetics, biology, immunology, epidemiology and microbiology.

Type of Appointment	Affiliation						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
Professor	6 (15.8%)	25 (65.8%)	1 (2.6%)		1 (2.6%)	5 (13.2%)	38
Associate Professor	6 (35.3%)	8 (47.1%)		1 (5.9%)	1 (5.9%)	1 (5.9%)	17
Professorial Fellow		2 (100.0%)					2
Postdoctoral Fellow	3 (23.1%)	9 (69.2%)				1 (7.7%)	13
Research Fellow	5 (29.4%)	11 (64.7%)				1 (5.9%)	17
Senior Lecturer	2 (40.0%)	2 (40.0%)				1 (20%)	5
Other	1 (5.9%)	13 (76.5%)	1 (5.9%)		1 (5.9%)	1 (5.9%)	17
Total respondents	23	68	2	1	3	10	109

Table 10: Types of appointment – self-identified[92]

A vast majority of respondents reported that they needed to source research materials to conduct their research; just six respondents indicated that they did not use either research materials or data in their research.[93] Table 11 illustrates the broad range of research materials that was used by respondents, with a fairly even distribution across categories.[94]

[92] Respondents were also given the option of choosing 'Director' or 'Lecturer', but no respondents chose these categories.

[93] Question 2 of the survey asked respondents whether they used research materials or data, and provided options as to which research materials they might use. Of the total respondents (122), 117 answered this question. While six indicated they did not use research materials or data, the remaining 111 used a variety of materials/data.

[94] Comments provided in respect of question 2 indicated that a number of other materials were also used by respondents, most notably human DNA, novel drugs, bacteria and epidemiological data.

Research Material	Number of Respondents Using Material (total n = 122)
Antibodies	72 (61.5%)
Cell lines	75 (64.1%)
Vectors	63 (53.9%)
Genes	63 (53.9%)
Genetically modified organisms	51 (43.6%)
Plasmids	64 (54.7%)
Fluids - animal	36 (30.8%)
Fluids - human	66 (56.4%)
Tissue - animal	55 (47.0%)
Tissue - human	64 (54.7%)
Genomic data	79 (67.5%)

Table 11: Research materials used by respondents

Eighty per cent of respondents indicated that they had received materials for research purposes, while 73 per cent answered that they had supplied materials to other researchers in Australia or overseas (see Table 12).[95] Respondents indicated that a range of research materials were received and supplied, the most common being cell lines, antibodies, vectors and plasmids. Genomic data was also frequently transferred, and human

[95] There is some discrepancy between data presented in Chapter 2 and data presented in this Chapter in that in the survey, scientists reported a more even spread between supplying and receiving materials. It is evident from the material presented in Chapter 2 that TTO officers tended to report greater numbers of incoming materials. There may be two explanations for this. First, the survey contained specific questions about supplying and receiving materials, which invariably prompted respondents to deal with both sets of questions. Second, a majority of scientists who participated in the survey were from very research active institutions. This was largely due to the fact that the methodology for sample selection targeted Australia's top publishing biomedical scientists. This may well explain the significant movement of materials both in and out for these scientists. In contrast, the TTO interviewees comprised representatives from a spread of research-intensive versus non-research-intensive institutions.

tissue and fluids were received far more frequently than they were supplied.[96]

	Response		Total number of respondents
	Yes	No	
Received Materials	98	11	109
Supplied Materials	89	15	104

Table 12: Rates of receiving and supplying materials

3.2.3 Limitations

There were some limitations to this survey. The first is clearly the low response rate, although as we have pointed out, it compares favourably with similar surveys. Another limitation is that respondents were able to skip questions, so that the response rates vary between questions. Percentages provided in the tables in this Chapter give the percentage of the total number of respondents shown in the last column in each row, thereby taking account of these variations in response rates to each question. The fact that the cohort who answered the survey were primarily from research institutes also made it more difficult to generalise about experiences involving transfers in other institutions. Nevertheless, sufficient respondents from universities answered to make these results meaningful.

3.3 METHODOLOGY FOR THE SCIENTIST INTERVIEWS

A series of interviews with scientists engaged in transferring materials was also planned as part of the study. Although it was originally anticipated that 20 or more interviews would be conducted, ultimately only eight interviews took place. One reason for this relatively low number was the difficulty encountered in finding willing participants. We also considered that the rich data obtained from the survey meant that the need for a larger volume of interviews was reduced.

These interviews were conducted using a similar methodology to that described in relation to the TTO interviews. The purpose of the scientist interviews was two-fold. First, we sought detailed descriptive data

[96] Around one third of respondents who received materials received human tissue and/or fluids.

against which to balance interviews with TTO personnel. Second, they provided an opportunity to canvass issues pertaining to MTAs from the perspective of scientists. Despite the relatively low number of interviews conducted, they were in-depth, and garnered useful data that nicely supplemented the survey results. The scientists who were interviewed were from similar research environments: four worked at research institutes and four were employed by universities. The scientist interviewee profile is represented in Table 13.

Level of Appointment	Affiliation		Total number of interviewees per appointment level
	University	Research Institute	
Professor	1	1	2
Associate Professor	2	2	4
Research Fellow	1	1	2

Table 13: Scientist interviewee profile

3.4 RESULTS

Generally speaking, we attempted to analyse the results presented in this chapter based on levels of experience of respondents and interviewees. Just as levels of experience had some impact on responses provided in the TTO interviews (see Chapter 2), we surmised that answers to the questions asked in the scientists interviews and survey would be contingent to some degree on respondents' familiarity with the MTA process. As such, our analysis rests primarily on the research environment of individual interviewees and respondents, and their appointment type within their institution.

3.4.1 The Role of MTAs

We asked a number of questions in the survey designed to tease out scientists' views on the role of MTAs in the transfer process. It seemed self-evident to us that scientists might hold a different view on the purpose for entering into MTAs than TTO officers. Within this series of questions, we sought to explore whether respondents' answers differed depending on whether they received or supplied materials. Respondents were able to select multiple 'purposes' in the relevant questions. Tables 14 and 15 indicate that there was no obvious difference in what receiving and supplying survey respondents identified to be the main purposes of MTAs.

'Purpose' of MTAs*	Perceived level of importance					Total number of respondents
	Extremely important	Somewhat important	Neutral	Not very important	Not important at all	
It's standard procedure to use an MTA	23 (26.1%)	27 (30.7%)	23 (26.1%)	7 (8.0%)	8 (9.1%)	88
To clarify ownership of a material	41 (45.1%)	32 (35.2%)	14 (15.4%)	3 (3.3%)	1 (1.1%)	91
To clarify terms of exchange	45 (49.5%)	33 (36.3%)	8 (8.8%)	4 (4.4%)	1 (1.1%)	91
To ensure you and/or the supplier are legally protected	38 (42.7%)	27 (30.3%)	13 (14.6%)	11 (12.4%)		89
For permission to use existing IP	39 (43.8%)	25 (28.1%)	19 (21.4%)	6 (6.7%)		89
To clarify permissible uses of material	49 (53.9%)	27 (29.7%)	9 (9.9%)	5 (5.5%)	1 (1.1%)	91
To clarify publication arrangements (permission to publish, authorship, attribution)	27 (29.7%)	39 (42.9%)	14 (15.3%)	9 (9.9%)	2 (2.2%)	91
To clarify rights to IP generated through use of the material	44 (47.9%)	29 (31.5%)	13 (14.1%)	5 (5.4%)	1 (1.1%)	92
For human material, to ensure compliance with ethical and legal obligations	51 (56.7%)	16 (17.8%)	19 (21.1%)	2 (2.2%)	2 (2.2%)	90

Table 14: Purpose of MTAs when receiving materials

*One disillusioned researcher commented that the purpose of MTAs in this context is to 'delay research by several months'!

'Purpose' of MTAs	Perceived level of importance					Total number of respondents
	Extremely important	Somewhat important	Neutral	Not very important	Not important at all	
To clarify ownership of a material	37 (46.3%)	25 (31.3%)	10 (12.6%)	5 (6.3%)	3 (3.8%)	80
To clarify terms of exchange	42 (51.9%)	24 (29.7%)	8 (9.9%)	4 (4.9%)	3 (3.7%)	81
To ensure you and/or the receiver are legally protected	32 (41.0%)	25 (32.1%)	13 (16.7%)	5 (6.4%)	3 (3.9%)	78
For permission to use existing IP	32 (40.6%)	24 (30.4%)	14 (17.7%)	6 (7.6%)	3 (3.8%)	79
To clarify permissible uses of material	40 (49.4%)	27 (33.3%)	8 (9.9%)	2 (2.5%)	4 (4.9%)	81
To specify requirements for return or destruction of material	22 (27.9%)	26 (32.9%)	15 (19.0%)	10 (12.7%)	6 (7.6%)	79
To clarify publication arrangements (permission to publish, authorship, attribution)	30 (37.0%)	31 (38.3%)	6 (7.4%)	8 (9.9%)	6 (7.4%)	81
To clarify rights to IP generated from use of the material	35 (44.3%)	25 (31.7%)	10 (12.7%)	5 (6.3%)	4 (5.1%)	79
For human material, to ensure compliance with ethical and legal obligations	45 (58.4%)	12 (15.6%)	13 (16.9%)	1 (1.3%)	6 (7.8%)	77

Table 15: Purpose of MTAs when supplying materials

Respondents attached importance to MTAs for a host of reasons, most notably clarification of the terms of exchange, permissible uses of a material and ownership of future IP, and in the case of human materials, to lay down the conditions for compliance with ethics and legal obligations. One respondent observed that in his experience, university research offices put little effort into IP-related clauses in MTA, but research institutes are a different matter.

There are several things that are perhaps a little surprising about the answers provided by respondents to these questions. The first is that clarifying publication arrangements did not feature as the prominent consideration for scientists. Although an important factor, it was by no means viewed as the central basis for executing MTAs. Considering that many TTO officers placed 'collaboration' and 'publication and acknowledgement' at the forefront when discussing the purpose of MTAs, this was unexpected.

Second, relatively few respondents supplying materials felt that MTAs were essentially a conduit to enforce the return or destruction of material. This might simply mean that they viewed MTAs through a wider lens and this was not a central purpose, or that they had not had any issues with return of materials to date. It might also be reflective of the types of materials being supplied, some of which may be supplied with no obligations for return or destruction attached to them. Finally, we anticipated that frustration with MTA processes would lead scientists to express a view that MTAs are 'a necessary evil', or part of 'standard procedure'. We asked respondents who had received materials whether this was a basis for MTAs; fewer scientists viewed this as a determinative factor than might have been expected. Indeed, it was the least important 'purpose' behind MTAs for respondents.

The interviews conveyed a similar picture. One interviewee commented on the importance of MTAs for 'tracking', and the fact that the requirement for formal documentation is economic (in that commercial returns are a possibility and it is important to ensure the returns come back to the research sector) and ethical. The central purpose cited by interviewees for using MTAs was protection: of publication/attribution rights (seven interviewees); of proportionate rights around IP (six interviewees); and against misuse (five interviewees). In relation to this latter ground, four interviewees also stressed the role of MTAs in controlling field of use, particularly in a competitive funding environment where researchers want to ensure their research efforts are not duplicated by others. As to whether MTAs accomplish this function in practice, it was clear that some interviewees felt that ethics obligations

are a more effective conduit to controlling the use of a material than MTAs (when dealing with human tissue). This matter is explored in more detail below at 3.4.6.

In short, it is difficult to point to a single, primary purpose for using MTAs, and respondents pointed to MTAs having a number of valuable functions. On the whole, there was an overriding sense that these roles contribute to a view that MTAs are useful.

The Significance of the MTA Process

Of course, this is not the end of the story, and even those who view MTAs as having a clear rationale might consider that these grounds are outweighed by other factors. As with TTO interviewees, we explored the process by which scientists transfer materials, in an attempt to make some assessment of whether certain processes are viewed more favourably by scientists, and whether their views on MTAs are contingent on the MTA processes in place within their institution. We started by asking respondents who they worked with during the transfer process, both for receipt and for supply of materials, as shown in Tables 16 and 17.

Who do you work with when negotiating an MTA for receipt of a material?	Place of Employment						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
I haven't had to negotiate	2 (25.0%)	3 (37.5%)				3 (37.5%)	8
TTO	8 (15.1%)	41 (77.4%)	1 (1.9%)			3 (5.7%)	53
Legal Office	10 (23.3%)	27 (62.8%)			1 (2.3%)	5 (11.6%)	43
Research Office	10 (43.5%)	8 (34.8%)			1 (4.3%)	4 (17.4%)	23
Lab manager	3 (30.0%)	6 (60.0%)				1 (10.0%)	10
I do it myself	2 (28.6%)	4 (57.1%)				1 (14.3%)	7
I don't know		1 (100%)					1
Other[97]		9 (90%)			1 (10%)		10

Table 16: MTA processes in place when receiving materials

[97] Ten respondents provided comments for this question. Of those, nine indicated that they dealt with their institution's Business Development Office. One indicated that they dealt with the Office of Commercialisation in their institution. These respondents were all from research institutes and all ten of them also selected other options. These other responses were primarily 'Legal Office' or 'TTO', and it was evident from some responses that the Legal Office and TTO in some institutes have been rolled into a single Business Development Office.

Who do you work with in your institution when negotiating an MTA for supply of a material?	Place of Employment						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
I haven't had to negotiate	1 (25.0%)	1 (25.0%)				2 (50.0%)	4
TTO	6 (15.0%)	31 (77.5%)	1 (2.5%)			2 (5.0%)	40
Legal Office	7 (20.6%)	25 (73.5%)			2 (5.9%)		34
Research Office	7 (38.9%)	8 (44.4%)	1 (5.6%)		1 (5.6%)	1 (5.6%)	18
Lab Manager	2 (33.3%)	3 (50.0%)			1 (16.7%)		6
I do it myself	2 (50.0%)	2 (50.0%)					4
I don't know							0

Table 17: MTA processes in place when supplying materials

Tables 16 and 17 clearly demonstrate that most parties across the board contacted their TTO or legal office to assist them in negotiating an MTA. This was the case whether MTAs were negotiated for the receipt or supply of a material. A considerable number of research offices in public institutions were also involved in assisting with transfers. Note that respondents were permitted to select more than one option where they dealt with multiple personnel. Some respondents clearly had relationships with multiple personnel, in that they selected more than one option when asked who they dealt with. These results are unsurprising when we consider that most institutions now have dedicated TTOs or staff to aid the process of contractual negotiation in cases of technology transfer. Results were consistent across the various types of respondent institutional categories. It is possible to conclude

that a vast majority of scientists are now familiar with the practice of engaging in formal transfers. Those respondents who indicated they had not had to negotiate an MTA were generally engaged in more junior roles and were more likely to indicate they were assisted by a Lab Manager. This appears to indicate that rather than not entering into formal MTAs, they were likely to seek advice from a colleague as to how to undertake the formal MTA process, rather than directly approaching their TTO, legal office or research office.

We also inquired as to whether there was any relationship between the process employed, and the views of respondents on whether MTAs were beneficial or not, as shown in Tables 18 and 19. In other words, was there any evidence to suggest that having particular processes in place led to increased satisfaction in the use of MTAs by scientists?

MTA process when receiving materials	Views on MTAs						Total number of respondents
	Very beneficial	Somewhat beneficial	Neutral	Rarely Beneficial	Never Beneficial	N/A	
I haven't had to negotiate	2 (28.6%)	3 (42.9%)	1 (14.3%)			1 (14.3%)	7
TTO	14 (26.4%)	17 (32.1%)	8 (15.1%)	9 (17.0%)	5 (9.4%)		53
Legal Office	13 (30.2%)	14 (32.6%)	8 (18.6%)	3 (7.0%)	5 (11.6%)		43
Research Office	7 (30.4%)	8 (34.8%)	1 (4.4%)	3 (13.0%)	4 (17.4%)		23
Lab Manager	4 (40.0%)	2 (20.0%)	3 (30.0%)	1 (10.0%)			10
I do it myself	2 (28.6%)	2 (28.6%)		1 (14.3%)	2 (28.6%)		7
I don't know			1 (100%)				1
Other*	3 (30.0%)	4 (40.0%)	2 (20.0%)	1 (10.0%)			10
Total	45	50	24	18	16	1	

Table 18: Views on MTAs against MTA processes when receiving materials

MTA processes when supplying	Views on MTAs						Total number of respondents
	Very beneficial	Somewhat beneficial	Neutral	Rarely beneficial	Never beneficial	N/A	
I haven't had to negotiate	1 (25.0%)	1 (25.0%)		2 (50.0%)			4
TTO	11 (27.5%)	13 (32.5%)	6 (15.0%)	9 (22.5%)	1 (2.5%)		40
Legal Office	11 (32.4%)	12 (35.3%)	4 (11.8%)	6 (17.6%)			34
Research Office	8 (44.4%)	4 (22.2%)	1 (5.6%)	4 (22.2%)	1 (5.6%)		18
Lab Manager	1 (16.7%)	3 (50.0%)		2 (33.3%)			6
I do it myself	2 (50.0%)		1 (25.0%)	1 (25.0%)			4
I don't know							0
Total	34	33	12	24	2	0	

Table 19: Views on MTAs against MTA processes when supplying materials

It was difficult to discern any strong patterns in respondents' perceptions of MTAs when viewed in light of who they consulted to conduct MTA negotiations and execution. Although it is not possible to definitively conclude that using technology transfer personnel leads to increased satisfaction on the part of scientists, generally speaking, respondents appeared to be more likely than not to find MTAs beneficial in this instance. For example, of those who had had dealings with their TTO, 60 per cent found MTAs beneficial as opposed to 25 per cent who found the process to be rarely or never beneficial. Of those who used a legal office, 67.7 per cent found MTAs to be beneficial while just 17.6 per cent found them to be rarely beneficial. There would appear to be grounds to argue that there was some degree of contentment with the MTA process established by most institutions. This is, however, contradicted to some extent by comments provided by respondents, and by statements made during interviews with scientists.

In response to questions asking whether MTAs are beneficial, many respondents gave conditional responses, commenting that they did consider that MTAs conferred benefits, but that there were problems with associated processes, either within their own institution, or with the other party. In relation to MTAs when receiving material, the following comments were typical:

> *MTAs are helpful to clarify, but they take so long to negotiate (even when no negotiating should be done) that they impede rapid progress.*
>
> *They are part of the procedure and may provide protection but usually do not come into play and could often be seen as delay and red tape.*
>
> *They are useful to clarify the terms of the arrangement. Sadly, legal officers get distracted by irrelevant detail and focus on legal niceties and overstate trivial risks.*

At the other end of the spectrum, some respondents saw MTAs as having no obvious benefits:

> *Takes months, lots of lawyers and prevents the research proceeding. [The] Australian environment is now so lawyer rich and risk averse that research is being crippled by trivial issues.*
>
> *MTAs hold up research and affect productivity and outcomes for patients. Driven by risk averse lawyers.*

> *They are a nuisance, waste time, and prevent me from doing the research I am funded to do.*

In total, 12 respondents provided comments that indicated some degree of dissatisfaction with the impact of MTA processes on their research. In relation to other questions, some respondents commented on 'poor advice from in-house' and the fact that 'the problem is often also at our end'. One stated that 'MTAs by some institutions are too demanding – even by my institution – and hamper open research and collaboration'. A greater number took issue with MTA processes with respect to their supply of materials. Twenty-one respondents gave comments that signified frustration at the 'overuse' of MTAs, and MTA processes. Some examples of comments made follow:

> *MTAs have a place where [there is] obvious IP or real risks to human rights, safety or confidentiality are obvious. But [they] should not be the default. They are way overused. Where the risks are minimal or close to zero they should not be necessary. A massive amount of research time and opportunity is lost for very dubious benefit overall. One must take into account the costs of staff (business and legal), costs on research and the opportunity costs to progress. If patient advocates knew they would be very unhappy.*

> *MTAs have become common practice and are largely defensive. Common sense would have steered many materials to be sent without an MTA.*

> *For material that has clear commercial value, potential for patenting or co-publication and/or associated safety issues, an MTA is important. Often, there is sharing of research tools (mainly plasmids) that do not fit these criteria, so an MTA is an unnecessary distraction for both the supplier and receiver.*

> *MTAs have been useful to us in formalising certain requirements and addressing key issues. The downside is the dealing with lawyers on both sides who easily lose track of the real purpose of the MTA – to help research happen.*

Some respondents expressed unreservedly negative sentiments about MTAs and processes accompanying them, including the following:

> *[There is a] total inability [on the part] of the Australian academic system to differentiate between critical and non-critical issues, and the 'feeding trough' behaviour of the legal profession and 100% risk averse behaviour of business*

> *development departments makes the vast majority of MTAs a carbuncle on Australian science.*
>
> *Of the hundreds of MTA-based transfers I have been involved in I have not once found them to be useful. They cause delay, generate unnecessary paperwork and generally hinder research.*
>
> *In theory one might be beneficial (but none have been so far).*

What is clear from analysing this data, is that a vast majority of respondents to the survey have a formal process in place for executing MTAs, and that there is not necessarily a connection between respondents viewing MTAs positively and the structure of MTA processes. Nevertheless, there was a clear theme amongst respondents' comments that more judicious use of MTAs would benefit everyone.

As far as interviewees were concerned, three interviewees from research institutes indicated that their business development office handled MTAs. In general, business development offices seemed to handle MTAs fairly efficiently and these interviewees had a good relationship with business development office staff. The remaining interviewees explained that MTAs in their institutions were handled by their legal office. These interviewees universally stated that the process for negotiating MTAs could be improved, and that delays could often be attributed to processes within their legal office.[98] Even though these interviewees remained positive about the value and role of MTAs, they expressed frustration nonetheless at the inherent inefficiencies institutional processes imposed on the speed with which MTAs could be concluded.

3.4.2 Opting Out: Do Scientists Use MTAs or Resort to Informal Transfer?

Given previous empirical work documenting frustration on the part of scientists with the necessity to enter into formalised MTAs, a primary aim in conducting this survey was to explore whether scientists adhered to institutional practices requiring MTAs. The TTO interviews reported in Chapter 2 generated evidence that TTO personnel, at least, believe that informal transfers, or transfers conducted without an MTA in place, are in decline. We explored this issue in the survey.

We asked respondents how they conduct transfers of materials. In addition to asking whether respondents conducted transfers informally,

[98] One interviewee was from a university where the DVCR was required to sign-off on MTAs.

we sought information on other methods used to transfer materials to enable a comparison between usage of MTAs versus other methods. That data is included in Tables 20 and 21.

Method of Transfer	Frequency of use					Total number of respondents
	Always	Frequently	Sometimes	Rarely	Never	
An MTA that is specific to that material	19 (20.1%)	40 (44.0%)	27 (29.7%)	4 (4.4%)	1 (1.1%)	91
An MTA that is part of a formal research collaboration	5 (5.8%)	20 (23.0%)	41 (47.1%)	14 (16.1%)	7 (8.1%)	87
An MTA that is part of a large-scale research consortium	2 (2.5%)	13 (16.1%)	16 (19.8%)	21 (26.0%)	29 (25.9%)	81
An MTA through an intermediary (eg Jackson Laboratories or Addgene)	1 (1.2%)	11 (13.6%)	27 (33.3%)	16 (19.8%)	26 (32.1%)	81
Informal exchange (without an MTA)	2 (2.3%)	19 (22.1%)	39 (45.4%)	19 (22.1%)	7 (8.1%)	86
I don't know where the materials come from	1 (1.5%)	2 (3.0%)	4 (5.8%)	4 (5.8%)	58 (84.1%)	69

Table 20: Methods of transfer when receiving materials

As Table 20 demonstrates, the most common method by which respondents received research materials *formally* was through an MTA specific to that material, followed by transfer under overarching agreements, via longer-term formal collaboration agreements or large-scale consortia. Ordering materials from intermediary depositories also factored prominently. What is surprising, however, is that a considerable number of respondents indicated they still transfer materials informally, without an MTA in place. Although it may be that for many respondents,

informal transfers happen only occasionally (45.4% indicated they occur 'sometimes'), this data does contradict the perception held by some TTO interviewees that informal transfers are becoming less frequent.

Method of transfer	Frequency of use					Total number of respondents
	Always	Frequently	Neutral	Sometimes	Never	
A formal MTA that is specific to that material	24 (28.2%)	32 (37.7%)	1 (1.2%)	23 (27.1%)	5 (5.9%)	85
An MTA that is part of a formal research collaboration	9 (11.4%)	22 (27.9%)	3 (3.8%)	36 (45.6%)	9 (11.4%)	79
An MTA that is part of a large-scale research consortium	5 (6.6%)	12 (15.8%)	6 (7.9%)	22 (29%)	31 (40.8%)	76
An MTA through an intermediary distributor	2 (2.8%)	6 (8.3%)	4 (5.6%)	17 (23.6%)	43 (60%)	72
An informal exchange (without a written MTA)	5 (6.0%)	18 (21.7%)	2 (2.4%)	37 (44.6%)	21 (25.3%)	83

Table 21: Methods of transfer when supplying materials

Table 21 tells a similar story. Not unexpectedly, respondents were slightly less likely to report that they transferred informally when supplying materials. Nonetheless, behind MTAs specific to a material and collaboration agreements, it was the most commonly used method of supplying materials.

As to who is transferring informally, we were able to gain some insight into the institutional alignment of parties involved in informal transfer. Of the 79 respondents who had received materials informally, 19 (24 per cent) indicated their research environment was a university, while 50 (63 per cent) were affiliated with a research institute. Of the 62 respondents who indicated they had supplied materials informally, 15 (24 per cent) were from a university research environment while 38 (61 per cent) selected research institute. Tables 22 and 23 shed some light on the level of appointment of those respondents who had transferred materials

informally, and the frequency with which they undertook informal transfers.

Frequency of Informal Receipt	Level of Appointment							Total number of respondents
	Professor	Associate Professor	Professorial Fellow	Postdoctoral Fellow	Research Fellow	Senior Lecturer	Other	
Always				1 (10.0%)	1 (6.7%)			2
Frequently	10 (30.3%)	3 (23.1%)	2 (100.0%)		3 (20.0%)		1 (11.1%)	19
Sometimes	16 (48.5%)	6 (46.15%)		8 (80.0%)	5 (33.3%)	1 (25.0%)	3 (33.3%)	39
Rarely	6 (18.2%)	3 (23.1%)		1 (10.0%)	5 (33.3%)	1 (25.0%)	3 (33.3%)	19
Never	1 (3.0%)	1 (7.7%)			1 (6.7%)	2 (50.0%)	2 (22.2%)	7
Total	33	13	2	10	15	4	9	86

Table 22: Frequency of informal receipt of materials by level of appointment

Frequency of Informal Supply	Level of Appointment							Total number of respondents
	Professor	Associate Professor	Professorial Fellow	Postdoctoral Fellow	Research Fellow	Senior Lecturer	Other	
Always	2 (6.1%)			2 (20.0%)			1 (12.5%)	5
Often	7 (21.1%)	2 (13.3%)	1 (50.0%)	4 (40.0%)	3 (23.1%)		1 (12.5%)	18
Sometimes					1 (7.7%)		1 (12.5%)	2
Rarely	15 (45.5%)	6 (40.0%)	1 (50.0%)	4 (40.0%)	6 (46.15%)	2 (100.0%)	3 (37.5%)	37
Never	9 (27.3%)	7 (46.7%)			3 (23.1%)		2 (25.0%)	21
Total	33	15	2	10	13	2	8	83

Table 23: Frequency of informal supply of materials by level of appointment

As these tables show, the frequency with which staff received materials without an MTA in place was contingent to some extent on seniority.[99] Informal transfers occurred across all levels of appointment, to differing degrees. What is interesting is the relatively low number of respondents who had *never* received a material informally.[100] Many respondents had engaged in informal transfers at some point, albeit infrequently in a good number of cases.

We also endeavoured to tease out *why* respondents resorted to informal transfers, and whether this correlated with a negative view of MTAs. It may be that in some cases the nature of the material dictates whether it is likely to be transferred informally or not. This was something that was difficult to ascertain from our survey data. However, it was possible to break down why materials may have been either received or supplied without an MTA in place. Tables 24 and 25 present this data.[101]

[99] A greater number of professorial respondents reported engaging in informal transfers, but this is not surprising considering that a greater number of respondents reported being at professorial level.

[100] Although, not all respondents answered these questions. When asked *why* they had received materials informally, 94 respondents answered the question, with 13 answering that they never received materials informally (that is, 81 appeared to indicate they had received materials informally). When asked *why* they had supplied materials informally, 86 respondents answered the question with 19 answering that they never supplied materials informally (that is, 68 respondents appeared to indicate they had supplied materials informally). Respondents were permitted to provide more than one reason for transferring informally (see Tables 24 and 25). Note also that these figures differ from the figures provided in Tables 20, 21, 22 and 23, which present data from questions asking *how* materials were transferred. There was some inconsistency between respondents' answers to each of these questions, and the later questions which asked *why* materials were *informally* transferred.

[101] Note that respondents were permitted to select multiple reasons for engaging in informal transfers.

Reason for Informal Receipt	Level of Appointment							Total number of respondents
	Professor	Associate Professor	Professorial Fellow	Postdoctoral Fellow	Research Fellow	Senior Lecturer	Other	
Long term collaboration	25 (69.4%)	6 (46.2%)	1 (50.0%)	6 (54.5%)	10 (66.7%)	2 (40.0%)	6 (50.0%)	56
Standard practice	11 (30.6%)	2 (15.4%)	1 (50.0%)		4 (26.7%)			18
Formalised exchanges too difficult	10 (27.8%)	2 (15.4%)	2 (100.0%)	1 (9.1%)			1 (8.3%)	16
Never receive materials informally	1 (2.8%)	1 (7.7%)		1 (9.1%)	2 (13.3%)	3 (60.0%)	5 (41.7%)	13
Don't know				2 (18.2%)	1 (6.7%)	1 (20.0%)		4
Other[102]	7 (19.4%)	5 (38.5%)		1 (9.1%)	2 (13.3%)		1 (8.3%)	16
Total number of respondents per level	36	13	2	11	15	5	12	

Table 24: Reasons for receiving material informally based on position type

[102] Respondents provided a range of reasons under this option. Some indicated that they 'rarely supply material informally', or that they did so before 'MTAs became normal practice'. Others stressed that the 'legal process [was] too slow', or that they transferred informally to 'assist colleagues' or in respect of 'collaborations between local institutes … [with] shared grants'. Trust was emphasised, as was the fact that the nature of the material can play a part.

Reason for Informal Supply	Level of Appointment							Total number of respondents
	Professor	Associate Professor	Professorial Fellow	Postdoctoral Fellow	Research Fellow	Senior Lecturer	Other	
Long term collaboration	23 (65.7%)	8 (57.1%)	1 (50.0%)	8 (88.9%)	5 (35.7%)	2 (66.7%)	5 (50.0%)	52
Standard practice	8 (22.9%)				3 (21.4%)		1 (10.0%)	12
Formalised exchanges too difficult	14 (40.0%)	1 (7.1%)	2 (100.0%)	1 (11.1%)	3 (21.4%)	1 (33.3%)	1 (10.0%)	23
Never supply materials informally	5 (14.3%)	5 (35.7%)			4 (28.6%)	1 (33.3%)	4 (40.0%)	19
Don't know		2 (14.3%)						2
Total number of respondents per level	35	14	2	9	14	3	10	

Table 25: Reasons for supplying material informally based on position

A very significant number of respondents who transfer informally indicated that they either receive (56 per cent) or supply (52 per cent) materials informally due to a long-term collaboration. Across the board, researchers at all levels cite this as the major ground for transferring materials without an MTA in place. Perhaps unsurprisingly, professorial respondents were more inclined to indicate that they transferred informally, and that the basis for this was either that they were engaged in a long-term collaboration, because it was 'standard practice', or because formalised exchanges are too difficult. Comments provided by a number of respondents reinforced that as MTAs become more entrenched, informal exchanges are likely to become less common on these grounds. It may be that these practices will take longer to filter down to professorial staff who conducted research during an MTA-free era.

It is possible to reach some conclusion on whether those engaged in informal transfers viewed MTAs positively or negatively. In plotting data on the frequency with which materials were transferred informally against respondents' views on MTAs, it is evident that some respondents who transferred materials informally on a frequent basis nevertheless regarded MTAs positively. This was especially the case for respondents who supplied materials informally. As Table 27 illustrates, of the 16 respondents who often supplied materials on an informal basis, nine regarded MTAs as very beneficial or somewhat beneficial. Of the 37 respondents who rarely supplied MTAs informally, 26 considered MTAs to be very beneficial or somewhat beneficial.

Table 26 reveals a similar pattern for respondents receiving materials. Although those respondents who received materials informally on a frequent basis were fairly evenly divided as to whether they regarded MTAs as beneficial or not, those who informally transferred 'sometimes' were more likely to regard MTAs as beneficial than not beneficial. The upshot of this data is that informal transfers do occur, but not necessarily because respondents have suffered adverse impacts as a result of using MTAs, or because respondents do not use MTAs. This is supported by the data from Tables 24 and 25 that suggests that a majority of informal transfers take place in the context of a collaborative relationship.

Frequency of informal transfers when receiving	Views on MTAs						Total number of respondents
	Very beneficial	Somewhat beneficial	Neutral	Rarely beneficial	Never beneficial	N/A	
Always		1 (50.0%)				1 (50.0%)	2
Frequently	3 (15.8%)	5 (26.3%)	2 (10.5%)	4 (21.1%)	5 (26.3%)		19
Sometimes	7 (17.9%)	16 (41.0%)	10 (25.6%)	2 (5.0%)	4 (10.3%)		39
Rarely	8 (41.1%)	7 (36.8%)	1 (5.3%)	3 (15.8%)			19
Never	4 (57.1%)		2 (28.3%)		1 (14.3%)		7

Table 26: Frequency of informal transfers against views on MTAs when receiving materials

Frequency of informal transfers when supplying	Views on MTAs						Total number of respondents
	Very beneficial	Somewhat beneficial	Neutral	Rarely beneficial	Never beneficial	N/A	
Always			1 (20.0%)	3 (60.0%)		1 (20.0%)	5
Often	2 (12.5%)	7 (43.8%)	3 (18.8%)	4 (25.0%)			16
Sometimes	1 (50.0%)	1 (50.0%)					2
Rarely	12 (32.4%)	14 (37.8%)	3 (8.0%)	6 (16.2%)	2 (5.0%)		37
Never	9 (42.9%)	9 (42.9%)	1 (4.8%)	2 (9.5%)			21

Table 27: Frequency of informal transfer against views on MTAs when supplying materials

Interview respondents told a similar story. Four interview respondents categorically stated that they never conduct external transfers informally.[103] Two further interviewees said they sometimes received materials without an MTA and did not bother chasing up an MTA where this was the case. Both said they would never send a material out without an MTA. The remaining two interviewees (one from a research institute and one from a university) stated that informal transfers still occur frequently, although only with trusted colleagues. They identified no problems from conducting transfers in this way.

Does Informality Matter? Problems Arising from Informal Transfers

It would appear from the scientist survey that respondents see very little adverse impact when materials are received informally. Recalling that 79 respondents reported that they had received materials informally, we then asked whether respondents had suffered any adverse effects from receiving materials informally. Eighty-one respondents answered this question.[104] An overwhelming 75 per cent of these respondents (61 respondents) stated they never encountered adverse effects. Just 9 per cent of respondents (seven in total) reported that they sometimes experienced adverse effects in these circumstances, while 16 per cent rarely had problems (13 respondents). These results are reported in Table 28.

[103] An MTA might not be required where larger collaboration agreements are in place.

[104] The reason for this discrepancy in number of responses is probably that some respondents who had not transferred informally went on to answer that they had also suffered no adverse effects.

Has research been adversely affected by informal receipt of materials?	Level of Appointment							Total number of respondents
	Professor	Associate Professor	Professorial Fellow	Postdoctoral Fellow	Research Fellow	Senior Lecturer	Other	
Always								
Often								
Sometimes	4 (11.4%)		1 (50.0%)	1 (10.0%)			1 (14.3%)	7
Rarely	4 (11.4%)			3 (30.0%)	4 (30.8%)	1 (50.0%)	1 (14.3%)	13
Never	27 (77.1%)	12 (100.0%)	1 (50.0%)	6 (60.0%)	9 (69.2%)	1 (50.0%)	5 (71.4%)	61
Total number of respondents per level	35	12	2	10	13	2	7	

Table 28: Reports of adverse effects in transferring informally

Upon further analysis, many respondents who reported no adverse effects from informal transfer still found formal MTAs to be beneficial. Despite just 20 respondents reporting having suffered an adverse effect as a result of receiving materials informally, 34 went on to identify specific adverse effects they had encountered.[105] It may be that they hadn't necessarily considered these implications to be 'adverse effects' until specifically asked, or that these impacts are also encountered when receiving materials under an MTA and are not specific to informal transfers.

Table 29 illustrates the nature of adverse effects respondents reported having been exposed to in the context of receiving materials. Of these impacts, uncertainty in relation to provenance, IP position and publication/acknowledgement featured most prominently.[106] Very few respondents reported having any issue in relation to problems establishing which parties should bear liability. It is probable that liability either is not an issue, in that there have been very few liability issues arising in relation to materials, or it is an issue of which researchers are not aware. It is interesting to note that the majority of respondents who reported adverse implications were at the professorial level. This may be because their junior colleagues were largely shielded by professorial staff from knowledge of these consequences. Again, however, it may simply reflect that fact that a greater number of survey respondents were professorial level.

[105] Note that respondents were able to elect multiple 'adverse effects'.

[106] Although, several respondents then went on to clarify that even if these impacts were suffered, they could easily be worked out researcher to researcher.

Implications of informal transfers	Level of Appointment							Total number of respondents
	Professor	Associate Professor	Professorial Fellow	Postdoctoral Fellow	Research Fellow	Senior Lecturer	Other	
Uncertain provenance	6 (33.3%)		1 (100.0%)	2 (50.0%)	2 (40.0%)	1 (50.0%)	1 (33.3%)	13
Liability uncertain						1 (50.0%)	1 (33.3%)	2
IP uncertain	8 (44.4%)	1 (100.0%)		1 (25.0%)	1 (20.0%)			11
Publication uncertain	9 (50.0%)	1 (100.0%)		2 (50.0%)	3 (60.0%)		1 (33.3%)	16
Total number of respondents per level	18	1	1	4	5	2	3	

Table 29: Negative implications of receiving materials informally, by position type

The questions were framed slightly differently when exploring the potential adverse impacts arising from the informal *supply* of materials. Respondents were asked to consider whether they had encountered specific effects from supplying informally, and whether they viewed those effects positively or negatively. The reason for this was that we surmised that some respondents would view these impacts not as negatives, but as positive aspects of supplying informally. Again, a greater number of professorial staff answered this question than other categories of respondent.[107]

The results are surprising because a number of respondents have a positive view of some impacts of transferring informally when outwardly they appear to be adverse. The data in respect of this question is contained in Table 30. Percentages are shown as a proportion of respondents who answered in respect of a particular 'effect'.

Nature of Effect	Views on MTAs					Total number of respondents
	Very Positive	Somewhat Positive	Neutral	Somewhat Negative	Very Negative	
Lack of clarity in relation to right to publish	3 (3.8%)	2 (2.5%)	31 (39.7%)	26 (33.3%)	16 (20.5%)	78
Lack of clarity in relation to IP rights	4 (51.3%)	5 (6.4%)	26 (33.3%)	28 (35.9%)	15 (19.2%)	78
Lack of clarity in relation to use of the material	2 (2.5%)	8 (10.3%)	28 (35.9%)	25 (32.1%)	15 (19.2%)	78
No restriction on the use of material	16 (20.5%)	13 (16.7%)	21 (27%)	15 (19.2%)	13 (16.7%)	78
Legal risks arising from use of the material	2 (2.6%)	4 (5.2%)	37 (48.1%)	20 (26%)	14 (18.2%)	77
Other implications	1 (3.7%)	2 (7.4%)	19 (70.2%)	2 (7.4%)	3 (11.1%)	27

Table 30: The nature of 'adverse' effects when supplying materials

[107] In total, 79 respondents answered this question. Of these, 47 were professorial staff (including 33 professors, 12 associate professors and 2 professorial fellows), while the remaining 32 fell into the categories of research fellows (12), senior lecturers (3) and 'other' (9).

From this data, we can draw the conclusion that some respondents viewed the fact that informal transfers impose no restrictions on the use of a material as a positive factor. To a certain extent, a lack of terms circumscribing rights to IP was also a positive aspect of informal transfers for some respondents. Comments provided by respondents also made it clear that a number of them considered that many of these 'effects' were so unlikely to occur, that they were willing to proceed with informal transfer rather than enter into MTAs. This invariably influenced their answers to this question. Examples of these responses follow:

> *MTAs often not worth the time and effort to protect against these kind of [sic] unlikely events.*
>
> *For low-risk materials – saves a lot of time.*

Some were explicit in their views on whether we frame these 'effects' as negative impacts, as the following comments demonstrate:

> *No wasted time, no extra costs for employees to manage MTAs, reduced stress on scientists who are asked to stop research to do the MTA. Improved collaborations based on trust.*
>
> *Lack of clarity etc would be a negative but an informal transfer doesn't necessarily mean there is lack of clarity in relation to publication and use or no restrictions on use, just that the heads of the university didn't sign a contract specifying it. Collaborators rarely just send specimens without an understanding between each other as to what they are for. Sometimes it is verbal, but usually there would be an email trail and we would expect each other [sic] to behave appropriately and terminate collaborations if this trust is violated.*
>
> *[It] all depends on what is agreed informally – the informal agreement could include clear details re publication, use of materials etc.*

In short, although a significant number of respondents indicated that they transferred informally, most of them did so infrequently, and certainly not on a regular basis. Informal transfers are reported as generating few problems and given that they are often between collaborators and involve low-risk materials, the boundaries of transfer remain well-defined. Indeed, this is exactly the sort of instance in which MTAs are probably not required.

By way of comparison, a large proportion of respondents who had never transferred informally when receiving materials also represented a large proportion of those who had never transferred informally when

supplying. This suggests that cultural factors drive informal exchanges of material and, as we have observed, the most notable are level of seniority and collaborative relationships between researchers.

3.4.3 Scientists and the MTA Process: Adverse Effects Brought About Through Use of MTAs

Given that few respondents claimed to have suffered adverse effects from transferring materials informally, we were interested to know whether a similar outcome pertained to transfers using formal MTAs. Again, it seemed logical to conclude that answers to these questions might be influenced by level of seniority and, accordingly, familiarity with the MTA process. Table 31 reveals the number of respondents who reported their research suffering adverse effects during the previous 12-month period, in the course of receiving materials under MTAs.

Frequency with which research adversely affected by an MTA	Level of Appointment							Total number of respondents
	Prof	Assoc Prof	Prof Fellow	Postdoc	Research Fellow	Senior Lecturer	Other	
Always			1 (50.0%)			3 (60.0%)		4 (4.2%)
Frequently	10 (27.8%)	3 (23.1%)			2 (13.3%)		1 (8.3%)	16 (17.0%)
Sometimes	13 (36.1%)			3 (27.3%)	6 (40.0%)		3 (25.0%)	25 (26.6%)
Rarely	5 (13.9%)	3 (23.1%)	1 (50.0%)	5 (45.5%)	3 (20.0%)	2 (40.0%)	2 (16.7%)	21 (22.3%)
Never	8 (22.2%)	7 (53.8%)		3 (27.3%)	4 (26.7%)		6 (50.0%)	28 (29.8%)
Total number of respondents per level	36	13	2	11	15	5	12	94

Table 31: Frequency of adverse effects when receiving materials under an MTA

Ninety-four respondents answered this question. Table 31 demonstrates that many respondents using MTAs experienced no, or few adverse effects during the previous 12-month period as a result of using MTAs when receiving materials. Nearly 30 per cent of respondents who

answered this question reported that their research had never been adversely impacted by an MTA (28 respondents), while the remaining 70.2 per cent (66 respondents) reported having suffered an adverse effect. Fifty-one point two per cent said that their research had rarely or never been affected (49 respondents in total). The fact that 22.3 per cent (21 respondents) said that they had rarely suffered an adverse effect suggests that they may well have suffered at least one adverse effect. This is backed up by data presented below whereby scientists were asked to select specific adverse effects suffered. Sixty-six respondents reported at least one adverse effect when answering this later question (see Table 32).

Returning to Table 31, just as significant is the fact that many respondents reported at least sometimes suffering adverse effects from receiving materials subject to MTAs during the previous 12 months (48 per cent or 45 respondents). Given that the vast majority of respondents who answered this question were professorial level, it is not surprising that this group was over-represented in the total number of respondents who reported adverse effects.[108] The number of research fellows who had sometimes or frequently been exposed to an adverse effect was also notable at eight (53.3 per cent of the total number of research fellows who responded to this question).

Table 32 provides a record of the data on the types of adverse effects that were encountered from the use of MTAs in receipt of materials.

[108] Twenty-seven respondents at professorial level had always, frequently or sometimes confronted adverse effects. Despite this, further analysis reveals that these particular respondents still found MTAs to be beneficial.

Particular adverse effect	Level of Appointment							Total number of respondents
	Professor	Associate Professor	Professorial Fellow	Postdoctoral Fellow	Research Fellow	Senior Lecturer	Other	
Delay in research	27 (96.4%)	6 (100.0%)	2 (100.0%)	7 (87.5%)	11 (100.0%)	5 (100.0%)	6 (100.0%)	64
Cessation in research	6 (21.4%)	1 (16.7%)	1 (50.0%)		1 (9.1%)	1 (20.0%)		10
Breakdown of collaboration	6 (21.4%)		1 (50.0%)			2 (40.0%)		9
Restricted ability to publish	6 (21.4%)		1 (50.0%)	1 (12.5%)	1 (9.1%)	2 (40.0%)		11
Restricted field of use	2 (7.1%)	1 (16.7%)	1 (50.0%)	2 (25.0%)	2 (18.2%)			8
Requirement to transfer/share IP with supplier	1 (3.6%)		1 (50.0%)	2 (25.0%)	2 (18.2%)			6
Requirement to report back results	5 (17.9%)	1 (16.7%)	1 (50.0%)		2 (18.2%)	2 (40.0%)		11
Restricted ability to clinically develop	2 (7.1%)							2
Total number of respondents per level	28	6	2	8	11	5	6	

Table 32: Types of adverse effects encountered when receiving materials

Table 32 reveals that an overwhelming number of respondents who reported adverse effects from the use of MTAs in receiving materials (64 in total) complained of delays in their research.[109] This constitutes 97 per cent of respondents who answered this question and identified specific adverse effects. Eight per cent (ten respondents) reported a cessation of research. We expected more respondents to report that restrictions on publication and requirements to report results were adverse effects of MTAs, although admittedly the fact that 22 respondents reported this as being a problem is concerning. Given that TTO interviewees thought that MTAs are important to conclusively define field of use, few survey respondents had any problems with MTAs in this respect. This may be because they have no intention of using the transferred materials outside the stipulated use, or because these terms are not enforced in the event that field of use terms are not adhered to.

A relatively low number of respondents had any issues with IP, but this is perhaps unsurprising when viewed in the context that very few materials transferred have commercial potential. TTO officers are probably more attuned to the importance of IP as a driver of MTAs, and view it as a 'sticking point' in negotiations. For researchers not directly involved in negotiating MTAs, IP-related concerns are unlikely to feature. A similar comment can be made in relation to the low levels of concern about restrictions on the ability of researchers to clinically develop products, as reported in Table 33; very few materials lead directly to a clinically-ready product. Cessation in research was a much more prevalent concern, which may be linked to the unreasonableness of what is asked for in MTAs. One respondent made the following comment:

> *An area that should be examined is hospital pathology laboratories who hide their diagnostic specimens behind MTAs that no researcher or university can ever agree to sign.*

Returning to Table 24, we examined the reasons respondents engage in informal transfer. Sixteen respondents indicated that they consider formalised exchanges to be too difficult. Of these 16, seven respondents still indicated that they find MTAs beneficial, while 12 considered MTAs to have little or no beneficial value.[110] Thirteen of these 16 respondents went on to specify particular adverse effects they had encountered in using MTAs. We were interested in examining whether there may be a link between these respondents suffering adverse effects as a result of

[109] Note that respondents were permitted to choose as many adverse effects as they had encountered.

[110] Four were neutral as to whether MTAs confer any benefits, indicating that they probably fall into the category of recognising few benefits associated with MTAs.

using MTAs, and their use of informal processes. Data on specific adverse effects identified by this cohort is represented in Table 33.

Adverse Effects Reported by Those who Transfer Informally	Number of respondents
Delay in research	12 (92.3%)
Cessation of research	4 (30.8%)
Breakdown in collaborative relationship	4 (30.8%)
Restricted ability to publish my research results	4 (30.8%)
Restricted field of research use	3 (23.1%)
Requirement to transfer IP to/share IP with the supplier of the materials	1 (7.7%)
Requirement to report my results to the supplier of the materials	4 (30.8%)
Restricted ability to clinically develop	2 (15.4%)

Table 33: Particular adverse effects encountered by those who transferred informally because MTAS are 'too difficult'

It is clear from Table 33 that of those respondents who sometimes transfer informally, delay is the overriding concern when they do use MTAs. In other words, frustrations with delay appear to drive informal transfers and there is a clear link between respondents reporting delays as being an issue and making the decision to transfer informally.

We also considered data on who supplied materials where adverse effects were suffered (reported in Table 34). Across the board, it is clear that Australian private suppliers were far less likely to be perceived as problematic when compared with other suppliers, especially where delays were concerned. This may also mean that fewer respondents actually received materials from private suppliers. Not surprisingly, there were also fewer complaints in relation to intermediaries such as Addgene on the question of delay. International research institutes and hospitals, on the other hand, were complained of in the context of delays by 40 per cent of respondents. Receipts of materials from international, private suppliers also featured prominently (27.4 per cent), suggesting that international transfers account for a significant number of delays when

receiving materials. In respect of other adverse effects, these were fairly evenly spread across types of suppliers.

When you experienced an adverse effect, who was the supplier?	AU Priv	Int Priv	Intermediary	AU Uni	Int Uni	AU RI/Hosp	Int RI/Hosp	Total number of respondents
Delay in research	8 (12.9%)	17 (27.4%)	12 (19.4%)	21 (33.9%)	18 (29.0%)	19 (30.6%)	25 (40.3%)	62[111]
Cessation in research	2 (20.0%)	2 (20.0%)	3 (30.0%)	6 (60.0%)	4 (40.0%)	7 (70.0%)	6 (60.0%)	10
Collaboration breakdown	1 (11.1%)	2 (22.2%)	2 (22.2%)	7 (77.8%)	5 (55.6%)	3 (33.3%)	4 (44.4%)	9
Restricted ability to publish	3 (27.3%)	5 (45.5%)	3 (27.3%)	4 (36.4%)	6 (54.5%)	5 (45.5%)	7 (63.6%)	11
Restricted field of use	2 (25.0%)	5 (62.5%)	2 (25.0%)	3 (37.5%)	5 (62.5%)	2 (25.0%)	4 (50.0%)	8
Transfer/share IP	1 (16.7%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	3 (50.0%)	3 (50.0%)	1 (16.7%)	6
Report back results	3 (30.0%)	6 (60.0%)	3 (30.0%)	3 (30.0%)	4 (40.0%)	5 (50.0%)	7 (70.0%)	10
Restricted ability to clinically develop		2 (100%)	2 (100%)	1 (50.0%)	2 (100%)		1 (50.0%)	2
Other	1 (33.3%)	2 (66.7%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	2 (66.7%)	2 (66.7%)	3

Table 34: Adverse effects when receiving based on who supplied material

[111] Table 32 reports that 64 respondents (of 66 total who answered this question) reported that delay was an adverse effect of MTAs, while Table 34 reports that 62 respondents (of a total of 64) reported delay as being an adverse effect. This discrepancy is due to the fact that 2 of the 64 respondents who reported delay as an adverse effect, failed to go on to the following question and specify who supplied materials in this event.

These results were consistent with observations made by interviewees. Commercial transactions with private companies, including pharmaceutical companies, were viewed by interviewees who dealt with them (five interviewees) as being straightforward and quick. International institutions (both university and research institute) were a different matter and were the most 'problematic' party to deal with (six interviewees dealt with international institutions, four specifically mentioned them as being a problem). They mentioned delays and additional complexities, and one also discussed the difficulties associated with complying with ethics requirements when transferring internationally.

How Tolerable Are Delays?

Delay was by far the most common adverse effect reported by respondents. Despite these concerns, 69 per cent of respondents indicated that they considered MTAs to be 'very beneficial' or 'somewhat beneficial' when supplying materials. Sixty-one per cent of respondents answered in this way in respect of receiving materials. These results thus appear to clearly indicate that MTAs are generally viewed as having a positive impact despite the fact they frequently delay research. The results are interesting because they are markedly similar regardless of whether respondents are engaged in receiving or supplying materials. This may reflect the fact that respondents answered both questions in a similar way. It may also hint at acceptance of MTAs as part of the business of exchanging materials, coupled with a certain degree of frustration with institutional processes driving transfers.

Comments received in respect of both these questions reinforce this. Even those respondents who commented in respect of receiving materials that they 'should be beneficial', or that they are 'useful' or 'helpful' often tempered their comments:

> *Sometimes MTAs are useful, but I have never had any problems with suppliers or the downstream use of material, and more often than not the MTA is an administrative step that slows down the process of obtaining the material.*

> *There are two types of MTA – some materials have significant ethical, commercial and scientific issues that need clarification – MTAs are essential. The other group are all the reagents for which that MTA has no commercial or scientific consequences. These are a massive waste of time and clarify/protect nothing.*

> *Takes months, lots of lawyers and prevents the research proceeding. Australian environment is now so lawyer rich and risk averse that research is being crippled over trivial issues.*
>
> *MTAs are helpful to clarify, but they take so long to negotiate (even when no negotiating should be done) that they impede rapid progress.*

Comments received from those supplying materials were markedly similar:

> *MTAs have a place where obvious IP or real risk to human rights, safety or confidentiality are obvious. But [MTAs] should not be the default. They are way overused. Where the risks are minimal or close to zero, they should not be necessary. A massive amount of research time and opportunity is lost for very dubious benefit overall. One must take into account the costs of staff (business and legal), costs on research and the opportunity cost to progress. If patient advocates knew they would be very unhappy.*
>
> *For a three-year grant, a 10-month delay kills the project.*
>
> *MTAs are useful because they clarify the terms of transfer but they often take so much time to negotiate that the resulting delays in research are difficult in three-year funding cycles.*

Given the relative breadth of the survey respondent affiliation profile,[112] it is clear that many are experienced in the use of transfers involving MTAs. This lends weight to the theory that, although researchers accept MTAs as an inevitable part of the business of material transfer, they consider the bureaucratic delays that accompany MTAs to be frustrating and unnecessary:

> *Due to grant and publication deadlines, delayed approval for an MTA is approval denied. Reason for delay: unrealistic expectations and bureaucratic confusion.*

We were not able to glean what an 'unacceptable' delay means for survey respondents. However, our interviews with scientists provide some limited insight into this issue.

Of the researchers interviewed, one commented that MTAs were universally processed by their Business Development Office quickly –

[112] In that many respondents were from institutions that are heavily engaged in transferring materials using MTAs.

generally within the working week. Another reported fairly straightforward MTA processes involving sign-off by the research group involved in transfers. This researcher said that MTAs were only really slowed down if the material involved was 'sensitive' (such as a transgenic animal as opposed to a plasmid, or DNA). Under these circumstances, slower negotiations were tolerated. All of the other interviewees had encountered delays of some description that caused them frustration. One interviewee commented that 50 per cent of transactions progress very smoothly and are completed within a week, 30 per cent are 'pretty smooth' and 20 per cent are problematic. The average turnaround time for this interviewee was four weeks, which 'you can cope with'. But some MTAs had been known to take 'months and months'. Another interviewee stated that their Business Development Office was really supportive in getting agreements in place, but that sometimes there were really annoying delays (including one that had taken more than a year).

The remaining interviewees were generally positive about MTAs but negative about the processes accompanying them. One interviewee said that the 'really fast' MTAs take about two weeks, but most can sit in in-trays for weeks on end. It really 'depends on the person you contact in the relevant area of the uni'. Another interviewee who is involved in around 30 to 50 MTAs per year, all of which go through their legal department, commented that she spends a lot of time chasing up MTAs to make sure things have not got stuck somewhere along the path. Simpler MTAs can be quick, but one took 18 months. Finally, one interviewee stated that their standard MTA template never seemed to be applicable for one reason or another, requiring tweaks by their legal contracts department that delayed negotiations. This interviewee said that international MTAs take months, while even local transfers often take at least a month. She estimated the average for outgoing transfers to be eight or nine weeks, usually due to delays by the recipient organisation.

3.4.4 The Possibility of Standardisation

Although we did not specifically ask survey respondents about the desirability of a uniform, standard agreement across Australian institutions, we did explore this in interviews with scientists. A number of respondents to the survey also took the opportunity to comment on this issue. One professorial respondent acknowledged that the current processes surrounding MTA negotiation resulted in 'undue costs and delay', as each institution insists on using their own MTA. Another respondent stated that 'the world would be a better place if there was a

standard agreement worldwide for my sort of work'. A number of respondents stated that a standard agreement would diminish the costs and time required for MTAs to be prepared each time a material is transferred. Another commented on the tendency of 'every institution want[ing] to use their own form or terms and this causes undue costs and delay.' The following insightful comment was received from one respondent:

> *They are so complicated only legal can understand them, and in my opinion legal cannot understand what we do. And it takes so long that I can barely remember what MTA is for what in the end. Take out the jargon and have a standard agreement with tick boxes to include/exclude things that SCIENTISTS can understand. And a summary of the research, materials and variables required. That would be much more meaningful.*

Another respondent who had endured an 18-month time delay in the negotiation of an important MTA had an interesting suggestion as to how standardisation might be achieved:

> *All NHMRC/ARC funded research in Australia should have one overarching piece of legislation – [this] would give Australia a massive advantage internationally and stop vast amounts of tax payers' money [being] spent on lawyers for every trivial research reagent.*

There was some general support for a standard MTA from our interviewees, with four agreeing that standards make life easier. Three of these interviewees had already seen the adoption of global MTAs between their institution and collaborating institutions, so that in effect they had already been exposed to the impact of a standard agreement.[113] In contrast, two interviewees doubted the usefulness of a standard agreement in the context of their research, because they dealt primarily with human tissue, and the complexities involved in human tissue and ethics requirements usually give rise to a requirement to tweak standard agreements.

3.4.5 Transferring Data: Converging Practices of Formalisation

Formal data transfer is becoming more prevalent in biological research. We wanted to explore the shift we observed in TTO interviews toward

[113] It should be noted that two of these interviewees still reported significant delays on the part of their institution in processing MTAs!

formalising the transfer of data, and to consider whether there were problems associated with this trend.

Although the transfer of data has always been ubiquitous in biological research, the emergence of new forms of research, where data is key, has heralded an exponential increase in the amounts of data generated. A majority of our survey respondents either received or supplied data in research relationships, as demonstrated by Table 35.

Sharing / Transfer of Data?	Institution Type						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
Yes, I supply	15 (17.9%)	59 (70.2%)	1 (1.2%)	1 (1.2%)	4 (4.8%)	4 (4.8%)	84
Yes, I receive	14 (19.4%)	49 (68.1%)	1 (1.4%)		2 (2.8%)	6 (8.3%)	72
No	4 (28.6%)	8 (57.1%)				2 (14.3%)	14

Table 35: Respondents transferring data

A preponderance of respondents across institution types transfer data. Of these, many undertake the transfers personally, with far fewer engaging the services of TTOs, legal or research offices. Table 36 indicates that the number of respondents who always or often organise the transfer of data without intervention from their institution is significant, and it hints at the amount of data that is still transferred informally across institutions.

Are you personally responsible for negotiating data transfers?	Institution Type						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
Always	4 (17.4%)	17 (73.9%)				2 (8.7%)	23
Often	6 (28.6%)	12 (57.1%)		1 (4.8%)	1 (4.8%)	1 (4.8%)	21
Sometimes	5 (21.7%)	14 (60.9%)	1 (4.3%)		1 (4.3%)	2 (8.7%)	23
Rarely	2 (18.2%)	9 (81.8%)					11
Never	1 (9.1%)	8 (72.7%)			1 (9.1%)	1 (9.1%)	11

Table 36: Scientist responsibility for data transfer

Of course, Table 36 may also indicate that messages about transferring data formally have not yet reached scientists, and that formal data transfer's time is yet to come. Having said this, some research institutes are more clearly equipped for formal data transfers than universities, with a number of respondents indicating they undertake transfers with the assistance of their TTO or legal office (Table 37). Several also sought the assistance of their lab manager.

Other parties responsible for organising transfer of data	Institution Type						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
TTO	2 (10.0%)	18 (90.0%)					20
Legal Office	1 (7.7%)	9 (69.2%)			3 (23.1%)		13
Research Office		1 (33.3%)		1 (33.3%)		1 (33.3%)	3
Lab Manager	2 (28.6%)	5 (71.4%)					7
Don't know	3 (75.0%)	1 (25.0%)					4

Table 37: Institutional responsibility for data transfer

A smaller number went on to indicate that their institution uses a written agreement to transfer data, as represented in Table 38.

Transfer of data under a written agreement?	Institution Type						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
Always	2 (10.5%)	13 (68.4%)			3 (15.8%)	1 (5.3%)	19
Often	2 (16.7%)	9 (75.0%)				1 (8.3%)	12
Sometimes	6 (30.0%)	13 (65.0%)		1 (5.0%)			20
Rarely	5 (20.0%)	16 (64.0%)	2 (8.0%)			2 (8.0%)	25
Never	3 (25.0%)	8 (66.7%)				2 (8.3%)	12

Table 38: Prevalence of transfer under a written agreement

Relatively speaking, however, these numbers are low, and markedly lower than those using written agreements to transfer materials. Of

these respondents, 29 thought their institution used the same MTA for transferring data as for transferring materials. This was the case for 22 respondents from research institutes, three from universities, three who classified their affiliation as 'other', and one who merited a dual classification. Thirty-five said that their institution used a different agreement (presumably one specific to data). Twenty-four of these were affiliated with research institutes, eight with universities, and three were dual classification respondents. It is important to remember also that some respondents may be transferring data under overarching collaboration agreements, which might be incorporated in their answers to these questions.

Taken together, Tables 36 and 38 suggest that many more respondents transfer data informally than formally. As to why data was transferred informally, a variety of reasons were provided to this specific question, as shown in Table 39.

Reasons for transferring data informally?	Institution Type						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
I always have	1 (5.9%)	13 (76.5%)				3 (17.6%)	17
No established procedure to use formal agreement	3 (17.6%)	12 (70.6%)	1 (5.9%)		1 (5.9%)		17
Collaboration agreement	11 (27.5%)	24 (60.0%)	2 (5.0%)		1 (2.5%)	2 (5.0%)	40
I trust the other party	7 (16.7%)	29 (69.0%)		1 (2.4%)	1 (2.4%)	4 (9.5%)	42
I'm not using the data myself		4 (100.0%)					4
There is no value in data		4 (100.0%)					4
The institution I work for encourages 'openness'	1 (25.0%)	1 (25.0%)				2 (50.0%)	4

Table 39: Reasons for informal transfer of data

This data corroborates the suggestion that a considerable amount of data is transferred under collaboration agreements, which are likely to provide umbrella terms under which data between collaborators is transferred. Trust also plays an important part, as does the fact that data transfers have never been a priority insofar as formal procedures are concerned, with 34 respondents indicating they transfer informally because they always have, or because no formal procedures exist. Much probably depends on the data in question – the question we ask in Chapter 5 of this Occasional Paper[114] is whether researchers identify value in data in the same way that the value of materials is recognised. We also consider whether the fact that data has traditionally been more freely shared is the reason why it remains less likely to be transferred via formal agreement.

The trend towards informal transfer of data does not necessarily signify that it is trouble free. Table 40 explores this issue.

Difficulties encountered when transferring informally	Institution Type						Total number of respondents
	Uni	RI	Hosp	Clinical Rooms	Other	Dual	
Always							
Often							
Sometimes	3 (42.9%)	4 (57.1%)					7
Rarely	3 (9.4%)	28 (87.5%)				1 (3.1%)	32
Never	10 (25.6%)	21 (53.8%)	1 (2.6%)	1 (2.6%)	1 (2.6%)	5 (12.8%)	39

Table 40: Problems arising from informal transfers of data

Perhaps surprisingly, issues arising because data is transferred informally appear from this data to be relatively infrequent, despite the fact it is potentially very valuable. Comments received in respect of this question suggest that the difficulties encountered by respondents are relatively manageable.

[114] See 5.5.

Logistical issues were mentioned by a considerable number of interview respondents, both TTO and scientist. One survey respondent encapsulated this neatly, noting that 'given the scale of our data, the most trouble I've had has been file size, for example, if we've had to ship hard drives.' Several survey respondents provided comments to the effect that an amount of effort needs to be expended in transferring data:

> *Recipients may not have the necessary expertise to manipulate the data so there can be some iterative communication before the recipient can use the data.*
>
> *Occasionally people have not undertaken the analyses that they have promised and so it has been a waste of effort to prepare the data for them.*

Aside from these comments, many survey respondents took the time to explicitly comment that they generally had no (or very minor) issues when transferring data informally, once the decision has been made that the recipient of the data is trustworthy. Just two respondents commented on the publication or attribution problems that may arise from informal transfer. One respondent stated that supplying data may be problematic where 'credit is not given', while another stated:

> *It is sometimes difficult to obtain important research information because of supposed ethical or privacy concerns and because others are afraid that their data may be used for publication without proper attribution or consultation.*

Many respondents were at pains to stress that much data is transferred under collaboration agreements. A considerable number pointed out that if data is valuable, it will always be transferred under a written agreement. Generally speaking, however, it would appear that data that requires disclosure in any event (for example for publication purposes), or that has no specific need for protection, will often be freely shared absent the execution of a written agreement.

Interviewees confirmed these conclusions. Four interviewees (three from universities, one from a research institute) had policies in place for the transfer of data, and always used written agreements. Of the remaining interviewees, in some instances data was transferred under collaboration agreements and on others it was transferred under another form of agreement, particularly where ethics approvals governed the movement of data concerning research subjects. On other occasions though, data was transferred with no written agreement in place. Interviewees commented on the fact that it is possible to control

the release of data in ways the release of samples cannot, with one stating that you can 'filter the data down to a point where it's not really useful [outside the use for which it is transferred].' Another interviewee referred to the fact that they publicly released a 'scaled-down' version of their data. Interviewees noted further that often publication requirements will mandate the release of data.

Two interviewees explicitly referred to the fact that transfers of data are certain to become a significantly more pronounced problem, and that 'data is going to be something that becomes a huge problem … because it is the legacy of the project for us, anyway'. This interviewee made the astute point that their data transfer agreements only remain in force up to the point of generation for primary research, with no coverage past this point. This raises issues associated with responsibility for the data and circumstances under which it might be stored and transferred:

> *[T]he agreements have all lapsed, … we had a collaborative agreement, … ethics has lapsed, none of that even exists, so we've just got all this data, on servers, and it's just here, and you know, it's really critical, because that data has all the interpretation attached to it as well. And all the annotation, and so much work has gone into it. … [I]t becomes very powerful and there's even less protections on that than there is on samples, so it's tricky.*

Admittedly this interviewee dealt with human tissue, which has additional complexities as highlighted by the following section. The practice for some interviewees in relation to data emanating from human tissue is to release aggregated rather than raw data. Others saw more value in sharing raw data only, and indeed viewed it as a research imperative to realise as much benefit from raw data as possible by sharing with collaborators under controlled arrangements.[115] But there is no doubt that issues around sharing of data and the conditions under which it is shared, are set to emerge as core concerns as the primacy of data in genomic research intensifies.

3.4.6 Human Tissue and the Convergence of MTAs and Ethics Requirements

One area where there seems to be little dispute that MTAs are imperative, is where human tissue samples are exchanged. Exchanges of human tissue are always interlaced with considerations around ethics

[115] This interviewee pointed out that statistically the benefits are greater when pooling or combining raw data.

obligations, which add a layer of protection, but also complexity. Many interviewees saw requirements for MTAs as separate from commitments imposed by ethics approvals, but some viewed the issues as being inextricably connected. Table 14 demonstrates that MTAs are viewed by 55 per cent of our survey respondents as being an important conduit to fulfilling ethics obligations where receiving human tissue is concerned. Forty-seven per cent of survey respondents viewed MTAs as being important in the context of ethics when supplying human tissue.[116]

One concern in this context is the management of human tissue and storage of data generated from human tissue into the future. As we pointed out in the preceding section, obligations under both ethics approvals and MTAs may lapse, leaving researchers to determine how material data sets are dealt with. This raises issues that have received apparently little consideration by ethics committees or technology transfer personnel. A number of our interviewees commented on the fact that broad consent is often obtained when collecting samples, leaving scope for de-identified samples to later be transferred to other researchers. Broad consent was perceived by some interviewees as also encapsulating the subsequent transfer of data.

As a further complicating factor, one interviewee noted that cell lines generated from samples may not technically be covered by ethics obligations, because they cease to be part of the 'human' subject from whom they were generated, and have data attached to them. This researcher had experienced a situation where the ethics committee had grappled with how to treat cell lines. The MTA under which the samples had been transferred did not cover data. These boundaries between materials and data are producing some interesting issues that are yet to be resolved.

3.5 CONCLUDING COMMENTS

There is no doubt that some of the issues identified by TTO personnel were also identified as being problematic by scientists. Again, delays emerged as the predominant issue for scientists, along with frustration that a significant amount of time is spent negotiating MTAs for research materials that are very unlikely to yield a commercial or clinical outcome. MTAs are now viewed as an inevitable part of the research process by scientists, but the issues that come with them are not happily tolerated. These concerns explain to some extent continued reliance on informal

[116] See Table 15.

collaboration and sharing. Although the role of MTAs is well understood, the processes and wrangling surrounding them are not.

We conclude this chapter with two quotes that nicely encapsulate scientists' views on MTAs.

> *Many need training in the importance of protecting data and specimens particularly where governed by ethical and contractual obligations. Our research is affected where some ignore MTAs, affect trust, and limit future collaboration opportunities. Where researchers also argue against MTAs and refuse to see their need, future collaboration is also limited.*

> *MTAs apply a huge burden on our work – working time, delay, cost, distraction, stress. They are also absolutely essential to our work – sometimes. The problem is that they are used too frequently when the value of the material/data does not necessitate an MTA. Most materials cannot generate any significant value to which the originator of the material can lay claim. And even when the terms of an MTA are breached, they are not enforceable unless the aggrieved party is willing to spend resources pursuing the claim. And this will not occur unless there is really significant value – much more value than what 99.9% of MTAs ever embody. So why do we all reach for the MTA booklet at the slightest drop of a hat? Is it because people do not (cannot?) assess risk before deciding to do more paperwork? It is not easy to predict the future so administrators are increasingly blindly insisting on agreements that are unnecessary. Skilled researchers are leaving Australian science in droves and one of the top reasons for it is that they feel that the red tape and paperwork is increasingly demanding, wasteful and costly. MTAs and the unnecessary delays caused by them is one of the sources of frustration. It is essential that Australian research clarifies when an MTA is essential and when the cost is too high to pursue. Guidance from outside would be helpful.*

CHAPTER 4

MTA TERMS ANALYSIS

4.1 INTRODUCTION

An overarching theme of the research presented in this Occasional Paper is the question of whether MTAs can have positive or detrimental consequences for the Australian research effort, particularly in the general field of biomedicine and, more specifically, for human genomics. So far, the focus of the empirical component of this research has been on examining the opinions of particular groups of people about the purpose, efficacy and effects of formalised material transfer agreements (MTAs).

This chapter provides a different form of evidence base from which to consider the effectiveness of formalised MTAs – an analysis of the MTA document itself. This analysis involves an examination of contractual terms across a number of different MTA forms to assess their value and whether complexities in the agreements themselves could be a cause of some of the difficulties associated with materials transfer that have been identified in interviews and in prior research.

4.2 BACKGROUND

One of the questions most commonly asked during the course of this study has been whether agreements can be standardised to improve their quality and efficiency. As noted in Chapter 1 of this Occasional Paper, standardisation was significantly advanced by the National Institutes of Health (NIH) in the US through the *Uniform Biological Material Transfer Agreement* (UBMTA). On 8 March 1995, the NIH published the final version of the UBMTA. The development of this initiative was undertaken on behalf of the Public Health Service and Centers for Disease Control.[117] Once finalised, participating institutions were required to sign up to the UBMTA and the signatories were recorded. The Association of University Technology Managers (AUTM) agreed to store these agreements once parties had signed up. It was hoped that the simplified five-page agreement, publicly available on the web,[118] would significantly improve the material exchange process. Once an institution signed up to the UBMTA, all that was required was a two-page 'Implementing Letter' for the UBMTA to be in force between the parties. Although a US initiative, many other countries were interested in it, and some institutions outside of the US became signatories, including some in Australia. At the outset, there was an expectation that an agreement may be approved on the assumption that it was a standard form with known and acceptable terms.

AUTM later published 14 MTA *Guiding Principles* applying to transfers of research materials between not-for profit institutions.[119] Importantly,

[117] Association of University Technology Managers (AUTM), <https://autm.net/surveys-and-tools/agreements/material-transfer-agreements/mta-toolkit/uniform-biological-material-transfer-agreement/>.

[118] Office of Technology Transfer, National Institutes of Health, *Resources: Forms and Model Agreements* <https://www.ott.nih.gov/resources>.

[119] Association of University Technology Managers (AUTM), *MTA Guiding Principles: Best Practices in Non-Profit to Non-Profit Transfers of Published Research Materials* <https://www.autm.net/resources-surveys/material-transfer-agreements/mta-guiding-principles/>.

these principles do not apply to materials for use in humans or in the clinic. They focus on open sharing by the original material provider, limiting reach-through rights and ensuring, as much as possible, that recipients do not share materials with third parties. Additionally, these 14 principles rely on the distinction between materials and unmodified/modified materials to distinguish between provider and receiver rights. Despite the significant UBMTA initiative, research conducted in the US and Canada in the early 2000s found that MTAs were continuing to create impediments to material transfer.[120] It was reported that the UBMTA, which was designed to standardise and streamline the exchange process, was being modified by some institutions.[121]

During the course of this research, we became aware of another standard form MTA, the Brunswick Agreement, which is a UK standard with at least 29 institution-signatories.[122] The Brunswick Agreement had similar origins and objectives to the US UBMTA. PraxisUnico, a not-for profit group supporting knowledge commercialisation in the UK, offers the Brunswick Agreement for free-download on its website and notes, regarding the content of the Agreement:

> *The approach is deliberately minimal, and is not intended to cater for all situations. In particular, it is not suitable for use with clinical materials. Situations in which there is known to be an IP position that needs careful treatment are also not suitable. However, we have avoided the inclusion of onerous IP terms 'just in case IP is an issue' by insisting that no one in the drafting group propose an amendment that they would not accept both as donor and recipient.*[123]

Although a number of Australian universities are signatories to the UBMTA, there were few indications from TTO interviews that it was the preferred option for material transfers between Australian institutions.

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120 John P Walsh, Charlene Cho and Wesley M Cohen, 'View from the Bench: Patents and Material Transfer' (2005) 309 *Science* 2002; John P Walsh, Charlene Cho and Wesley M Cohen, 'Patents, Material Transfers and Access to Research Inputs in Biomedical Research' (Final Report, National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions, 20 September 2005) <http://www2.druid.dk/conferences/viewpaper.php?id=776&cf=8>.

121 Tania Bubela, Jenilee Guebert and Amrita Mishra, 'Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories and Litigation' (2015) 13(2) *PLOS Biology* e1002060, 3 <https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002060>.

122 Brunswick Group, *Brunswick Template Agreements* (1 February 2011) PraxisAuril <https://www.praxisunico.org.uk/resource/brunswick-template-agreements>.

123 Ibid.

This is notwithstanding that many were familiar with the UBMTA, particularly given that one of the major materials intermediaries in genome editing, Addgene, has chosen to use it exclusively. Our interviews revealed that the UBMTA is seen as too US-centric and therefore not particularly useful in the context of exchanges between Australian institutions and with institutions in jurisdictions other than the US.[124] There was no indication of any familiarity with the Brunswick Agreement in our interviews. There were also no reports of other commonly used MTA standard-form agreements in Australia,[125] although it was reported to us that the Garvan Institute of Medical Research has created an online web-based system to share materials, based on the UBMTA.[126]

The ostensible lack of interest in standard-form MTAs in Australia is not due to a lack of debate about their efficacy. In 2004, the Australian Law Reform Commission (ALRC), in the final report on its inquiry into the impact of gene patents on human health, recommended that Biotechnology Australia collaborate with other key stakeholders to create a standard, similar to the UBMTA in the US.[127] However, Biotechnology Australia did not respond to the ALRC report recommendation and has since been disbanded. The 2010 Australian Government response to the ALRC inquiry simply stated that 'Biotechnology Australia no longer exists' and that it will 'investigate options for developing model materials transfer agreements for use by research organizations' involving stakeholder consultation.[128] To the best of our knowledge, the Australian Government has, to date, conducted no further investigation into standardisation of MTAs.

This background information indicated to us that the analysis of MTAs reported in this chapter was unlikely to reveal much in the way of standardisation. We nevertheless expected that there would be a degree of similarity in the broad types of terms included in the MTAs we

[124] These are discussed in Chapter 2 and the analysis on TTO interviews. The full results of the inquiry and opinions of TTO officers on the UBMTA and standardisation are included in that chapter.

[125] This was based on the authors' knowledge in the field and research that they conducted. We also inquired about the use of standards in TTO interviews and no standard was commonly in use although we identified a number of current efforts and a number of commonly preferred agreements from particular institutions.

[126] Australian Law Reform Commission, *Genes and ingenuity: Gene patenting and human health,* Report No 99 (2004) [17.103].

[127] Ibid [17.108]; Recommendation 17.5.

[128] Australian Government*, Australian Government Response to Senate Community Affairs References Committee Gene Patents Report* (23 November 2011), 24–5 [Response to Recommendation 12.1].

analysed – as in many standard types of agreements – but that it would be the content of the terms which would vary.[129]

This chapter provides an account of:

1. the extent to which MTAs are already in standard (or template) form;
2. the extent to which specific MTA terms vary between agreements and the consequences of these variations; and
3. the extent to which specific terms align with the expectations and hopes of the groups involved in materials transfer.

4.3 METHODOLOGY

4.3.1 Sources of MTAs

In total, 45 agreements were collected and analysed, noting that two of these were data transfer agreements (DTAs) rather than MTAs. To maintain consistency and comparability with the other empirical elements of this project, our primary source for agreements was the institutions from which interviews were sourced. During interviews, we routinely asked interviewees to provide us with copies of their template MTAs. Some interviewees who used templates declined to provide us with a copy of their institutional MTA(s), while a number did not use a template. However, a sufficient number of template MTAs were provided to us for meaningful analysis.

The UBMTA and the Brunswick Agreement were also included in our analysis, as were specific agreements relating to transfer of human tissue from the US-based National Institutes of Health and the UK Biobank.[130] All of these are publicly available. An online MTA publicly available from CSIRO was included as an example of an MTA drafted by a large, publicly-funded research institute.[131] The CSIRO MTA is not a standard in

[129] A note on terminology in this chapter: Generally, we refer to MTAs as agreements. This may mean a contract or another form of agreement.

[130] UK Biobank, *Resources* (24 August 2018) <https://www.ukbiobank.ac.uk/resources/>.

[131] Commonwealth Scientific and Industrial Research Organisation, *Hairpin RNAi vectors for plants – Material Transfer Agreement* (25 January 2016)

widespread use like the UBMTA, but is an Australian template agreement for a suite of materials. Some other publicly available agreements recommended to us by interviewees were also included. The data set is heavily represented by MTAs from universities, as this was the largest interview group. The next largest group is research institutes.

4.3.2 Types of MTAs

The agreements collected can be grouped into two classes. Agreements are either 'standards' or 'templates.' From our TTO interviews we knew that many agreements and the terms in them are negotiated and altered, and that these flexible agreements are generally referred to as templates. Standards apply to the class of agreements where parties sign up without the power to negotiate. Examples include the UBMTA, the Brunswick Agreement, agreements in use by consortia, and agreements executed by third party intermediaries such as Addgene (noting that they use the UBMTA), UK Biobank and other biobanks and repositories. In this chapter, we distinguish between standards and templates to reflect this difference.

Two of the agreements dealt with exchanges of plant-based materials. These were the CSIRO Agreement and the Standard Material Transfer Agreement (SMTA) associated with the International Treaty on Plant Genetic Resources for Food and Agriculture. These agreements were included in our analysis for two reasons. First, seven of our TTO interviewees indicated that they engaged in transfers of some plant-based materials to varying degrees. For two interviewees this was the predominant type of material transferred. For consistency we considered it important to include these agreements, but to identify them in our results. Second, these agreements share many commonalities with MTAs for other biomaterials, hence terms contained within these different forms of agreement are capable of direct comparison.

Finally, as noted above, two of the agreements were DTAs. Although the transfer of data presents some different issues to the transfer of materials, it became evident that many terms were common between both forms of agreement. Further, many MTAs include terms for the transfer of data, which led to our decision to include the DTAs in our analysis.

<https://www.csiro.au/en/Do-business/Collaborative-research/Active-opportunities/RNAi-Material-Transfer-Agreement>.

4.3.3 Coding Process

Agreements were subject to coding analysis using NVivo Version 11. Qualitative coding analysis was conducted on all 45 agreements from 28 different sources. Up to three agreements per institution were accepted, provided that the agreements were used for different purposes. Four organisations had three agreements. Each agreement was classified using each of these criteria:

- type of institutional or organisational source;
- supplier, receiver or neutral;
- length; and
- material type (where specified).

Of the 45 agreements analysed in this chapter:

- twenty-three came from 14 different universities;
- nine were from research institutes (including CSIRO);
- two research consortia agreements were provided confidentially;
- five came from biobanks and biorepositories including the UK Biobank,[132] the American Type Culture Collection (ATCC)[133] and three others that cannot be identified due to confidentiality obligations; and
- six were standard-form MTAs, and were classified as third-party agreements. These included the UBMTA and accompanying Implementing Letter, the Brunswick Agreement (which included one MTA for human materials and one for non-human materials),[134] the NIH standard agreement dealing with human

[132] UK Biobank, *Annex II: Material Transfer Agreement for data/and or samples* (20 August 2012) <http://www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Material-Transfer-Agreement.pdf>.

[133] American Type Culture Collection, *Material Transfer Agreement* (15 November 2011) <https://www.atcc.org/~/media/PDFs/MTA_2.ashx>.

[134] Brunswick Group, *Brunswick Template Agreements* (1 February 2011) PraxisAuril <https://www.praxisunico.org.uk/resource/brunswick-template-agreements>.

tissue[135] and the International Treaty on Plant Genetic Resources for Food and Agriculture SMTA.[136]

Twenty-eight of the agreements were provided by suppliers of materials, six were provided by receivers, nine were neutral in the sense that they were the third-party standard MTAs that could be used both by suppliers and by receivers, and three were neutral in the sense that the source of the MTA used it both for supply and for receipt of materials.

Each of the MTAs was subject to thematic analysis of individual terms. Themes for coding were both inductive and deductive.[137] Deductive themes were derived from the existing MTA literature (as with the interview component of this study) and from analysis of the interview transcripts. The themes were refined to focus on potential sticking points in MTA negotiations. During coding, further inductive themes emerged.

Generalisations were made where appropriate, although in many cases it was difficult to do so given the variance in the wording of each agreement. Interpretation of terms was generally undertaken using broad common-sense meanings, rather than using strict interpretation of individual clauses in individual agreements, as the goal was to gain a picture of the general make-up of MTAs. We also note that because the MTAs were standards or templates, they were missing particulars such as definition of materials being exchanged, parties, and other specific details, which sometimes made interpretation difficult.

4.3.4 Limitations of Terms Analysis

The most significant limitation of this study is that the sample does not include the full gamut of MTAs used for the transfer of research materials across Australia. While we acknowledge this limitation, it was never our aim to be comprehensive. Rather, it was to point to some of the features commonly seen in our sample that could reduce the efficiency and efficacy of material exchanges, and to suggest ways to circumvent these concerns.

We also note that in analysing codes, we attempted to draw the analysis from within the coded text. Fundamental contractual principles require

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[135] Office of Technology Transfer, National Institutes of Health, *Resources: Forms and Model Agreements* <https://www.ott.nih.gov/resources>.

[136] Food and Agriculture Organisation, *Standard Material Transfer Agreement* (16 June 2006) <http://www.fao.org/3/a-bc083e.pdf>.

[137] Jennifer Fereday and Eimear Muir-Cochrane, 'Demonstrating Rigor Using Thematic Analysis: A Hybrid Approach of Inductive and Deductive Coding and Theme Development' (2006) 5(1) *International Journal of Qualitative Methods* 7.

reference to the contract as a whole, the simplest example being to incorporate defined terms into the reading of a provision. Although it would negate the advantage of coding to go back to each agreement to interpret each provision for analysis, the artificiality of conducting a legal analysis without such reference is acknowledged. The way in which the coding was undertaken did provide some broader context in that in the initial phase, codes were applied based on a reading of the contract as a whole and with respect to related provisions.

Finally, we recognise that our analysis involved comparison between agreements designed to perform different functions, in respect of different materials, and on behalf of different parties. In particular, the standards and templates provided by third parties cannot be directly compared with those provided by individual institutions (although we would hope to see some common aspects). MTAs provided by biobanks will invariably differ to those provided by other parties, and DTAs raise different issues again. Where possible, we have pointed out discrepancies in agreement terms that were due to differing agreement types.

4.4 RESULTS

Details of the agreements according to the variables identified above are provided in Table 41.

Classification of source of agreement	Data Agreement?	Legal form specified in writing	Length of Contract	MTA Specifically for Human Tissue	Supplier or receiver specific	Type of material specified
University	Not Applicable	Agreement	10 or more Pages	Not Applicable	Supplier	Any materials
University	Not Applicable	Agreement	10 or more Pages	Not Applicable	Receiver	Any materials
University	Not Applicable	Agreement	10 or more Pages	Not Applicable	Supplier	Any materials
University	Not Applicable	Deed	4- 9 Pages	Not Applicable	Not specified	Any materials
University	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Supplier	Biological
University	Specific Data Agreement	MOU	4- 9 Pages	Not Applicable	Receiver	Not Applicable
University	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Supplier	Any materials
University	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Supplier	Other
University	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Supplier	Any materials
University	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Receiver	Any materials

University	Not Applicable	Deed	4- 9 Pages	Not Applicable	Not specified	Any materials
University	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Supplier	Any materials
University	Not Applicable	Deed	4- 9 Pages	Not Applicable	Supplier	Any materials
University	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Any materials
University	Unassigned	Agreement	2-4 Pages	Not Applicable	Supplier	Any materials
University	Not Applicable	Agreement	2-4 Pages	Not Applicable	Receiver	Any materials
University	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Biological
University	Not Applicable	Agreement	2-4 Pages	Not Applicable	Receiver	Any materials
University	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Biological
University	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Biological
University	Not Applicable	Agreement	2 Pages or Less	Not Applicable	Supplier	Biological
University	Not Applicable	Agreement	2 Pages or Less	Not Applicable	Not specified	Any materials
University	Not Applicable	Agreement	2 Pages or Less	Not Applicable	Supplier	Any materials

Research Institute	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Supplier	Any materials
Research Institute (CSIRO)	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Supplier	Other
Research Institute	Not Applicable	Agreement	2-4 Pages	Not Applicable	Receiver	Any materials
Research Institute	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Any materials
Research Institute	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Any materials
Research Institute	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Any materials
Research Institute	Not Applicable	Agreement	2 Pages or Less	Not Applicable	Supplier	Any materials
Research Institute	Specific Data Agreement	Agreement	2 Pages or Less	Not Applicable	Supplier	Not Applicable
Research Institute	Not Applicable	Agreement	2 Pages or Less	Not Applicable	Supplier	Other
Research consortia	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Not Applicable	Biological
Research consortia	Not Applicable	Agreement	4- 9 Pages	Yes	Not Applicable	Human
Biobank or biorepository (UK Biobank)	Not Applicable	Agreement	10 or more Pages	Not Applicable	Supplier	Other

Biobank or biorepository	Not Applicable	Agreement	4- 9 Pages	Unassigned	Supplier	Other
Biobank or biorepository	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Other
Biobank or biorepository	Not Applicable	Agreement	2-4 Pages	Not Applicable	Supplier	Other
Biobank or biorepository (ATCC)	Not Applicable	Contract	2-4 Pages	Not Applicable	Supplier	Other
3rd Party (International Treaty on Plant Genetic Resources SMTA)	Not Applicable	Agreement	10 or more Pages	Not Applicable	Not Applicable	Plant
3rd Party (Brunswick Agreement – Human Tissue Transfers)	Not Applicable	Agreement	4- 9 Pages	Yes	Not Applicable	Human
3rd Party (UBMTA and Implementing Letter)	Not Applicable	Agreement	4- 9 Pages	Not Applicable	Not Applicable	Biological
3rd Party (NIH – general)	Not Applicable	Agreement	2-4 Pages	Not Applicable	Not Applicable	Biological
3rd Party (NIH MTA for Human Tissue Transfers)	Not Applicable	Agreement	2-4 Pages	Yes	Not Applicable	Human
3rd Party (Brunswick Agreement – General)	Not Applicable	Agreement	2 Pages or Less	Not Applicable	Not Applicable	Any materials

Table 41: Source classifications of MTAs

Clearly, the vast majority of agreements (28) were supplier agreements, which was not surprising, since many suppliers of materials will seek to use their own MTA when transferring materials out.

4.5 POSSIBLE INDICATORS OF MTA COMPLEXITY

One of the key concerns relating to MTAs is their complexity. Unnecessary complexity is one of the reasons why formalised MTAs can hinder the process of materials exchange, leading to delays in research. There are sound arguments for promoting simplicity. In particular, MTAs are generally over research materials that are likely to be of minimal commercial value and accordingly should not be subject to onerous terms. Furthermore, they should be simple and short to facilitate and expedite sharing. We used length of agreements as a proxy for complexity on the basis that longer agreements are likely to include more terms, to be characterised by increased complexity and, in this way, to impose more onerous obligations. We explored this issue by grouping page length into four categories: 1–2, 3–4, 5–9 and 10 or more pages. As these categories were indicative only, this assessment included all pages in the MTA document, including schedules and title pages. We recognise that length is influenced to some extent by document format, although upon our observation this did not alter document length dramatically. Length may enable some initial observations to be made as to whether reading or negotiating the agreement in question is likely to be more time consuming.

There was no uniformity in length of agreement, although the bulk were between three and nine pages long. There were only five agreements which had 10 or more pages (10 per cent of agreements assessed). Seventeen agreements were five to nine pages in length (38 per cent), sixteen were three to four pages (36 per cent) and seven were one to two pages (16 per cent). We used the NVivo matrix query function to assess whether there was any relationship between length, type of institution, or type of material being exchanged

4.5.1 Type of Institution

The first question was ‘does page-length depend upon the *type of institution* that created it?’ The analysis of this question is set out in Figure 1, below. While most of the lengthy agreements were university-based (three agreements), this observation may be explained simply on the basis that more agreements overall were sourced from universities. It may also be partially explained on the basis that universities are likely

to need MTAs that cover a broader range of materials compared with specialist consortia and research institutes. Research consortia agreements fell squarely within the 4–9 page length,[138] and it is interesting to note that a number of standards provided by third-party suppliers were lengthy.[139] The significant length of the remaining third-party MTAs can no doubt be explained by the fact of their broad scope, in that they are not limited in terms of whether they apply to receipt or supply, by type of material, or by whom they may be used.

One point we may draw from the data is that research institutions and research consortia were the only groups that did not provide any agreements falling into the '10 pages or more' category. In other words, they have fewer very long and potentially complicated agreements. This is unsurprising based on our interviews, which indicated that, on average, research institute TTOs managed the highest volume of MTAs per year and thus had greater experience in drafting and negotiating MTAs. Consequently, we expected that they would use more streamlined agreements. Of course, it is difficult to draw definitive conclusions on this issue given that so few agreements exceeded 10 pages.

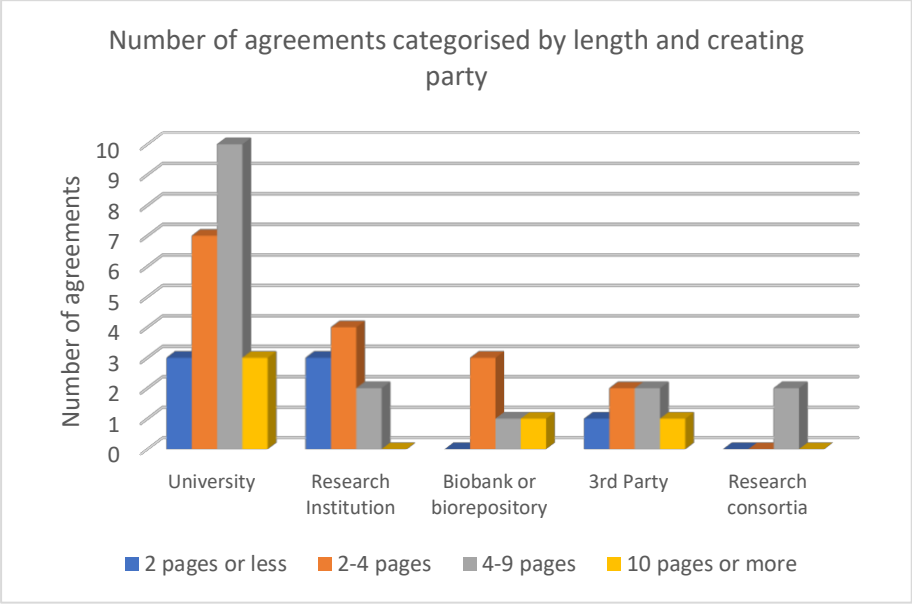

Figure 1: Number of agreements categorised by creating party and length of agreement

[138] Although the sample size was just two.

[139] This category included the UBMTA which at five pages (plus the Implementing Letter at two pages) is a relatively succinct agreement.

4.5.2 Type of Materials

A similar analysis was conducted to consider whether page-length depends on the *type of materials* contemplated in the agreement. The 'type' of material was defined by looking at the agreements themselves, for example, the title or definition of the material, or purpose for the agreement. These results are set out in Figure 2. There was a spread in length of agreement for each of the types of material, and we cannot say that length can be explained by the fact that a particular type of material requires more detailed terms. However, considering those agreements that could be categorised as either 4–9 pages or 10 or more pages, a majority covered unspecified ['any'] types of material. This might be expected, as those agreements are written to be applicable to a broader set of materials and potential situations that may arise.

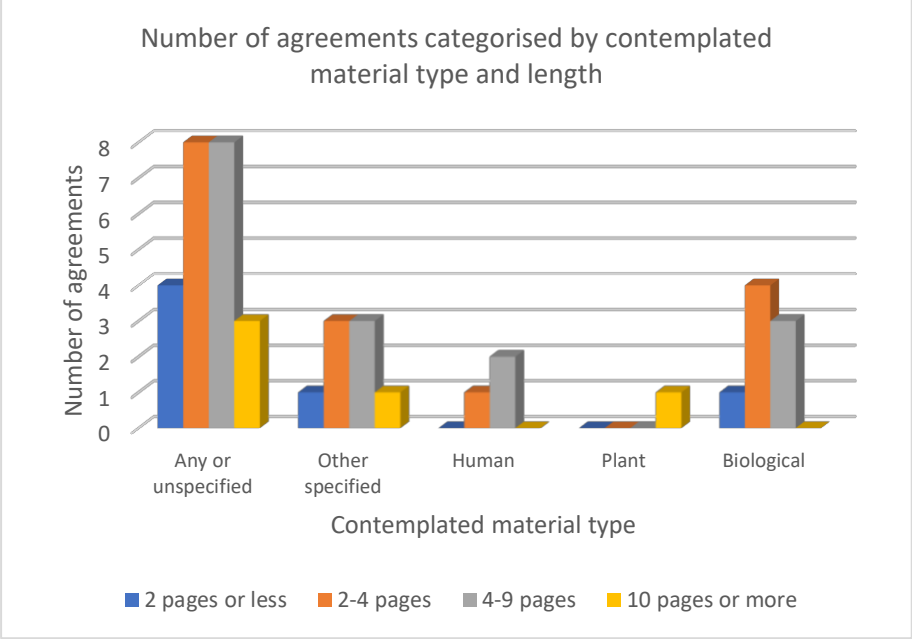

Figure 2: Number of agreements categorised by the type of material the agreement was to be used for and the length of the agreement

While it is difficult to draw any clear conclusions from the analysis of agreement length, we can say that there is a large degree of difference in length between agreements, even though they appear to cover similar materials and are being used by similar types of organisations. The reasons for these differences may be better understood through an analysis of individual terms.

4.6 THEMATIC ANALYSIS OF CONTRACTUAL TERMS

4.6.1 Definitional Terms

Definitions are not promissory terms, and, as such, are not capable of being breached. They do, however, give meaning to particular words and assist with interpretation. It became clear that the key words that impact most significantly on the reading of an MTA document include the following: 'material', 'derivative', 'modification', 'data' and 'commercial'. Not all MTAs included definitions of materials and derivatives. Reasons for these omissions might be that the words are given their ordinary meaning in the context of scientific MTA exchanges, or that they are defined by context or by the understanding of the parties based on previous exchanges or prior dealings.

Materials

All but three of the agreements examined contained or provided for a definition of material.[140] Not surprisingly, there were more definitions of 'material' than any other term. Three classes of definitions for materials were identified:

- a *general* definition of any material that could come within the boundaries of the MTA. These definitions tend to articulate whether data, progeny and derivatives are a part of the material, and may encompass broad categories of materials, such as biological, chemical or human materials;

- a *specified* description of the material that is the subject of the MTA. In this case, there will simply be a space left in the written document to insert a description of the material being transferred (for example a particular cell line), or a reference to a separate schedule; or

- a *combined* definition with both broad parameters and a reference to the specific material.

[140] Two of these agreements were DTAs, and we would not expect to see a definition of 'material', or of progeny, derivatives or modifications (discussed further below).

Table 42 provides examples of these three classes of definitions.[141]

Class of definition	Example
Class 1 General	The Original Material, Progeny, Unmodified Derivatives and any Original Material contained in Modifications.
Class 2 Specified	*[Insert a description of the material to be provided including the volume and the relevant characteristics].*
Class 3 Combined	*Description of the materials*: *[insert]* Biological samples linked to clinical, mutation and epidemiological data. Without limiting the above, for the purpose of this Agreement, 'Materials' also includes any progeny, unmodified derivatives or replicates of any materials supplied any combination or mixture of any materials with other substances.

Table 42: Class descriptions of materials

Some agreements contained more than one clause to cover these different classes of definitions. To some extent, whether or not a broad or specific definition is employed in an agreement depends on the nature of the MTA and the materials being transferred. Broad definitions alone are rare. Table 43 details the spread of agreements across the categories identified above. The UBMTA is a good example of an agreement that provides a combined definition. Agreements containing a specified definition included the International Treaty on Plant Genetic Resources SMTA and the NIH agreement dealing with human material. The UK Biobank and the ATCC Agreements are examples of public agreements offering broad definitions.

[141] These are taken from agreements provided, but some words have been altered to neutralize the definition from a specific material type or to de-identify parties.

Providers	Class of definition of material		
	Broad	Specified	Combined
University	1	8[142]	13
Research Institute		6	2
Research Consortia			2
Biobank	3[143]		2
Third Party		3[144]	2[145]

Table 43: Classes of definitions of materials in MTAs from the various categories of provider

The widespread use of definitional terms attests to the fact that it is best practice to include some sort of short definitional term for the material covered by the agreement. Ideally this should comprise a *general* definition stipulating whether progeny and modifications are included and articulating the broad material type (for example, biologicals, human tissue). It should also include a *specific* reference to the material in respect of which the agreement has been executed.

Progeny

There were eight specific definitions of 'progeny' across the MTA sample, each of which included the key descriptor 'unmodified descendants'. This definition may be useful for clarity in cases where viruses, cells and/or organisms (especially animals such as mice) are transferred as 'material'. The ATCC Agreement and the UBMTA both defined progeny. The similarity in the definition of progeny across this cohort reflects the consistency with which progeny were treated within agreements. In

142 This included the CSIRO Agreement.

143 This included the ATCC Agreement and the UK Biobank Agreement.

144 This included the NIH Human Tissue Agreement, the Brunswick (general) Agreement and the International Plant Treaty SMTA.

145 This included the UBMTA and the NIH (general) Agreement.

general, progeny 'belong to'[146] the supplier separately or as incorporated into a combined definition of material, as discussed above.

Derivatives

Definitions of 'derivatives' were included in 19 agreements (32 definitions in total). Interestingly, 12 of the 19 agreements defining derivatives were from universities. Three were from third-parties,[147] two were provided by research consortia and just one of the research institute and biobank agreements contained a definition. Some referred more specifically to 'modified derivatives' (or 'modifications': nine agreements) or 'unmodified derivatives' (six agreements). Across the agreements, there was consistency in the definition of 'unmodified derivatives'. As an example: 'unmodified derivative means any substance or material which constitutes an unmodified functional sub-unit or product expressed by the material.' The UBMTA and ATCC Agreement define unmodified derivative in these terms. It makes some sense that unmodified derivatives would be subject to the same ownership and associated obligations as the transferred materials.

A number of agreements did not distinguish between modified or unmodified derivatives. This may have ownership and intellectual property (IP) implications. If this broad definition is adopted and ownership of all derivatives and associated IP are claimed by a particular party, an inappropriate assertion of rights might result.

Modification(s)

Ten definitions of 'modifications' appeared in the MTA sample: six in university agreements, two in third party agreements[148] and one each in the categories of research institute and biobank. One example was: 'substances created by the recipient which contain/incorporate the material'. The distinction that the material is provided by the supplier and that the modifications are made by the recipient, is particularly important in the context of ownership claims. However, most agreements contained the added proviso that, to the extent the material is incorporated in the modification, property in the material remains with

[146] We use this word in the general sense that they had a better property interest than the receiver but where their possessory interest may be better classified as custody or control rather than ownership e.g. where ownership vests in a third party (who is not a party to the MTA in question).

[147] These definitions were contained in the ATCC Agreement, the UBMTA and the NIH Agreement.

[148] These agreements were the ATCC Agreement and the UBMTA.

the supplier. This may create difficulties in the context of on-transferring the modification.

Definitional clauses generally

In summary, definitions varied across agreements and were entirely absent from many. For consistency and to reduce complexity across MTAs, we suggest that, at the very least, both material and modification should be defined. There are good grounds to argue that unmodified derivative can be understood without further definition and might be removed to enhance simplicity.

4.6.2 Provenance, Ownership and Title

We also considered the inclusion of terms impacting on provenance and ownership. It is clear from an examination of our interview data that many parties involved in MTA negotiations shared concerns about the issue of provenance, namely, where the material came from and the ownership status of both tangible property and IP. Ownership and control are determined to some degree by how a number of other terms contained in MTAs are interpreted, and invariably the definitions discussed above. Intellectual property is dealt with in a later section.

Provenance

We have seen in earlier chapters that a key role of the MTA is to provide clarity on the provenance of material, so that the parties know where the material originated from and what rights and obligations arise as a consequence.[149] Indeed, as we have pointed out, delineating provenance could be seen as the core purpose of the MTA.

There are a number of ways in which a research material's 'chain of custody' might be chronicled via an MTA. These are discussed below and include terms relating to ownership or title, terms relating to on-sharing, and terms that confirm ethics approvals and obligations. Terms imposing obligations to report back to suppliers of materials are also an effective method of tracking provenance.[150] Fourteen agreements had a total of 21 clauses that could be construed as otherwise warranting the provenance of material.

The lack of terms dealing squarely with the historical interchange of materials was unexpected, as many TTO interviewees had articulated it

[149] See 1.3.3.

[150] See below 4.6.5, *Reporting Requirements*

to be a central concern. In addition to template MTAs, we received a small sample of documents used to assist in the preparation of MTAs, which often contained questions for researchers to populate relating to the provenance of material. This, combined with TTO interview data, suggests that TTO personnel routinely track provenance. It seems odd, therefore, that provenance is not specifically addressed in all MTAs, and clarified during the course of the transfer process. One explanation may be that often, materials that are the subject of transfer involve samples collected, or materials developed by researchers at the supplying institution. This negates the need to include representations as to the original source of the material, or the authority of the supplying institution to transfer. Invariably, however, materials are shared multiple times and freely. It may also be possible to surmise that those drafting agreements are of the view that the terms mentioned above adequately record provenance.

Three agreements contained terms specifying that the supplier was either the owner or creator of the material being transferred. The ATCC Agreement is an example. Seven agreements had terms confirming that the supplier had authority to transfer a material,[151] in some cases warranting they had permission from the original source of the material to transfer to the receiver. The UK Biobank Agreement, the ATCC Agreement and the CSIRO Agreement fell into this category. Three agreements had terms that essentially put the burden on the receiver to ensure that all the appropriate permissions were in place, but two of these referred only to IP rights. One biobank MTA incorporated a provision that warranted the chain of custody over the material in question had been maintained. One university agreement required details of the source of the material to be listed.

Provided the combined effect of relevant MTA terms is to provide some clarity regarding the ownership status of a material, an MTA will be performing an important function. It might be beneficial for some MTAs to include terms specifying the source of the material (noting that in some instances this will be confidential, for example, for human tissue). One option is to list the 'chain of custody' of the material, along with any rights or conditions attached, in a schedule, with accompanying references to any relevant agreement(s), particularly if the material originated from a party other than the supplier.

We suggest that, in general, where the supplier is not the original source of the material, they should provide clear documentation to show they

[151] In three cases this was stated to include, but not be limited to, relevant ethics approvals.

have permission to transfer the material or should warrant that they have permission to pass the material on. In the alternative, the supplier might provide the receiver with the details of the originator so that the receiver could negotiate a direct MTA with them, or, more simply, ensure their consent to the transfer. Particular problems are likely to arise where a material is incorporated into a modification/derivative product that is intended to be transferred. The question here is whether any residual rights remain with the original source of the material.

Title

Clear title is important for many reasons. It is clearly a crucial aspect of documenting the path a material has travelled, as discussed in the preceding section. At a basic level, it is important for characterising the legal relationship between parties, with respect to remedies for enforcement. For example, if ownership/possession remains with the supplier, the relationship between the parties may be characterised as a bailment (regardless of any contractual arrangements). This is an important issue, which is discussed further in Chapter 5.[152] Ownership is also important to ensure recognition of scientific contribution for publication purposes, and in follow-on inventions and future commercialisation opportunities.

A considerable number of agreements in the sample included terms relating to ownership of the material after transfer. Twenty-six expressly stipulated that the supplier owned the material once transferred.[153] A majority of these agreements were provided by suppliers. Just three were standard agreements for incoming materials, while two were designed to be used for either supply or receipt of materials (one of which was the UBMTA). Two agreements explicitly provided that title passed to the receiver.[154] One of these agreements was the NIH MTA template.

[152] See 5.3.

[153] Sixteen of these agreements were university agreements and seven were provided by research institutes. One was the UK Biobank Agreement, while two were third party agreements: The ATCC MTA and the UBMTA.

[154] One agreement was difficult to classify at this level as it seemingly purported to maintain and relinquish some control of the material. Closer examination of the terms revealed that the supplier maintains future legal title in the 'gene or allele mutation that makes the organism unique' in the animal. However, it is made available as a 'service to the research community' (ie defining the scope of use to research) and the receiver 'accepts full ownership, custody and control of the animal(s) except that to the extent the Government has any patent, invention or any other intellectual property rights in the animal(s), and the Government retains these rights.' (In this case the supplier is provided by a Government Agency.) If a

Another five agreements used language of 'custodianship' in place of ownership, by referring either to custodianship passing to those that control the physical sample, or by referring to the supplying party as remaining the 'custodian' of the material.[155] These agreements were all provided by either research consortia or biobanks. As such, the language is perhaps more understandable. It may also be that the 'custodianship' terminology had been adopted due to the questionable status of property in human tissue,[156] and to ensure that some degree of control over the material is retained.[157] Provisions of this nature also provide recognition that parties other than the supplier may have some form of ownership or interest in the material. This may be important for human tissue where a donor retains some rights, a not uncommon scenario that will be contingent on the terms contained in a biobank agreement.

Twelve agreements contained no explicit statement of legal title. Two were DTAs, while a further six could be construed as implicitly vesting title in the supplier.[158] One implicitly passed title to the receiver, while two left the matter open. One of these was the Plant Treaty SMTA and, as such, ownership is likely to implicitly pass to the receiver. Finally, the CSIRO Agreement stated that title remained with the developer of the materials, with CSIRO acting as an intermediary distributor.

This clearly indicates that the common position in MTAs is for the supplier to retain ownership over materials once transferred. Whilst materials are capable of ownership in most situations, the situation is more equivocal for human tissue. The language of custodianship makes good sense in such circumstances. Ownership of IP generated from using the materials is, of course, a different question which is dealt with later in this chapter.

material is not, or does not contain patented material there is unlikely to be a recognised IP right to the material.

155 In that they provide that the supplier retains custodianship these latter three agreements may be more accurately grouped with those that state that title remains with the supplier.

156 See 5.4.

157 Two agreements state that 'it is not appropriate to speak about ownership in relation to material or derivatives; therefore the term of ownership shall not be used.'

158 Including both Brunswick templates.

4.6.3 Derivatives, Modifications and Progeny

Derivatives

It would seem to be generally accepted practice that ownership of unmodified derivatives ordinarily resides with the supplier. The question of who owns modified derivatives is more complex. There were 28 agreements that contained 40 instances of terms relating to ownership of derivatives. These were split into categories depending on whether the supplier or receiver claimed ownership or whether co-ownership was evident. Nine terms specified outright supplier ownership,[159] while three further agreements provided for supplier ownership coupled with the grant of a non-exclusive licence to the receiver.[160] A majority of terms specifying supplier ownership tended to vest minimal rights in the receiver. Whilst receivers may be willing to accept such terms because of the importance of the material to their research efforts, there may be negative consequences of doing so. The ability to retain rights to publish research results and to continue to research, clinically develop and commercially develop derivatives all need to be considered. One third of the agreements with terms vesting ownership of derivatives in the supplier also included terms providing the (discretionary) right to veto publication. Others provided the right to delay publication.

Seven agreements specified that ownership resided in the receiver,[161] while a further four specified that the receiver owned modifications, with an option of granting co-ownership.[162] Three agreements allowed exclusively for joint ownership of modifications.[163] One agreement contained a broad selection of clauses from which parties might choose an ownership position, leaving this as a matter for negotiation at the time a transaction is entered into. The spread of terms governing ownership of modified derivatives is demonstrated in Table 44 below. Provisions vesting ownership of modified derivatives in the receiver promote the broad position that recipients will own any changes they develop. This seems to be a reasonable position for inclusion in a standard or template, and would be appropriate for most MTA situations. The inclusion of a requirement to re-negotiate commercial uses might assist, as can be

[159] Comprising seven university agreements and two research institute agreements.

[160] These were all university agreements.

[161] This included three research institute agreements (which implicitly vested ownership of modified derivatives in the receiver), two university agreements, the ATCC Agreement and the Plant Treaty.

[162] In addition to the UBMTA, this included one university agreement, one research institute and one biobank agreement.

[163] Including two university agreements and one research institute agreement.

found in the UBMTA. Joint ownership is also a viable option rather than outright supplier ownership. Of the eight agreements providing for co-ownership in some manner:

- two referred to any modifications (regardless of contribution) being vested jointly in the recipient and the supplier as joint tenants – with the original material contained in the modification still belonging to the supplier;
- four said that 'collaborative' efforts would result in the possibility of joint ownership, with three stating joint ownership 'may be' negotiated and the other stating it 'will be' negotiated;
- one stated that modifications 'created in collaboration' or 'contributed in any way' by the supplier will be owned as tenants in common with equal shares; and
- another said that 'ownership and IP will be determined in good faith' depending upon relative contributions.

	Ownership Provisions						
	Supplier only	Supplier + Non-exclusive licence	Supplier + Co-ownership	Supplier + Receiver + Co-ownership	Receiver + Co-ownership	Receiver only	Co-ownership only
University	7	3		1	1	2	2
Research Institute	2				1		1
Research Consortia							
Biobank					1		
Third Party					1	2	

Table 44: Ownership provisions relating to modified derivatives in MTAs from the various categories of provider

We suggest that best practice requires that:

- unmodified derivatives be owned by the supplier (or originator); and

- modifications/modified derivatives should be owned by the receiver unless there is evidence of joint creation, in which case agreements should reflect the parties' contributions through co-ownership. It makes good sense that the supplier retain ownership over the original materials remaining in the modifications.

Progeny

The position taken across the agreements was clear: where the supplier or originator retains ownership of the material, progeny are also the property of the supplier or the originator. Seventeen agreements had specific provisions to this effect, and many more specified ownership of progeny through their inclusive definitions of materials or the descriptions in the allocation of ownership of derivatives. No agreements gave the ownership of progeny away to the receiver, except the few agreements that distinguished between unmodified and modified progeny.

Data

As previously outlined, although we asked for data agreements from any party who indicated that they used them, we were provided with only two *sui generis* DTAs.[164] However, there were a total of 78 terms relating to data contained in 33 agreements under examination (31 MTAs and the 2 DTAs). We analysed issues such as who claimed the data; precisely what was claimed; whether there were licensing-back provisions; and other provisions. The provisions can be summarised as follows:

- the two DTAs both included provisions that vested ownership of transferred data in the supplier;

- one (university) agreement contained a term specifying that all data (provided by the supplier or created by the receiver) was claimed by the supplier;

- six agreements specified that data originating with the supplier and transferred to the receiver was to remain the property of the supplier;[165]

[164] See above, 4.3.1.

[165] The UK Biobank Agreement is included in this number, which comprised primarily universities.

- two (research consortia) agreements had terms specifying possible joint-ownership of research data and future results; and
- many contained terms relating to confidential information, although the way in which it was referred to varied. Particular terms relating to confidential information are considered later in this chapter, but to the extent they were broad enough to capture research data, they are also noted here.

Of all the data-related provisions, the highest sub-category related to obligations to share research outputs with suppliers. These obligations are summarised in Table 45.

Obligations over results data	No. of agreements
i. An express or implied requirement on the receiver to disclose data giving rise to an IP claim (usually patents)[166]	5
ii. An obligation for the receiver to notify, inform or report results and information to the supplier[167]	22
iii. An obligation for the receiver to provide the supplier with a non-exclusive, royalty-free license to use any know-how, data, results or invention for research or teaching[168]	8
iv. A provision specifying that the *receiver* must maintain confidentiality in the data created through use of a material[169]	4
v. A provision specifying that the *supplier* must maintain confidentiality upon receiving a report on data created through use of a material	1

Table 45: Number of agreements with provisions that create obligations over data

[166] The UK Biobank was included in this category given that it contains a term that provides:

> 4.7 The Applicant will provide UK Biobank with:
>
> …
>
> 4.7.2 a copy of any patents whose claims cover, or are intended to cover, an Applicant Generated Invention within two months of their publication.

[167] One of these agreements was a DTA. The agreements were provided by universities (twelve), research institutes (six) and biobanks (four), including the UK Biobank.

[168] In addition to the UK Biobank, the institutions that included this term were universities (two), research institutes (three) and biobanks (two).

[169] For an example see the UK Biobank Agreement.

The drafting styles and terms used across these provisions were highly diverse and difficult to generalise beyond these purposive groupings. The analysis shows that it is common that material suppliers require reporting and notification on the use of materials (and/or associated data), with many requiring access to data and results generated by the receiver. There was an evident trend to require the receiver to license back (non-exclusive and royalty free) the rights to use any know-how, data, results or invention for research or teaching. The receiver may delay the licence to facilitate IP protection in the same way as a supplier may for publications: the delay must be reasonable and subject to an appropriate time limit.

There were a number of other data-related provisions within the agreements examined. The most common theme through these agreements was a provision providing for destruction of confidential information, either at the request of the supplier or at the point of termination of relevant agreements (more than half specified termination). Other common purposes of data-related provisions included: data management conditions (such as complying with privacy laws, or making sure all actors using data were aware of its confidential nature or how the data should be stored); and disclosure of confidential information (the obligation of confidentiality, who it extends to and how to discharge the obligation). One provision in a university agreement specifically claimed the informational aspects of materials, progeny unmodified and modified derivatives as confidential information (this might be expected if the data is linked to a provisional patent application or is otherwise likely to generate a commercial outcome). Finally, one provision in a research institute agreement required recipients of material to agree not to seek IP protection over inventions using the confidential information.

4.6.4 Research Use and Publication

Field of Use

Our interview data revealed that field of use provisions tend to be prevalent and highly specific, extending to the specific research that may be undertaken and the types of experiments to be conducted. Although most agreements tended to include a provision for field of use, they did not specify the actual limitations on use. Thirty-five of the forty-five agreements contained a provision to specify field of use for a specified research material. Twenty-eight agreements clarified what would or might be included in the field of use provision. Just six agreements contained a clause placing precise parameters around field of use without making provision for further clarification. The UK Biobank is a

good example of such an agreement.[170] Twelve agreements did the opposite – rather than providing a universal clause delineating field of use, they allowed the addition of a customised description.[171] The Brunswick Agreements are a good case in point.[172]

Just four agreements contained no provision for specifying field of use: two agreements were in respect of particular collaborations and no doubt included provision for specification of field of use in overarching collaboration agreements, and one agreement referenced a schedule, which was not included in the standard agreement made available to us. The schedule may well have included a field of use or permitted purposes field. Finally, the UBMTA does not contain a field of use provision as such, although it does set parameters around the broad scope of the requisite field of use. The Implementing Letter further requires the particulars of each transfer to be set out. Although the UBMTA does not have a distinct field of use provision, the general terms of licence conditions include field of use restrictions (including teaching and academic research only, non-human use, restrictions on use for clinical trials or diagnostic purposes, or that a material is non-transferrable). Nevertheless, the UBMTA does not require field of use to be stated with as much specificity as many agreements.

Evidence gathered in TTO interviews confirmed that field of use provisions are in widespread use, and are considered to be an important component of an MTA. TTO personnel described field of use provisions as being very specific and quite restrictive in that 'they're usually restricted to the project described' and 'you want to make sure those rights are really tightly protected.' In combination with analysis of the agreements provided and our interview evidence, it was possible to glean that field of use restrictions generally focus on:

- the 'purpose' of the project;
- duration or time frame of the agreement;
- whether the agreement is for experimental purposes or may encompass commercial research;
- limiting the lab or personnel permitted to use the material;

[170] Other agreements that fell into this category included the ATCC Agreement and the Plant Treaty.

[171] This included the two DTAs.

[172] In addition to the Brunswick Agreement, the NIH MTA was such an agreement.

- the type of research (such as biomedical, food and agriculture);
- use in human subjects or for clinical purposes;[173]
- the work to be undertaken; and
- details of experiments to be conducted.

With the exception of the UBMTA, the analysis shows that generic field of use provisions are routinely included, or that their absence is clearly explained. One risk with field of use provisions that impose tight restrictions on use of materials is that they could undermine the purpose of the material transfer. The AUTM MTA Guiding Principles[174] illustrate this point. Principle 3 requires that researchers make materials available to other non-profit organisations[175] and Principle 7 states that a:

> *Provider should not require a Statement of Work from the Recipient. For published materials, consistent with the freedom of academic research, the Provider should not require the Recipient to provide a detailed Statement of Work.*

A statement of work is not dissimilar to a field of use. Further, the Implementing Letter clearly states that 'the purpose of this letter is to provide a record of the biological material transfer'. These words indicate that the focus of the UBMTA is on enabling a record of transfer, rather than restricting permitted uses. In contrast, Australian template MTAs appear to place a concern on carefully guarding research fields and reducing the risk of competition. Given this questionable motive, we suggest that best practice requires that field of use restrictions be used judiciously.

Publication

As we have noted in earlier chapters of this Occasional Paper, the retention of the right to publish, particularly from the perspective of recipients of materials, is of critical importance. The need to retain

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173 See further below, *Exclusion of Clinical Uses*.

174 AUTM, *MTA Guiding Principles* <https://autm.net/surveys-and-tools/agreements/material-transfer-agreements/mta-guiding-principles>.

175 '**3. Provider should make Material available to other nonprofit institutions.** If Material is a unique resource Provider should commit to making Material available to other investigators for basic research under terms no more restrictive than the UBMTA to satisfy a need to reproduce published data and build upon published results. This is only to the degree that there are sufficient quantities available, and that the Material is not otherwise available commercially or easily manufactured by the requestor.'

publication rights was recognised by TTO personnel, given that many see the purpose of MTAs as facilitators of research. Quite how well this is echoed in MTAs is an open question.

Thirty agreements included publication-related clauses, with a total of over 70 discernible terms across those agreements. The term most commonly employed imposed a right on the part of the supplier to approve publications, and to reasonably delay publication for the purpose of determining whether to grant approval. Twenty-two agreements (containing 39 relevant terms) included this obligation to seek approval. Thirteen of these terms were in agreements provided by universities, five were from research institutes, three were from one particular biobank and one was a research consortium agreement. A term of this nature also appeared in the two Brunswick Agreements.

Two main grounds for restricting publication were to protect confidential information, or to protect other IP rights (often, time to apply for protection was incorporated). Protection of confidential information appeared in 19 of the 22 agreements. Fifteen included a term relating to IP (generally to retain existing rights, or to obtain new IP protection over materials) to justify delays. Thirteen agreements overlapped, in that they included both confidential information and protection over other IP rights.

Fourteen of the thirty agreements included a term requiring the receiver to inform the supplier of intention to publish the results of research using the material. Often this included a time qualification about when the notification was required. This ranged from 15 to 45 days *prior to* publication. These terms did not provide capacity to withhold approval. Despite references in these terms to 'review', there was no reference to the implications of review, and reviews appeared to be confined to notification of publication and reporting results contained therein. Notably, there was significant overlap in the agreements containing terms relating to publication: 10 of the 14 agreements with a notification clause also contained the right to reasonably delay publication. Four contained only a notification clause. Included in the cohort were seven agreements received from universities, five from (three different) research institutes, and two from biobanks (one of which was the UK Biobank).

Six further agreements contained terms that allowed suppliers to veto (without reason) or unreasonably delay publications. Five of these agreements were from universities, and the remaining one was the UK Biobank Agreement. This is not to say that these terms would necessarily result in the unreasonable withholding of approval, but they do provide

suppliers with the legal capacity to do so. Ideally, provisions providing broad unfettered power to delay or prevent publications should not be included in MTAs.

There were 12 other terms across six agreements that could be classified as publication-related provisions. Three were good faith provisions aimed at resolving issues that might arise in publication matters. While these might have negated the impact of the veto powers in the six agreements discussed in the preceding paragraph, none of the good faith provisions were contained in the same agreements that contained the publication-veto provisions. Two of the six agreements had provisions requiring acknowledgment of the source of the material in the publication (this included the UBMTA). All of the remaining provisions were one-off and dealt with specific situations. One example was a provision providing permissions for students of the receiver to publish. Permission for students to access and publish using materials provided by MTAs was discussed specifically in some TTO interviews, with some interviewees suggesting that particular permissions are required in some circumstances. This term seems to reflect these comments.

There was little consistency in wording across the publication limitation terms. The most common terms related to reasonable delay of publication in order for suppliers to protect their IP or confidential information. Yet these terms were highly variable and ranged in length from two to nine lines. A majority, but by no means all, included the words ‘reasonably’, ‘not unreasonably’, ‘good faith’, and ‘best endeavors’ with regard to giving approval or negotiating changes to a manuscript.

Other terms included words to the effect that if the supplier ‘fails to object’ then they will be ‘deemed to have consented’. The effect of these provisos is to provide a buffer against the power on the part of a supplier to prevent publication. The terms are also generally limited to a time period in which the supplier could seek to protect its prior interests in materials and confidential information.

As to what constitutes a ‘reasonable’ period to delay publication, evidence from interviewees suggests that ideally review should no take longer than 14 days. Where protective action is necessary, a further delay of 30 days may be tolerated. The reality is that the existence of publication clauses does not equate with their enforcement – despite their existence in MTAs they are unlikely to be enforced. Further, they do not seem to be terms that MTA negotiators spend time arguing over: interviewees indicated that often their inclusion is tolerated.

Nevertheless, good practice dictates that, should these clauses appear in MTAs, shorter time periods are clearly preferable.

Attribution and Authorship

Given the importance researchers attach to the receipt of appropriate credit for work, we expected that terms requiring source or author acknowledgement would be common. This was confirmed in that 35 agreements included terms which could be construed as requiring attribution of the institutional source of the material, or acknowledgement of the lead scientist (or group). Seventeen of these agreements were provided by universities, six by research institutes, four by biobanks (including the UK Biobank) and two from a research consortium. The remaining six were third party agreements: these being ATCC, the NIH MTA, the NIH Human Tissue Agreement, the UBMTA and both Brunswick Agreements.

Some terms within these agreements were drafted with greater specificity than others. For example, eight agreements made reference in some way to the application of generally accepted principles of authorship when determining whether to attribute authorship to the supplier of a material. Six referred to 'acknowledging' the 'contributions' of a specific party, generally the supplier of the material. An example is the NIH Human Tissue Agreement, which provides that the 'RECIPIENT [of a material] will acknowledge [the] PROVIDER'S contribution of human materials unless requested otherwise by [the] PROVIDER.' This generic template required input of the names of the party to the agreement; the other five agreements required that outputs be attributed to a named party (that is, the supplier of the material). Two agreements referenced a specific authorship policy: not surprisingly, these agreements were those provided by research consortia, which we would expect to have clearly drafted policies. One university agreement required that its staff and students be named as joint authors in any resulting publications. One further agreement required attribution of a particular funding source, and the CSIRO agreement required citation of a particular scholarly paper.

Clearly, precisely delineated authorship guidelines should be used where possible to determine the authorship of publications generated from research using a particular material, although principles of ethical research would dictate that authorship must be based on an appropriate contribution. Generally speaking, supply of materials alone is insufficient justification to warrant the provision of rights to authorship.

Ethics and Consent

A key focus of our study is the impact of MTAs on biomedical research, hence we were interested in ascertaining the extent to which transfers are governed by ethics approvals and consents. It became apparent that not all MTAs specifically require details on ethics permissions or donor consent. Of the 45 agreements analysed, 17 included ethics-related terms. Six agreements had terms that related to both donor consent to research using a sample, and other ethical requirements. All of these agreements dealt with transfers of human tissue. Included among them were the UK Biobank Agreement and the Brunswick Human Tissue MTA.[176] Eleven other agreements had terms that related to ethical requirements (that may extend to donor consent although it was not specifically mentioned). Interestingly, two agreements falling into this latter category were DTAs.[177] This highlights the importance of ensuring that appropriate ethical principles govern transfer of data, and raises the question as to why so few institutions use DTAs.

Terms classified as relating to donor consent dealt with the scope of consent given and the capacity for the research that was the subject of the MTA to be performed. These terms differed in content and included reference to:

- evidence that patients expressly withhold consent to future research;
- the effect of patient withdrawal on destruction of material;
- compliance with applicable laws and regulations, and re-consent requirements;
- undertakings that receivers will not attempt to identify participants or make contact directly; and
- the right to terminate the agreement if ethical approval is withdrawn.

Terms relating more generally to ethical requirements tended to be broader in scope. In some cases, the receiver was given this responsibility. Examples included:

[176] The other agreements were provided by a research consortium and biobanks.

[177] Agreements containing terms pertaining to ethics approvals were provided by universities (six), research institutes (two) and a research consortium. They also included the two NIH Agreements.

- a duty on part of the receiver to obtain 'all appropriate ethics approvals for the use of the materials'; and

- a duty on the receiver to ensure that the research will be 'performed within the scope of patient consent or in compliance with article 32 of the Declaration of Helsinki'.[178]

There were other instances where the supplier was required to ensure that there was compliance with ethical obligations. Examples included:

- confirmation that the [supplier] has obtained all approvals, authorisations and assurances necessary including, but not limited to, approval of the relevant ethical committee; and

- confirmation that samples were collected pursuant to the rules of the appropriate Institutional Review Board.

Some agreements provided for the sharing of personally identifiable material with the receiver. Particular obligations arising from sharing were also included in these agreements. Associated with this, the provisions dealt with obligations relating to sharing/not sharing associated data with third parties, and with commercial uses of the data, including consulting and licensing.

The terms relating to ethical concerns varied greatly. Many of the agreements included a general provision about complying with applicable laws, guidelines and codes. In theory, this would cover all relevant situations. However, difficulties will arise where these laws and guidelines do not clearly articulate the limitations on material and data transfers, particularly in terms of data sharing and certain aspects of consent. In these cases, specific provisions assist in dealing with grey areas. This is particularly important where materials might be transferred to jurisdictions with different (particularly less stringent) levels of protection than Australia. Consent raises particular issues: requiring

[178] World Medical Association, 'Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects', (18th WMA General Assembly, Helsinki, Finland, June 1964) <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>.

'Article 32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.'

ethics approval might not be sufficient in and of itself, to comprehensively manage donor consent.[179]

Exclusion of Clinical Uses

Thirty-eight agreements contained terms that limited the field of use by excluding uses of the materials in humans for the purposes of testing or treatment.[180] The language was broadly similar between agreements, though subtle differences were evident. Twenty-six agreements specifically prohibited use of materials in human subjects. Some expressly distinguished between in vivo and in vitro uses. In some instances, these conditions were covered in a schedule elaborating on conditions of use, field of use or purpose of use. Other agreements had these conditions set out as a separate term within the body of the agreement. Two of the twenty-six agreements qualified that if supplier consent was obtained, particular types of activities could be undertaken. Of the MTAs that excluded use in humans, fifteen were provided by universities, five by research institutes (including the CSIRO MTA), two by research consortia and five by third parties. This latter category comprised the ATCC Agreement, the NIH Human Tissue MTA, the NIH MTA, and both Brunswick Agreements.

Another 12 contained prohibitions on clinical and diagnostic use without the written consent of the supplier. All of the terms in this category were phrased so that the use in question was prohibited unless consent (usually written) had been obtained, rather than permitted with consent. This is notable as the similarity across the agreements makes it clear that the basic position is that the material may not be used clinically unless there is express consent to the contrary. This is the position taken in the UBMTA, which contains such a provision, as did agreements provided by seven universities, one research institute and three biobanks.

There is no real dispute that routine MTAs should exclude use in humans. Bespoke agreements for clinical/diagnostic uses, or for research involving humans must include particular safeguards and, possibly, commercial considerations.

[179] Don Chalmers et al, 'A Role for Research Ethics Committees in Exchanges of Biospecimens through Material Transfer Agreements' (2014) 11 *Journal of Bioethical Inquiry* 301.

[180] Obviously neither of the DTAs included this term, nor did the Plant Treaty Agreement.

Animals

General provisions requiring compliance with ethics approvals would apply to the use of animals to a similar extent as research involving humans. In addition, eight agreements contained terms specific to the use of animals, including:

- applicability of animal welfare laws and regulations, as well as appropriate ethics approvals;
- links to key research regulations and guidelines;
- a specific term that: 'The recipient agrees to not use the Materials and or any derivatives of the Material in the treatment of humans and/or non-laboratory animals.' Other agreements also limited use to laboratory animals only;
- a specific term that: 'Materials will only be used in vivo animal or in vitro laboratory experimental work'; and
- specific reference to the use of patented material in laboratory animals.

On-sharing of Material and Modifications

Thirty-nine agreements included terms dealing with the ability of parties to transfer materials and modifications. For completeness, terms dealing with capacity to assign materials were included in this analysis. If any possibility of sharing was retained (even with a requirement for consent from the supplier), these were coded as permitting sharing. The agreement that demonstrated the most liberal approach to sharing was the Plant Treaty, which promoted sharing of materials but nonetheless included lengthy provisions on potential commercialisation outcomes and accounting of profits to the original suppliers.

A greater number of agreements (36) could be interpreted as leaving open the possibility of allowing sharing,[181] than the number that denied it in some respect (23).[182] Just two MTAs prohibited on-sharing (whether

[181] Note that one of these agreements was a DTA.

[182] As with many of these results, the proportion of agreements that allow some sharing and those that deny some sharing is not equal to one as agreements could be dual coded, and assignment and on-sharing materials clauses are not mutually exclusive.

through licensing or assignment) outright.[183] Twenty MTAs and one DTA precluded assignment. This number incorporated universities (11), research institutes (five), biobanks (four)[184] and the ATCC Agreement. The fact that a significant number of agreements barred assignment is unsurprising when considered in the context of the discussion on title in materials above. Given that the overwhelming trend is for suppliers of materials to retain title in transferred materials,[185] it is of little surprise that further assignment of those materials and derivatives is expressly excluded. On the other hand, sub-licensing appears to be tolerated and is consistent with a sharing culture.

The assignment coding category only encompassed terms which expressly referred to 'no assignment'. Even within the category of agreements that expressly allowed sharing, additional requirements were often present, requiring, for example, consent of the original supplier, or for the transfer to be executed between the original supplier and the third party seeking the material. Perhaps confusingly, six agreements prohibited the transfer of rights and obligations under the primary MTA, but allowed sub-licensing of materials. (see Table 45). These clauses illustrate the complexity in interpretation of MTA provisions, which may inevitably impact sharing of materials. This difficulty is evident in the examples cited in Table 46, but also in the broader set of sharing conditions that must go through suppliers. For example, the ATCC Agreement requires that written notice of all transfers be provided to the ATCC so that the ATCC might maintain a chain of custody of the material. The UK Biobank MTA provides that the receiver is responsible for the acts, defaults and omissions of its sub-contractors. The NIH MTA template provides that cross-bred or genetically modified organisms developed by the receiver may be transferred to non-profit institutions, but only for research or teaching purposes.[186]

In effect, there is little that material recipients may share without prior written approval from the original supplier, even when they have made new products. In most cases, best practice would appear to dictate that suppliers allow on-sharing provided supplier consent has been obtained, or include a trigger provision to prompt entry by a third-party seeking access to the subject materials, into a new agreement with the supplier.

[183] One of these agreements was the CSIRO Agreement. Given that the subject materials are not the property of the CSIRO, a prohibition on further transfer is to be expected.

[184] Including the UK Biobank.

[185] See above 4.6.2.

[186] NIH MTA template, cl 8.

This encourages more extensive use of existing materials. Aligned with this, receivers should be allowed to share modifications without limitation if the limitation is on the basis that the modification incorporates the material.

	Yes potentially	No	Assessment of position
1	'[The material] Will not be provided without [Supplier's] written consent'	'The Recipient … will have the right, without restriction, to distribute substances created by the recipient through the use of the original material only if those substances are not Progeny, Unmodified derivatives or Modifications.'	Supplier consent may facilitate sharing.
2	'A party must not …. Transfer any of its rights or obligations under this agreement without the prior written consent of the other party.'	'The Recipient must not distribute, release, or in any way disclose or permit access to the Materials or any Derivatives to any person or entity other than its employees and agents who are directly involved in the Research Program and who are made aware of and agree to be bound by the obligations under this agreement.'	Written supplier consent may facilitate sharing.
3	'The recipient must not assign, subcontract or transfer any of its rights or obligations under this document without the prior written consent [of the institution].'	'The Recipient must not provide the Materials to any other person.'	Written supplier consent may facilitate sharing.
4[187]	'The recipient will neither assign, transfer, mortgage, charge not part with any of its interests, rights, duties or obligations under this Agreement.'	'The recipient … will not permit the Data or any part of it to come into the possession or control of any other organization or any individual other than those employees who are involved in the Research under direct supervision of the Investigator. The Recipient will not transfer the Data in whole or in part to third parties without the relevant third party entering into a separate Data Transfer Agreement with'	No on-sharing with parties outside the project. New agreement required with the original supplier and a new party.
5	'may only be used for the Permitted Purpose, namely… solely by the …. Researchers (and in particular are not to be shared with any other person without … explicit written approval)'	'excluded any right … to sub-license'	Written supplier approval may facilitate sharing.
6	'The recipient shall not supply the materials to any other party and the Recipient and the Recipient Scientist shall refer to [the supplier] any other party and the recipient and the recipient scientist shall refer to [the supplier] any request for the Materials, from anyone other than those persons working under the Recipient Scientist's direct supervision.'	See left.	No on-sharing with parties outside the project. New agreement required with the original supplier and a new party.

Table 46: Provisions relating to on-sharing of materials

[187] This was a data sharing agreement.

Other Restrictions on Use

A number of other agreements contained terms that could be construed as imposing limitations on scope of use, or additional obligations over the material or its use. Forty-four of the forty-five agreements evidenced such obligations.

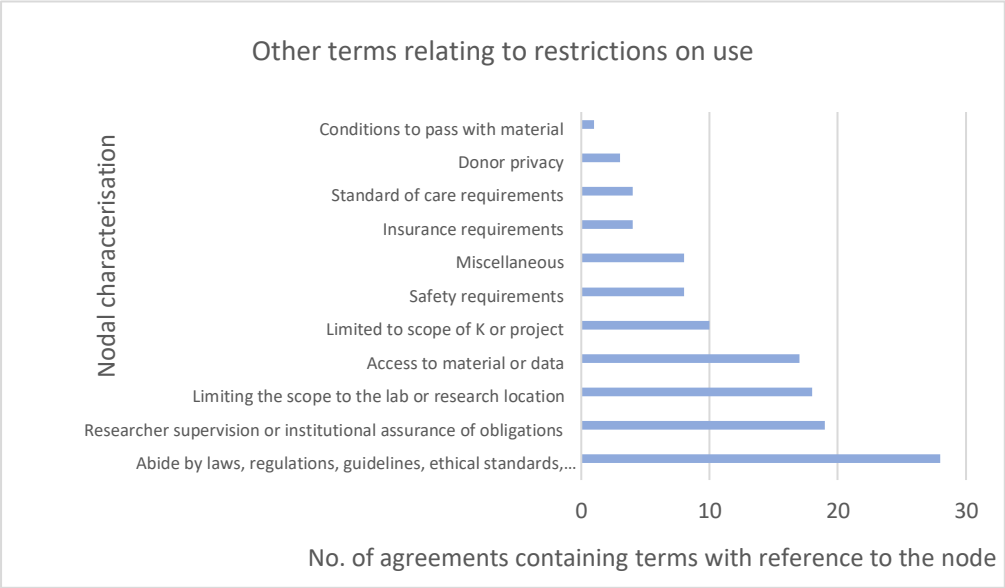

Figure 3: Restrictions or obligations over material and use in MTAs not captured in earlier analysis

4.6.5 Intellectual Property, Commercialisation and Confidential Information

Intellectual Property Ownership: Background and Future

In many instances, IP rights will already subsist in materials being transferred ('background IP'). In others, IP will be generated through use of the transferred materials. Generally, background IP will be owned by the supplier of a material, but in others (particularly where materials have travelled a path involving multiple parties to get to the supplier), third parties may own IP. There seems to be a default position across the agreements analysed that background IP will (not unreasonably) remain the property of the supplier of a material. The picture in relation to ownership of future IP is far more complicated.

Thirty-four agreements contained terms relating to ownership of background IP and demonstrated that, in many situations, suppliers will retain ownership of background IP. This may extend to include IP in

progeny but, either expressly or by implication, does not usually carry over into modified materials. Many of these agreements expressly provided that background IP remained the property of the supplier, although a number did so by implication. Four further agreements were unclear but could possibly be construed as vesting background IP in the supplier. Of the remainder, the fact that such provision was not made was, on the whole, unsurprising. Three agreements were provided by biobanks, one was the NIH Human Tissue MTA, one was the Brunswick Human Tissue MTA and one was the Plant Treaty. Just one was provided by a university.

Nine agreements included 'out of the ordinary' terms in relation to background IP:

- some made it clear that recipients had no implied licences over background IP;
- three noted that that licences over background IP may be required to be entered into (one also required payment of a fee, if this occurred);
- two stated that background IP may exist and may be owned by non-contracting parties;
- two set out relevant patents for a particular material;
- one stated that the supplier provided no warranty against misuse of background IP; and
- another included a term that the receiver would not seek to reverse engineer the material.

As for future IP, there were various permutations of terms relating to potential future IP, which have been coded into five categories, as shown in Table 47. Overall, 40 of the 45 MTAs had terms relating to ownership of future IP. These terms did not always extend to capacity to exploit the IP as this was often dealt with in commercialisation provisions (dealt with below).

Categorisation of terms relating to claimed IP	Effect	No. of agreements
A. Supplier has right to most/all future IP	Covers claims to IP where the supplier has rights to all or in effect most of the IP that will or could possibly arise.	14
B. Supplier retains IP in the invention/material that is licensed (not modifications but may include progeny)	Covers situations where the supplier retains ownership of IP in the material and any progeny but not modified derivatives.	23
C. IP is subject to discussion/ agreement	Covers IP where any new IP is subject to discussion between the supplier and receiver.	12
D. Receiver has rights to any IP	Covers claims to IP where the receiver has the right to all or most IP that will or potentially could arise.	10
E. Co-ownership	Covers claims to IP where co-ownership of any IP is set out in the agreement.	10

Table 47: Allocation of IP rights

The agreements that fell within category A were the most restrictive in terms of provisions imposing reach-through rights over receiver-generated IP.[188] Nevertheless, the imposition of these terms was not hard and fast, with two agreements providing that co-ownership could be negotiated in some instances, and four conditioning supplier ownership, in that it might not extend to modified derivatives. On this last point, it was not uncommon for MTAs to include a provision retaining IP rights in materials provided, but to leave some ambiguity around the question of whether this included modifications. In total, twenty-three agreements could be construed as leaving some scope for arguing that IP in modifications could be claimed by the receiver (category B in Table 47). Thirteen of these twenty-three agreements also contained terms relevant to categories C, D and E with regard to modified

[188] These agreements comprised 11 university agreements and three research institute agreements (including the CSIRO Agreement). Significantly, many of these 14 agreements were provided by institutions that are involved in a large number of MTA transactions, countering the argument advanced in Chapter Two that more experienced TTO officers are less concerned with commercialisation as a purpose behind MTAs.

derivatives/modifications. Some were coded to more than one category because a variety of options were provided regarding ownership of future IP, the choice of term being contingent on particular events:

- seven were dual coded because the ownership of IP over modifications would be subject to further discussion and agreement (category C);
- eight were dual coded because ownership of IP over modifications would unequivocally be vested in the receiver (category D); and
- six were dual coded because the agreements specified that IP over modifications would be co-owned (category E).

In summary, very few agreements unconditionally claimed supplier ownership of all future IP generated. What is clear is that the allocation of rights over future IP is not uniform. Without more information, it is not clear whether the terms operative in particular agreements were dependent on matters such as: the subject of the material transfer; prior dealings between parties; stance in respect of commercialisation; or equity of contribution.

Interview data and other research indicate that it is best practice for receivers to have the right to claim IP over modifications, unless the originator makes a substantial contribution to the development of the modification.

Indemnification for IP Infringement

In some instances, use of a material would infringe background IP held by the supplier of the material in the absence of the MTA. In others, that use might infringe IP held by third parties. Provisions providing indemnification in the case of infringement of IP rights held by third parties were common across the agreements examined. Two of the agreements provided by research consortia included provision for supplier indemnification. Thirty agreements included provision for receiver indemnification.

We have already discussed the problems associated with maintaining an accurate record of provenance. In terms of IP, it is theoretically easier for a receiver to track a registerable interest such as a patent associated with a material. As such, it is arguably less problematic to require that the receiver provide an indemnity for improper use of IP rights subsisting in

the material.[189] Nevertheless, we argue that receivers of materials should be cautious about accepting clauses requiring them to indemnify suppliers with respect to IP infringement. Suppliers should be required to inform receivers of any IP subsisting in the material of which they are aware, and to provide permission for use in the research that is the subject of the MTA.

Future Commercialisation

There were 33 agreements that had terms relating to future commercialisation.[190] Twenty-seven stated that the prospect of commercialisation would trigger further negotiations, while thirteen stipulated conditions governing commercialisation of IP in greater detail.[191]

There was a diversity of terms relating to use of future IP. A number specified that ownership would be determined based on contribution. There were a number of other variants in how commercialisation of future IP should be determined, some options being:

- in accordance with joint tenancy (one);
- subject to agreement, noting that the recipient will have a perpetual non-exclusive, royalty-free license to use any inventions (three);
- no limitation to be imposed on access to the material by other parties (one);
- fixed percentages of profits (one);
- suppliers to have the right to exploit derivatives (including modifications) without restriction, or to force recipients to transfer ownership (two); and

[189] Although this is clearly not the case for non-registrable IP rights.

[190] Twelve agreements contained no provisions relating to commercialisation. Eight were silent (including the UK Biobank Agreement, the Brunswick Human Tissue MTA, a research consortia agreement and five university agreements). Four were specifically stated to be non-commercial MTAs with no prospect to commercialise (the NIH Human Tissue Agreement and NIH MTA, the CSIRO Agreement and one university agreement) and one university agreement specifically stated materials were supplied for non-commercial purposes only.

[191] For five of these MTAs, this was the only commercialisation provision contained in the agreement. The remainder also included provision for negotiation.

- recipients not to exploit any products for profit or commercial purposes without further agreement (one).

Of the 27 agreements which indicated that commercialisation would require additional negotiation:

- 14 deferred the matter and left it to the parties to negotiate;
- 17 gave the supplier discretion to allow (or disallow) commercialisation (or set out that there was no implicit right for the receiver to commercialise); and
- two provided that if the future IP was solely created by one of the parties further agreement would be necessary, but if jointly created between supplier and receiver then the requirement to re-negotiate was initiated.

There was a degree of overlap between provisions and these categories were not mutually exclusive. Many agreements set out that negotiation would take place on the premise that parties' respective contributions would be recognised. Table 48 illustrates the language used where the supplier was given discretion to allow commercialisation. While there is some variety across the 'cornerstone' language used in the relevant terms, the broad meaning expressed in these terms was comparable.

	Words or position within a term					
	'Good faith'	'No obligation on supplier to grant' or 'absolute discretion of the supplier to grant'	Some compensation for material use (express or implied)	No disclosure of information or use without consent	Supplier may grant exclusive or non-exclusive rights to exploit products of the material to others	May enter into an agreement for revenue sharing
Number of occurrences across the 16 terms	6	6	2	9	1	1

Table 48: Supplier-friendly language used in negotiating commercial uses

It is difficult to define a best practice term in respect of a positively couched right to commercialise, as this is dependent upon the material

and the research use. The preferable position is to defer commercialisation decisions to be agreed upon if the potential for commercialisation arises.

Confidential Information

Confidential information was a difficult item to track. Thirty-six of the 45 agreements contained express terms relating to confidential information,[192] but these terms were quite diverse. Some related to research and study data whereas others defined (or used these terms) differently. In this way, much like materials and derivatives, the interpretation was dependent on the agreement in question, which renders generalisation difficult. Terms covered such matters as: when data disclosed under the agreement would no longer be regarded as confidential; to whom confidential data could be disclosed (it was rare for disclosure to be permitted to parties not privy to the agreement); the responsibility of parties for the actions of their employees provided with access to the requisite confidential information; and use of confidential information in accordance with the purpose for which it was provided.

The most important consideration with regard to confidential information is that it should not impact upon publication, although it may be appropriate to delay publication for a reasonable period of time to secure other IP rights.

Reporting Requirements

Just over half of the 45 MTAs had terms which required reporting of some kind. This was not unexpected, as it is one of the few methods of quasi-enforcement that is likely to be available to suppliers. Across all the agreements, terms specifying reporting requirements included:

- all results;
- experiments and research reports generally;
- notification of modifications and derivatives produced;

[192] The agreements which did not contain terms relating to confidential information included the ATCC MTA, the Plant Treaty Agreement, the UBMTA, the NIH MTA, the CSIRO Agreement and four university agreements. One of these university agreements, despite not including an explicit term dealing with confidential information, nonetheless provided as follows:

> The Recipient shall keep confidential any Materials and information concerning or relating to the Material. No reference may be made to the Material in any publication without the written consent of [supplier].

- know-how;
- inventions and discoveries; and
- patent filing and IP rights created.

In terms of frequency, reports were required: on (or prior to) termination; annually; 14 days before public presentation; on request; or at an unspecified time. Reporting and monitoring is clearly an important element of material transfers. However, it should not be unduly onerous. In general, reporting at the end of a project seems reasonable. If the scope of use is broader, it may be appropriate to require more frequent reviews.

4.6.6 Boilerplate Terms

Costs and Fees

Twenty-three agreements included provisions relating to costs, 17 of which provided for the supplier to recoup costs for preparation, transportation, packaging, insurance and any duties. Only one was clearly designed to capture profit, rather than repayment of expenses. It is likely that these provisions would be more widespread in commercial agreements, as suggested by many of our TTO interviewees.

Obligations on Completion

Here we sought to capture terms imposing obligations over materials upon completion of a project/agreement. Thirty-eight agreements had terms fitting this description.[193] An obligation to destroy materials (35 agreements) was treated separately to an obligation to return samples, although 33 agreements had overlapping requirements to destroy or return.

Five agreements specifically required the destruction or return of derivatives. In each of those agreements the definition of derivatives meant that destruction extended to recipient-made modifications. One specifically mentioned progeny – although because so many agreements include progeny in the definition of 'materials', it may be assumed that for the most part an obligation to destroy progeny is incorporated into

[193] Of those that did not, two were university agreements for the receipt of material, two were university agreements for the supply of material, one was a university agreement for receipt or supply, and two could be identified as facilitative agreements (the NIH MTA and the CSIRO Agreement).

an obligation to destroy materials (35). Thirteen agreements separately mentioned destruction of confidential information.[194]

Eight agreements differed slightly in their requirements for destruction or return:

- four required written confirmation of the destruction – one formally as a statutory declaration;
- two provided for storage of the left-over materials by the recipient (but not use without further permission);
- one allowed for other choices on completion by written consent of the supplier; and
- one required return of the material *at any time* upon request.

The practicality of requiring destruction or return of modifications is questionable. Rather, it seems more workable for the parties to agree on destruction or return of a material on completion, taking into account: ongoing research requirements and value in the material; whether return is possible; and whether it is unclear that the supplier will accept return of and maintenance of the material. We suggest that in these circumstances the agreement should provide an option for the receiver to remain the physical custodian of the material but not use that material for ongoing research without further agreement.

Governing Law

Governing law emerged as a sticking point from TTO personnel interviews, particularly when dealing with US institutions. However, it was also reported in TTO interviews by some parties as a concern between parties in different Australian states disagreeing on particular jurisdictional terms.

Thirty-six MTAs had terms relating to jurisdiction, while nine remained silent on the issue. Most MTAs specifying governing law (31) deferred to the supplying party. The UBMTA template is a good example of an agreement where jurisdiction is silent.[195] It is likely that this would negate some of the delay that can result from including terms relating to governing law. Taking into account low levels of MTA enforcement, silence may be an appropriate approach for non-commercial MTAs. This may be helpful in overcoming this sticking point in negotiation, although

[194] This included both data transfer agreements.

[195] Also included were the NIH MTA and one of the data sharing agreements.

it may also create other interpretational difficulties and introduce ambiguity. A better approach is probably to require that jurisdiction be determined as being the venue where the breach occurs, or according with the jurisdiction of the responding party. Surprisingly few MTAs took this approach, although it was an approach supported by a considerable number of TTO interviewees.

Dispute Resolution

Although provision for dispute resolution was not raised in MTA interviews, it was included in the contractual analysis as dispute resolution clauses appeared in 11 of the 46 MTAs, in accordance with standard commercial language. Given that dispute resolution clauses are a generally common term, it seems prudent to include them in MTAs.

Liability

Some liability provisions have already been captured in the IP and ownership discussion. This analysis encapsulated two key types of general liabilities: exclusion of liability relating to the material (including its use and possible risks directly connected with transfer, use and storage of the material), and liability for other activities in connection with the MTA and transfer. Protection against potential liability was viewed as an extremely important aspect of MTAs by interviewees involved in supplying materials. This function was confirmed in our analysis of MTAs. Forty-five agreements contained liability terms, making this the most common term in the agreements considered. The types of terms are summarised in Table 49.

Liability Terms	No of agreements with relevant terms
Material specific - liability with supplier	1
Material specific - liability with receiver	42
Broad liability - liability with supplier	0
Broad liability - liability with receiver	36
Other	5

Table 49: Liability terms in MTAs

In the vast majority of agreements, liability vested primarily in the receiver. Many of the material-related warranties were in the form of

acknowledgements on the part of a receiver that the materials were given as is, that they may be hazardous and that suppliers did not warrant that they were necessarily fit for purpose. Suppliers tended to be made liable for any loss or damage resulting from transport, storage and use of the material, or use in connection with the proposed projects.

Broader liability terms indemnified suppliers against any loss arising in connection with a material or from the exercise of the MTA to the full extent permitted at law. Where these terms were with US institutions they often included 'hold harmless' language which was discussed during MTA interviews, and was sometimes viewed as a sticking point. General liability terms were often very long clauses, listing the classes of people indemnified, the types of loss, harm or damage, and actions that would be indemnified. This might include claims related to infringement of IP rights[196] or other legal claims, or other demands in connection with processing or executing an agreement, including matters 'not reasonably foreseeable' and indirect losses. They also frequently mentioned reimbursement for legal costs and other fees.

It is appropriate to share liability between parties so that each party is responsible for their own actions; receivers should be liable for their actions in undertaking the research specified in the MTA, and suppliers for actions involved in handling a material until it is in the custody of the receiver.

Licensing Back

Twelve agreements contained provisions that provided that the receiver would license-back at least some results of research to the supplier provided they were used for research purposes. Most of these agreements involved non-exclusive, royalty-free licences to use particular materials or data. Some allowed sub-licensing of these rights, although others did not. Not surprisingly, these agreements were provided by research consortia (two), biobanks (four including the UK Biobank), research institutes (three including the CSIRO Agreement) and just two universities. In most of these cases, sharing results with the original supplier of the material is to be expected.

There are instances where a licence-back is required, and in this instance best practice would allow the supplier to be provided with a non-exclusive, research-only licence to use modifications created by the receiver.

[196] As discussed above 4.6.5, *Indemnification for IP Infringement*.

Termination

Twenty-four agreements had termination clauses. Publicly available agreements that contained such terms included the UBMTA, the UK Biobank Agreement, the Plant Treaty Agreement SMTA, the NIH Human Tissue MTA and the CSIRO Agreement. Of the 24 agreements containing termination clauses, two allowed termination by either party for breach of an obligation without remedy, one within five days and the other within 14 days. Only one allowed termination for breach of a term without qualification. Of those agreements providing for unilateral termination, one gave any party the right to terminate with seven days' notice. Other unilateral termination rights required 30 days, 60 days and three months' notice.

Unless there is a basis for exercising the unilateral right to termination, there is a risk that research could be stalled, particularly if the notice period is short. The only justification for a short notice period is where there is a serious and un-remedied breach of an ethics requirement, for example, dealing with human tissue inconsistently with consent or ethics obligations.

4.7 CONCLUSIONS

Based on current practice as assessed through interview data and analysis of this sample of 45 MTA documents, improvements could be made to template MTAs to better manage concerns of institutions and support research transfers. Adopting common key terms would be the first step towards standardisation that may remove some of the burden imposed on researchers and TTOs. It remains unclear whether parties would agree to standardisation in light of the 'bespoke' nature of many transfers. However, streamlining provisions so that rights are more proportionately balanced for effort and risk is likely to result in expedited processes.

The analysis presented in this chapter shows that there is a high level of variability in template MTAs across Australia, and divergence from standard form agreements such as the UBMTA. The variance in length of template agreements is one indicator of diversity, though we were unable to find a clear correlation between length and complexity. Some key points of concern in some of the agreements analysed in this chapter include:

- the lack of a clear distinction between modified and unmodified derivatives;
- inadequacy in addressing provenance of the materials, in light of the fact that this was reported as one of the key rationales for entering into formal MTAs in interviews reported in Chapters 2 and 3;
- restrictions on field of use that could stifle rather than promote research uses;
- lack of clarity around what constitutes reasonable restrictions on publication; and
- the imposition of strict terms with regard to rights to future intellectual property which would better be left to future negotiation, as would other decisions about future commercialisation and other non-research uses (particularly clinical use in the context of human tissue).

CHAPTER 5

REVISITING THE FUNCTION AND FORM OF THE MATERIAL TRANSFER AGREEMENT

5.1 INTRODUCTION

There is no doubt that the research landscape in publicly funded institutions has altered irrevocably, and that the push to commercialise and formalise is unlikely to abate. As a consequence, the material transfer agreement (MTA) is here to stay. Many of the issues with MTAs identified in this Occasional Paper can be ironed out through changes to organisational structure and streamlining of the MTA process and the MTA document. We argue that the promotion of simplicity is a key component of MTA remediation.

The purpose of this discussion chapter is to revisit the function and form of MTAs and, in broad terms, to examine the drivers for MTAs and whether standardisation is an appropriate weapon in the simplification armoury. In the course of the discussion, we canvass several issues that are likely to surface in the immediate future, or that already exist and are likely to persist despite best efforts at simplification. The aim of the discussion is to highlight where we might focus our attention in the longer term and where further study is warranted. We covered many issues during our discussion in Chapters 2, 3 and 4. The aim of this chapter is not to revisit all of those issues, but to focus on particular issues requiring further research and analysis.

To this end, we consider the relevance of our evidence on the perceived purpose behind MTAs, and the function of MTAs as a device for record-keeping. We have emphasised in earlier chapters that the provenance of material is perhaps the most important factor in justifying the use of MTAs. Failure to adequately address provenance, when combined with other risk factors can have a detrimental effect on the process of transferring and using materials for research purposes.

We also consider the implications of informal transfers, or transfers without accompanying MTAs, and the legal status of these transfers. We then specifically highlight issues surrounding the transfer of human tissue and whether it is likely that complexity in this area will ever diminish. This issue is very much a live one given that it is compounded by the relationship between private contracting and ethics requirements. Difficult questions surrounding the status of human tissue as property are briefly addressed, as this matter is central to the subject of ownership and control of human tissue samples, core concepts in ascertaining the legitimacy of their transfer.

We also examine the prospect that data transfer will face increasing levels of formalisation and offer some conclusions as to the impact this is likely to have on the open sharing of data in public research. Data

transfer is at a crossroads, and the question we ask is whether the almost inevitable trend toward increased formalisation should be viewed positively.

Finally, we make some comment on the form of MTAs, specifically, the desirability and viability of uniformity via standardisation of MTAs.

5.2 THE FUNCTION OF MTAS: WHAT ARE THEY PERCEIVED TO DO? WHAT SHOULD THEY DO?

5.2.1 What Are MTAs Perceived To Do?

Much of the discussion in interviews with technology transfer office (TTO) personnel and scientists reported in Chapters 2 and 3 was devoted to exploring the perceived function of MTAs, and whether views on their purpose align with how they operate in practice. Some of the questions in the scientist survey were also designed to elicit respondents' views on the main purpose of MTAs.

To reiterate, our data from interviews with TTO personnel presented in Chapter 2 clearly demonstrates that, across the board, rationales for MTAs were broadly facilitative of research, in terms of promoting collaboration, allowing provenance to be recorded and tracked, and increasing certainty and clarity.[197] As to more specific motivations, some TTO personnel saw the justifications for MTAs as including protection or indemnification,[198] and acknowledgement in or co-authorship of publications based on research use of transferred materials (54 per cent of interviewees, 6 per cent saying it was the main purpose).[199] The securing of intellectual property rights also featured prominently for 71 per cent of interviewees,[200] with 26 per cent considering it to be the primary purpose of MTAs.

From the perspective of scientists, the survey data reported in Chapter 3 showed that MTAs were seen as useful for a range of reasons, none of which were dominant.[201] Clarification of the terms of exchange and ownership of material were viewed as being important, and many

[197] See above 2.3.2.

[198] Fifty-eight per cent of interviewees stated it to be a purpose, 16 per cent claimed it to be the main purpose.

[199] Fifty-four per cent of interviewees referred to it as a purpose, six per cent said it was the main purpose.

[200] 71 per cent of interviewees referred to it as a purpose.

[201] See above 3.4.1.

scientists saw MTAs as effective tools to stipulate permissible uses of a material. Other key purposes were the protection of intellectual property, indemnification (particularly for those receiving materials) and, to a lesser extent, the clarification of rights around publication, authorship and attribution.

The use of MTAs as a basis for protecting rights around publication was more prominent among interviewed scientists,[202] but the trend in the survey data to downplay the use of MTAs to protect the right to publish was surprising, particularly as MTAs were viewed by many as a device to facilitate collaboration. Another surprising facet of these results was the relevance attached to clauses providing a conduit to ownership of future intellectual property, given that scientists would be well aware that very few research projects lead to a commercialisable outcome. Perhaps this perception that intellectual property terms are important can be attributed more to a desire on the part of scientists to ensure that rights to intellectual property do not inhibit their research, rather than any acknowledgement that it is important for their institution to secure future intellectual property.

The analysis of contractual terms contained in Chapter 4 did not fully align with these findings. Whilst a number of MTAs included terms dealing with provenance of the material being transferred, this issue was not explicitly addressed in all agreements.[203] Ownership of the material, and of unmodified derivatives and progeny[204] was generally more clearly dealt with, and in most cases tended to remain with the supplier. Provisions relating to ownership of modified derivatives were, however, more varied, ranging from supplier ownership, to receiver ownership, to co-ownership.[205] Restrictions on the fields of use of the material were similarly mixed, with some MTAs imposing quite stringent limitations around the permissible uses of particular materials.[206] Finally, a vast majority of MTAs left open the possibility of further sharing of materials, although virtually all required prior written approval from the supplier.[207] Taken together, these analyses suggest that institutions take steps in their agreements to maintain a chain of custody and ensure some control over the various paths a material may take. Whether this function of

[202] Ibid.

[203] See above 4.6.2. Fourteen agreements had terms that specifically addressed the issue of provenance.

[204] See above 4.6.3.

[205] Ibid.

[206] See above 4.6.4, *Field of Use, Exclusion of Clinical Uses*.

[207] See above 4.6.4, *On-Sharing of Material and Modifications*.

recording provenance is unduly complicated by the inclusion of a multiplicity of other terms in MTAs is an open question.

A significantly high number of MTAs contained terms giving suppliers of materials the right to vet publications.[208] Even more provided the supplier of a material with a right of attribution or acknowledgement of contribution in publications.[209] There was also a diversity of terms relating to background and future intellectual property ownership, and rights to future commercialisation.[210] This analysis of terms in template and standard MTAs indicates that, despite the rhetoric of facilitating collaborative research, in a number of instances the MTA terms ensure that the supplier retains ongoing control over the uses to which the materials might be put and outcomes of these uses.

It should also be noted that the analysis of terms in Chapter 4 related to both standard and template MTAs. One of the problems identified in earlier studies reported in Chapter 1 was the irresistible urge to tinker with these templates and standards. As such, even for those templates or standards that impose minimal restrictions on research uses and their outcomes, there is still a risk that they could be modified in ways that impose greater levels of control and more restrictions on use, during the negotiation process.

5.2.2 What Should MTAs Do?

As we have already noted, one of the main purposes of MTAs is to enable those in possession of materials to track their provenance. If all that is required of an MTA is this relatively simple record-keeping function, it could be achieved through the use of a simple letter of agreement, or other more technologically advanced alternatives. For example, blockchain technology is already being applied as a means of tracking provenance in some areas, including data transfers,[211] and may well be more broadly applicable to material transfers.

We noted in Chapter 1 that empirical studies undertaken prior to the study reported in this Occasional Paper have shown that there can be significant misconceptions as to the levels of risk associated with the transfer of materials by the TTOs charged with the task of negotiating

208 See above 4.6.4, *Publication*.

209 See above 4.6.4, *Attribution and Authorship*.

210 See above 4.6.5.

211 Ricardo Neisse, Gary Steri, and Igor Nai-Fovino, 'A Blockchain-based Approach for Data Accountability and Provenance Tracking' (Paper presented at the International Conference on Availability, Reliability and Security, Reggio Calabria, Italy, 29 August – 1 September 2017) <https://arxiv.org/pdf/1706.04507.pdf>.

MTA terms on behalf of their institutions.[212] One consequence is that a disproportionate amount of time can be spent negotiating MTAs where simple agreements would suffice. Exaggerated notions of risk can also lead to inefficient organisational structures and processes.[213]

Our study supports the proposition that these perceptions of risk rarely reflect reality, whether cast as the risk of being sued, the risk of not being able to prevent misuse of the material once transferred, or the risk of missing out on the bounty of commercialisation (for example). The reality is that, once materials are transferred, they are rarely tracked and there is only the remotest of possibilities that MTAs will be enforced through judicial processes. There is also a remote likelihood that materials transferred for research purposes will result in commercialisable outcomes that the supplier should rightfully be entitled to share. The analysis of TTO interviews presented in Chapter 2 showed that the more experienced TTOs have the most efficient processes for negotiating and executing MTAs. We posit that one of the reasons for this is that they have a good understanding of risks involved when transferring materials. Hence, they understand when simple transfers suffice, and when greater complexity is required.

In Chapter 2, we presented clear evidence that increased levels of bureaucratisation of MTA procedures tend to produce more protracted MTA processes, leading to delays and frustration on the part of researchers. The question we ask here is: what measures might be taken to address these idiosyncratic, organisational impediments to efficiency? We argue that, in most cases, simplicity in agreement format will suffice to safeguard the interests of parties to an exchange, recognising that complexity might be needed in a limited number of cases. The following is a non-exhaustive list of circumstances where complex agreements necessitating negotiations might be warranted:

- where human tissue is being transferred;
- where commercial outcomes from use of the material are likely; and
- where clinical uses of the material are being contemplated.

We argue that the only rationalisation for escalating to complexity in other areas is miscalculated assessment of risk. There are a number of strategies that could be used to discourage tendencies to protect against

[212] See above 1.3.3.

[213] See above 2.3.2.

misconceived risks and expedite the process of negotiating MTAs. The *first* is to achieve a fundamental shift in the way that 'success' in material transfers is perceived within institutions, bearing in mind that most are undertaken primarily to enhance collaborative relationships and research. Changing the core measures of success of TTOs to reflect their role as facilitators of collaboration and dissemination may have some traction.[214] As Bubela and Caulfield point out, this will require TTOs to become far more transparent.[215]

Traditional indicators of university performance have generally focused on patents, R&D data and publications.[216] Those evaluating TTO performance have followed this methodological trend in a variety of areas, most notably translation and commercialisation. Gross licensing income, number of licences executed per year, and number of spin outs have all been put forward as possible measures of TTO performance.[217] Commercialisation pressure is a reality and these measurement tools focus heavily on financial motivations rather than innovation, dissemination and collaboration.[218] They also fail to reflect long-term reality in that they rarely track the longevity of spin-outs[219] or maintenance of patent portfolios.

More diverse measurement tools have been proposed as a way of measuring the socio-economic impact of public sector research on the innovation process.[220] Although a departure from traditional measurement tools, these metrics would enable a more holistic, societal view of the role of university research in the innovation process.[221] In the case of MTAs, it might be envisaged that an obvious indicator of 'success' is number of MTAs executed. Turnaround time would likewise be a fairly straightforward metric against which to measure TTO performance. If we view the transfer of knowledge as a desired output from public institutions, measures taken by institutions to expedite knowledge

214 Tania M Bubela and Timothy Caulfield, 'Role and Reality: Technology Transfer at Canadian Universities' (2010) 28 *Trends in Biotechnology* 447, 451.

215 Ibid.

216 See, eg, Wesley Cohen, Richard Nelson and John Walsh, 'Links and Impacts: The Influence of Public Research on Industrial R&D' (2002) 48 *Management Science* 1.

217 Brady Huggett, 'Reinventing Tech Transfer: US University Technology Transfer Offices Are Adopting New Models in Search of Increased Return on Research Investment' (2014) 32(12) *Nature Biotechnology* 1184, 1186.

218 Bubela and Caulfield, above n 214.

219 Ibid 449.

220 Organisation for Economic Cooperation and Development, *Science, Technology and Innovation Indicators in a Changing World: Responding to Policy Needs* (OECD Publishing, 2007) ch 10.

221 Ibid.

transfer could be seen as conduits to open and efficient sharing of knowledge.

A *second* strategy to effectively overcome risk aversion is the education of those involved in negotiating and drafting MTAs. It is critical to engender an understanding of the limited circumstances in which complexity is justified. Disseminating information about the low prospects of commercial success associated with a majority of materials would also be essential. We recognise, however, that while information dissemination is an important step in prompting changes in behaviour, it is rarely a catalyst in itself for voluntary behavioural change.[222] More sophisticated behavioural change models warrant contemplation in order to achieve increased understanding and sustainable changes in behaviour.[223] The utilisation of programs offered by industry organisations such as the Association of University Technology Managers (AUTM) in the US and Knowledge Commercialisation Australia (KCA) in Australia would increase understanding of the benefits of streamlining technology transfer. Coupled with formal in-house training of technology transfer personnel, industry organisation-run programs offer a real opportunity to educate as to best practice.

Thirdly, as we have emphasised throughout this Occasional Paper, the development and use of standardised MTAs across the Australian research sector could be one of the most effective tools in creating a more efficient material transfer process. The goal is to achieve cultural shift toward maintaining simplicity in MTAs in a vast majority of cases and relinquishing unrealistic expectations about commercial benefits and fears about legal liability. Endorsing simplicity during the process of negotiating for the transfer of materials is key to eradicating risk-averse behaviour. Bubela and Caulfield's study involving Canadian TTO personnel demonstrates that TTO personnel possess a surprisingly social view of their roles in promoting the research agendas of their universities.[224] This supports the proposition that change in culture will not be impossible to achieve, and that the metrics against which TTO performance should be measured align more closely with those identified above.

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[222] Theresa M Marteau, Amanda J Sowden and David Armstrong, 'Implementing Research Findings into Practice: Beyond the Information Deficit Model' in Andrew Haines and Anna Donald (eds), *Getting Research Findings into Practice* (BMJ Publishing Group, 2nd ed, 2007).

[223] Doug McKenzie-Mohr and P Wesley Schultz, 'Choosing Effective Behavior Change Tools' (2014) 20(1) *Social Marketing Quarterly* 35.

[224] Bubela and Caulfield, above n 214, 451.

There is little doubt that delays in research caused by impediments to timely access to research materials have the potential to derail research projects, particularly in respect of projects with a short funding life span. Many TTO staff clearly find the time taken to negotiate MTAs vexing, given the breadth of their remit, the time entailed in negotiating materials transfers and the negligible financial return on this time investment.[225] It goes without saying that researchers find these delays equally vexing. Similar to negotiating patent licences,[226] negotiating an MTA is an example of a low-reward task where cost routinely exceeds return. Streamlining MTA processes would be the most beneficial course any institution could take, and a number of our interviewees confirmed that they had realised significant benefits upon reforming MTA processes and treating them as lower stake transactions.

Our interviewees reported that, in many institutions, processes for completing, reviewing, and executing MTAs were unnecessarily protracted. A requirement for multiple parties to review the legal implications of an agreement is unrealistic and unnecessary. Requiring MTA sign-off by members of the senior executive is, likewise, a policy that is difficult to justify. These practices invariably stem from the inflated notions of risk discussed above, rather than any real need to institute comprehensive review processes. Overcoming the necessity for an extended process of review and execution is key to reducing delays. Simplifying agreements is one step toward achieving this aim, but altering perceptions of risk to encourage the simplification of MTA processes is even more fundamental. Chapter 2 has clearly shown that, with experience, TTOs can streamline MTA transactions and focus on the key goal of transferring materials to facilitate research.

5.3 BUREAUCRATS AND BUCCANEERS: THE STATUS OF INFORMAL TRANSFERS

Despite the push towards increasing formalisation of material transfers within universities and research institutes, our evidence provides a clear indication that transfers of material are still undertaken without MTAs in place. Although less frequent than it was one to two decades ago, our interviews and survey data show that both TTO personnel and researchers recognise that the practice still occurs to some extent, though it is difficult to state the quantum with any precision. It seems that researchers are most likely to share informally with other research

[225] Katherine Ku and James Henderson, 'The MTA – Rip it Up and Start Again?' (2007) 25(7) *Nature Biotechnology* 721.

[226] Simone Fishburn, 'Tables turning for TTOs' (2014) 7(3) *SciBX* Translational Notes 1, doi:10.1038/scibx.2014.77.

collaborators than unknown third parties. Though researchers recognise the value of formalised MTA processes, even if only as a 'necessary evil', it is clear that unless ways are found to circumvent the bureaucratic impediments to sharing, the attraction of informal transfers may become irresistible. The question is: does this matter? The challenge is that once a material has been transferred, monitoring its use becomes difficult. The legal status of 'informal' transfers of biological materials, therefore, warrants consideration.

5.3.1 Material Transfer: The Primacy of Contract

There is no doubt that an MTA constitutes a legally binding agreement governing the transfer of a tangible research material between parties,[227] or 'a contract that governs the transfer of tangible research materials between two organizations (a provider and a recipient) when the recipient intends to use it for his or her own (research) purposes.'[228] Bennett, Streitz and Gacel explain that:

> *Under such an agreement, the provider maintains ownership of the property transferred. Transferred property is held by the receiving party according to terms stipulated in a legally binding contract. The contract, therefore, governs the transfer of tangible biological materials between two or more parties. … [It] may need to account for the transfer of IP rights as well.*[229]

In most instances, then, a formal MTA is a contract governing a property transaction between two parties.

If an MTA involves a transfer of certain property rights between two institutions, what is the status of an informal transfer between researchers at different institutions? The view of one TTO interviewee from a research institute on informal transfers was succinctly put as follows: 'we have a simple mantra, if there's no MTA then you're dealing in stolen goods'.

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[227] Alan B Bennett, Wendy D Streitz and Rafael A Gaucel, 'Specific Issues with Material Transfer Agreements' in Anatole Krattiger et al (eds), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, (MIHR, PIPRA, Oswaldo Cruz Foundation, bioDevelopments-International Institute, 2007) 697, 698.

[228] International Society for Biological and Environmental Repositories, *Best Practices: Recommendations for Repositories* (4th ed, 2018) M.2.5.1.

[229] Bennett, Streitz and Gaucel, above n 227, 699.

Implied Contract

Is it really the case that the transfer of a material without an MTA in place equates to a dealing in stolen property? Might it be argued that a transfer of material to a collaborator might take place under an implied contract, with terms akin to those found in a written MTA?

One difficulty with such arguments is that it is unlikely that a researcher has the capacity to contract on behalf of the institution for which they work. If this is the case, the contract would be invalid for lack of capacity. The situation might be different where the practice of informal transfer is condoned by the institution: it might be arguable in this case that authority to contract is delegated to individual researchers, thus creating an implied contract. The terms of such a contract are likely to replicate those that have previously existed between the collaborating researchers, who may have an ongoing relationship. However, the answer to this question is by no means clear.

In addition, materials are usually transferred for free or on a cost recovery basis, raising the question of what will constitute sufficient consideration. Traditionally, consideration may be a right, interest, profit or benefit accruing to one party, or alternatively, some forebearance, detriment, loss or responsibility given, suffered, or undertaken by the other.[230] More recently, consideration has been defined more simply as constituting the price for which a promise is bought, being an act or forbearance of one party.[231] The critical question will be whether the parties intended contractual relations. If intention can, in fact, be pointed to, consideration will often be taken as a given.[232] Nominal consideration may suffice. It may be possible to discern some nominal or token consideration in the conduct of the transaction, which, if deliberately included, may be indicative of an intention to form a contract.[233] Agreement by an institution receiving a material to pay delivery and freight costs or the costs of importation may constitute sufficient nominal consideration, as may the sharing of research results generated by the receiver of the material where the parties exchanging the material are engaged in a collaborative relationship. Even a promise to conduct

[230] LexisNexis, *Halsbury's Laws of Australia*, (as at 17 September 2018) 110 Contract '5 Requirement of Consideration' [110-560]: Definition in terms of benefit and detriment, citing *Currie v Misa* (1875) LR 10 Ex 153, 162 per Lush J.

[231] *Dunlop Pneumatic Tyre Co Ltd v Selfridge and Co Ltd* [1915] AC 847, 855 per Lord Dunedin; *Australian Woollen Mills Pty Ltd v Commonwealth* (1954) 92 CLR 424.

[232] *New Zealand Shipping Co Ltd v AM Satterthwaite & Co Ltd* [1975] AC 154, 167 per Lord Wilberforce.

[233] See, eg, *Mountford v Scott* [1975] 1 All ER 198.

research on a material might conceivably be adequate consideration. Although the supplier of the material may well place value on these forms of consideration, this is not imperative.[234]

In summary, it may well be that a valid contract will be made out on the basis that there is an intention between the parties to contract, and valid consideration has passed between the parties. A sticking point may be that the lack of capacity on the part of a researcher renders any implied contract invalid.

5.3.2 Characterisation of the Legal Status of Transfers: Gift or Bailment?

There has been some analysis of whether the transfer of material from one researcher to another without a fee constitutes a gift or a bailment of the material, particularly in the context of human tissue. The legal status of human tissue donated for research is explored in 5.4. Here the focus is more general, on the characterisation of any type of gratuitous transfer of material for research.

Gifts

Gifts of goods may be demonstrated by an intention to pass ownership, and delivery of the goods.[235] Although this definition implies that the supplier has ownership, a possessory title will be a sufficient basis on which to convey a gift. On the face of it, a researcher holding a material certainly has possession of that material, suggesting they have the capacity to transfer that possession gratuitously. There is an argument, however, that possession vests in the institution through which they are employed, and that without specific permission to the researcher to transfer possession, a valid gift is never effected. Implied permission by the institution (turning a blind eye to informal transfers) might overcome this problem. Where there is no pre-existing contract, the provision of the material might be described as a gratuitous gift by one researcher to another. Similarly, if it could be argued that a contract fails to exist for want of consideration, the result could still be an executory gift.[236]

Yet given the scope of the concept of consideration, it is relatively easy to establish that valid consideration is exchanged, taking the transfer outside the realm of a gift into contract. It is possibly the case that

[234] *Chappell v Co Ltd v Nestle Co Ltd* [1960] AC 87, 114 per Lord Somervell.

[235] Generally on the part of the donor rather than the donee: *Dewar v Dewar* [1975] 1 WLR 1532.

[236] *Milroy v Lord* (1862) 4 De GF & J 264 per Turner J.

transfers to other researchers (with the implied or actual consent of the institution) that are not conditional on any requirement to return the material to the supplier are absolute gifts. In contrast, those that are conditional on a requirement to return the material if asked by the supplier (or upon conclusion of the transaction) might more appropriately be classified as bailments (see below), provided there is some expectation the materials will be returned.

One niggling problem is that of associated choses in action and other related intangibles that might be transferred with the material. It is arguable that whenever a material is transferred it will be accompanied by some sort of chose in action, which might be in the form of data, confidential information or a right to modify materials and produce derivatives.[237] Choses in action might be recognised either in common law or in equity: those just mentioned would likely be recognised as legal (ie recognised at common law as possessory-based interests and their offshoots, which were traditionally part of the jurisdiction of the common law). A variety of 'rights' and 'permissions' have been held to be legal choses in action,[238] including intellectual property rights,[239] although admittedly the case law deals primarily with copyright.[240] Despite the fact that material might be capable of being transferred by oral agreement,[241] legal transfers of choses in action may be required to be in writing.[242] This would operate to invalidate the transfer of intangibles that accompany a transfer of a material.

[237] Cameron Stewart et al, 'The Problems of Biobanking and the Law of Gifts' in Imogen Goold et al (eds), *Persons, Parts and Property: How Should We Regulate Human Tissue in the 21st Century?* (Hart Publishing, 2014) 25, 35; Cameron Stewart, Jennifer Fleming and Ian Kerridge, 'The Law of Gifts, Conditional Donation and Biobanking' (2013) 21 *Journal of Law and Medicine* 351. See also Dianne Nicol 'Property in Human Tissue and the Right of Commercialisation: The Interface Between Tangible and Intellectual Property' (2004) 30(2) *Monash University Law Review* 139, 149.

[238] See LexisNexis, *Halsbury's Laws of England*, vol 13 (at 2017) Choses in Action, '(2) Classification' [7].

[239] See *Halsbury's Laws of England*, vol 13 (at 2017) Choses in Action, '(2) Classification' [9].

[240] See, eg, *Paterson Zochonis & Co Ltd v Merfarken Packaging Ltd* [1986] 3 All ER 522, CA.

[241] See, eg, *Riccard v Pritchard* (1855) 1 K & J 277.

[242] *Civil Law (Property) Act 2006* (ACT) s 205; *Law of Property Act 2000* (NT) s 183; *Conveyancing Act 1919* (NSW) s 12; *Property Law Act 1974* (Qld) ss 199, 200; *Law of Property Act 1936* (SA) s 15; *Conveyancing and Law of Property Act 1884* (Tas) s 86; *Property Law Act 1958* (Vic) s 134; *Property Law Act 1969* (WA) s 20.

An additional requirement is that legal transfers of choses in action must be absolute.[243] This stipulation that a transfer must be absolute might also be difficult to overcome. 'Rights' accompanying materials are rarely transferred absolutely from researcher to researcher; as our evidence demonstrates, often a researcher transferring a material and associated know-how or choses in action will retain the right to use the material under the same conditions. Similarly, multi-partite transfers might take place, where various researchers in numerous institutions simultaneously take possession of and use a material. This problem does not manifest where an MTA is used, because an MTA will usually make provision for the transfer of intangibles and specify the field of use. All is not lost, however, as equity may operate to validate the non-written and non-absolute gift of a chose in action, provided there is sufficient intent that the receiver acquire its benefit.[244] It may be possible to sustain an argument that an equitable transfer of the chose in action occurred, overcoming the requirement for writing and absolute transfer.

Bailment

Similar issues arise in respect of capacity to bail the property. A bailment occurs where a bailor (the possessor of goods) puts a bailee (the receiver of goods) knowingly and willingly in possession of goods for a limited period of time. Consideration is not required as bailments may be gratuitous (in that only one party benefits from the arrangement).[245] Another traditional requirement of bailment relationships was redelivery of goods, although this requirement has also been superseded by modern interpretations that do not stipulate redelivery, but merely 'any grant of possession which does not by itself convey the whole of the interest enjoyed (or purportedly enjoyed) by the grantor.'[246] It is clear from our interview and survey data that materials are frequently transferred for research purposes without any expectation that they will be re-delivered. Due to the modern interpretation of the redelivery requirement, this fact will not in itself be an impediment to the establishment of a bailment relationship.[247] The outright transfer of ownership will not comprise a bailment, however, so that if, say, the materials are given to another researcher because the supplier has no

[243] Note that the Western Australian legislation provides that part of a chose in action may be assigned at equity: *Property Law Act 1969* (WA) s 20.

[244] See, eg, *Pennington v Waine* [2002] 1 WLR 2075; *Norman v FCT* (1963) 109 CLR 9, 30.

[245] Norman Palmer, *Palmer on Bailment* (Thompson Reuters (Legal) Ltd, 3rd ed, 2009), 32–36 [1-033]–[1-035].

[246] Ibid 5 [1-004].

[247] Nicol, 'Property in Human Tissue', above n 237, 150.

intention of conducting further research in the area, this negates any argument that a bailment arises.

The bailment relationship is capable of arising in complex, multipartite situations, with multiple bailors and bailees.[248] Where goods are passed on to multiple parties through sub-bailments, sub-bailees likely assume the position of bailees to the original bailor, this relationship arising whether or not the original bailor (the head bailor) knew that possession of the material would be passed on. For example, if a research institute has a material that is informally transferred to a researcher (the bailee), and subsequently another (the sub-bailee), the sub-bailee would hold the material subject to the original bailment and its attendant conditions. If the transfer to the bailee was instead under an MTA, the informal transfer to the sub-bailee would probably be governed by the terms of the MTA. This would provide significantly more clarity, and aptly demonstrates that MTAs are useful not only to track provenance, but in delineating the terms of subsequent transfers of research materials.

Where an original bailor consents to a sub-bailment, there is case law to suggest that the terms of the sub-bailment are also relevant to the relationship between the head-bailor and the sub-bailee.[249] This may be an advantage to either party where the obligations attendant upon the bailment exceed those that exist at common law.[250]

The above analysis does not resolve questions around the status of associated choses in action, know-how or data, and whether they are included in any bailment that arises. Bailment has generally not been extended to intangibles because there is no right to possession. It is arguable that intangibles delivered with tangible property would constitute a single good, with the attendant remedies this would afford. Although there is no authority directly on point, an argument to this effect has been mounted in respect of software,[251] and hardware and software delivered together have been held to constitute 'goods' in the context of Sale of Goods legislation.[252]

An even more difficult question arises in respect of intangibles delivered independent of tangible goods – for example, data transferred without any written agreement in place. This issue is discussed below,[253] although

[248] Palmer, above n 245, 3 [1-003].

[249] *Sandeman Coprimar SA v Transitos y Transportes Integrales SL* [2003] QB 1270 [61].

[250] Ibid. See also Palmer, above n 245, 20–1 [1-021].

[251] Palmer, above n 245, 1544–7 [30-022]–[30-024].

[252] *St Albans City and DC v International Computers Ltd* [1996] 4 All ER 481 CA.

[253] See below, 5.5.3.

it is sufficient to note at this stage that there is some scope to argue that intangibles (eg confidential information) are capable of being bailed provided they are capable of possession, the key concept in any bailment.

5.3.3 The Upshot

Transfers without an MTA in place invariably present problems insofar as the legal status of those transfers is concerned. If a contract cannot be implied, an argument might be mounted that the materials have been gifted (if given on the understanding that the transfer is absolute), or bailed (if there is some expectation that the materials will be returned). An overriding problem is that of capacity, and whether a researcher has the capacity to transfer materials on behalf of the institution. This might be the thorniest issue of all. While we are not persuaded this amounts to dealing in stolen property, it explains why some people might make that argument. Although an allegation that the property has been stolen may not be able to be sustained, the lack of capacity on the part of a researcher to transfer might give rise to an appropriate remedy.

5.4 THE SPLEEN AROUND TRANSFERS OF HUMAN TISSUE

5.4.1 Unresolved Questions Around Ownership of Human Tissue

Ownership of human tissue raises even more complex legal issues, which warrant further exploration. There is a significant body of literature dealing with the issue of tissue donation and ownership,[254] and a growing body of case law. It is well-established law that a body part will constitute property capable of ownership if there has been some application of work and skill (such as dissection or preservation).[255] Preserved tissue,[256] body parts,[257] body tissue removed during surgery,[258] and cell lines

[254] See, eg, Imogen Goold, 'Property in Human Biomaterials' in Ian Freckleton and Kerry Peterson (eds), *Tensions and Traumas in Health Law* (The Federation Press, 2017) 367; Imogen Goold et al (eds), *Persons, Parts and Property: How Should We Regulate Human Tissue in the 21st Century?* (Hart Publishing, 2014); Loane Skene, 'Proprietary Interests in Human Bodily Material: *Yearworth*, Recent Australian Cases on Stored Semen and Their Implications' (2012) 20(2) *Medical Law Review* 227; Nicol, 'Property in Human Tissue', above n 237.

[255] *Doodeward v Spence* (1908) 8 CLR 406.

[256] Ibid.

[257] *R v Kelly* [1999] 2 WLR 384; *AB and Others v Leeds Teaching Hospital NHS Trust* [2005] 2 WLR 358.

[258] *Roche v Douglas* [2000] WASC 146 (7 June 2000) (Master Sanderson).

developed from tissue samples are now considered capable of giving rise to a possessory interest on the part of the researcher/institution,[259] which may or may not fall short of ownership.[260] There has also been some recognition judicially that we will probably see the law develop to accommodate the concept of body parts as property if they have some use or significance beyond mere existence.[261] Separation from the body may be a sufficient precondition to status as property, without the need for work and skill. There is judicial comment to suggest that once body parts have acquired the status of property through the acquisition of skill, they are capable of being stolen.[262]

As to whether donors of tissue samples retain an interest in the sample, this is a more intractable question. There is authority that males and their beneficiaries retain a property interest in stored sperm provided for reproductive purposes either after cancer treatment[263] or after death.[264] However, there is some doubt as to whether a person ever *owns* tissue, particularly during the period it remains in their body.[265] Once tissue has been removed from a patient, it is questionable on the basis of current authority that the patient will acquire a possessory interest, particularly where they are aware that tissue has been donated for research purposes (perhaps in addition to removal for therapeutic purposes).[266]

The usual practice is now to obtain broad consent on donated tissue samples, ensuring comprehensive rights to use the tissue in unspecified research. Research ethics obligations, privacy laws, contract and other laws are all available to donors should there be misuse of their donated

[259] *Moore v Regents of the University of California*, 249 Cl Rptr 494 (Cal Ct App, 1988); *Greenberg v Miami Childrens' Hospital Research Institute Inc,* 264 F Supp 2d 1064 (Fla, 2003).

[260] Jane Kaye et al, 'Trends and Challenges in Biobanking' in Ian Freckleton and Kerry Peterson (eds), *Tensions and Traumas in Health Law* (The Federation Press, 2017) 415, 429. See also *Re Organ Retention Group Litigation* [2005] QB 621, [148].

[261] *R v Kelly* [1999] 2 WLR 384.

[262] Ibid.

[263] See, eg, *Yearworth v North Bristol NHS Trust* [2009] 2 All ER 986; *Roblin v Public Trustee* (ACT) [2015] ACTSC 100 (24 April 2015).

[264] See, eg, *Re Estate of Edwards* (2011) 81 NSWLR 198; *Re H, AE (No 2)* [2012] SASC 177; *Cresswell v AG for the State of Queensland* [2018] QSC 142.

[265] *Moore v Regents of the University of California*, 249 Cl Rptr 494 (Cal Ct App, 1988); *Greenberg v Miami Childrens' Hospital Research Institute Inc,* 264 F Supp 2d 1064 (Fla, 2003); *R v Bentham* [2005] 1 WLR 1057, [8].

[266] *Moore v Regents of the University of California*, 249 Cl Rptr 494 (Cal Ct App, 1988); *Greenberg v Miami Childrens' Hospital Research Institute Inc,* 264 F Supp 2d 1064 (Fla, 2003).

tissue or the information residing in it.[267] However, it is still unclear whether the donor has a residual property right over their donated tissue. There remains a lack of clear authority for recognising property rights in tissue samples where work and skill has not been applied,[268] but no reason in theory why they could not be recognised, aside from historical anomaly.[269]

It is difficult to see the difference between sperm removed and stored either before or after death, and other body parts. Separating and preserving sperm is a sufficient precondition to recognising property rights therein. This 'low' level of work and skill renders it probable that acquiring tissue samples would involve sufficient work and skill to satisfy this requirement. It is certainly the case that significant skill is involved in excising tissue, in sequencing DNA, and in the myriad other actions that occur before institutions take possession of tissue samples. However, one clear difference is that, in the sperm cases, the donors retained an ongoing intention to use their sperm in the future, whereas in the case of donated tissue for research there is no clear reason why the donor may seek to retain any such ongoing right to use that tissue.[270] Arguably, though, they do have the intention to retain a right to control use of their tissue, for example that it is not used for commercial purposes.[271]

What is the combined effect of an ostensible lack of a possessory right on the part of the donor, and the acquisition of broad consent from the donor? A researcher receiving a sample from a donor (whether it be by bailment or gift),[272] probably acquires a possessory interest in that sample upon receipt. It would appear they may well have a more legitimate possessory interest in the tissue sample than the donor. They will unequivocally have possessory rights over materials generated from

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267 Dianne Nicol et al, 'Impressions on the Body, Property and Research' in Imogen Goold et al (eds) *Persons, Parts and Property: How Should We Regulate Human Tissue in the 21st Century?* (Hart Publishing, 2014) 9.

268 Although see *Roche v Douglas* [2000] WASC 146 (7 June 2000) 338 (Master Sanderson); *Yearworth v North Bristol NHS Trust* [2009] 2 All ER 986; *Bazley v Wesley Monash IVF Pty Ltd* (2011) 2 Qd R 207, 215; The decision in *Holdich v Lothian Health Board* 2014 SLT 495 would appear to have narrowed the decision in *Yearworth*.

269 See, eg, Imogen Goold and Simon Douglas, 'Property in Biomaterials: A New Methodology' (2016) 75 *Cambridge Law Journal* 478; Imogen Goold, 'Property in Human Biomaterials', above n 254; Justice James Edelman, 'Property Rights to our Bodies and Their Products' (2015) 39(2) *University of Western Australia Law Review* 47.

270 Nicol et al, above n 267.

271 Ibid.

272 See above 5.3.2.

the tissue sample, given that they have applied skill in producing these materials. If, then, a researcher or, more accurately, their institution,[273] has a proprietary right over tissue samples provided to them by a donor, there is nothing precluding them from dealing in tissue samples and derivative materials that have been subjected to work and skill as they see fit in the context of property law (recognising that other laws and ethical obligations come into play).

5.4.2 Donation of Tissue as a Gift

Stewart et al have argued that donations of human tissue samples to biobanks are in the nature of conditional gifts; conditions that might be implied into the gift include conditions that allow the donor to withdraw their tissue or request that it be destroyed.[274] As alluded to above, Stewart et al also suggest that intangible choses in action generally accompany donations of tissue by donors.[275]

It is possible to conceive of other 'rights' that accompany the tissue donation that may constitute choses in action, for example, the right to associated know-how or data transferred with a sample. In the absence of an express condition, possession of tissue donations will generally vest in the institution conducting the research,[276] and in the case of networked research communities, affiliated researchers would be bound by the conditions under which the tissue was donated.[277]

5.4.3 Donation of Tissue as a Bailment

Although bailments are generally in the nature of contractual agreements, donations of tissue samples for research fit into the non-contractual sphere, because there is no contractual agreement as such.[278] As noted earlier in this chapter, this will not preclude a finding that a bailment exists;[279] the modern view of bailment is that, in order for a bailment to exist,

[273] *The Washington University v Catalona,* 437 F Supp 2d 985 (ED Mo, 2006).

[274] Stewart et al, above n 237, 37.

[275] Ibid 35; Stewart, Fleming and Kerridge, above n 237; See also Dianne Nicol, 'Property in Human Tissue', above n 237, 149.

[276] Stewart et al, above n 237, 36–7, citing *The Washington University v Catalona,* 490 F 3d 667 (2007).

[277] Stewart et al, above n 237, 37.

[278] Dianne Nicol, 'Property in Human Tissue', above n 237, 149.

[279] Palmer, above n 245, 10–11 [1-012].

> *[w]hat is fundamental is not contract, but the bailee's consent. The duties of a bailee arise out of the voluntary assumption of possession of another's goods.*[280]

It is now well-established that a right to immediate possession on the part of the bailor will suffice.[281] Despite judicial reluctance to lay down an authoritative foundation for recognising possessory rights in human tissue, there is a compelling argument that in this modern medical era, possessory rights arise upon separation of human tissue from the human body, and that this should be capable of giving rise to a bailment relationship where tissue is donated for research purposes.[282] As Palmer observes, this would be consistent with conventional statutes governing modern medicine, which tend to imply property rights in tissue.[283]

5.4.4 The Upshot

To conclude, the threshold question of whether property vests in human tissue is unresolved, and definitive conclusions as to the status of donations by donors, and transfers between researchers, are not easy to reach. In any case, if an argument can be sustained that a donation of human tissue constitutes either a gift or a bailment, possessory rights would pass to the institution. Accompanying choses in action, including data and know-how, are also capable of being transferred upon the same grounds discussed above.

It is not possible on the basis of current case law to definitively resolve the question of whether a donor has a possessory interest in a tissue sample. Given that it appears possible for the recipient of a tissue sample (a researcher or their institution) to claim a possessory interest in the sample, whether through gift or bailment or through the exercise of a low level of work and skill, there seems to be no impediment to their ability to further transfer that sample should they see fit. In short, researchers may acquire a possessory interest through gift or bailment from a donor, or through the transformation of a sample into property

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280 *East West Corp v DKBS AF* 1912 [2003] QB 1509, [24]; *The Pioneer Container* [1994] 2 AC 324 PC; See further *Yearworth v North Bristol NHS Trust* [2009] 2 All ER 986, [48(a)].

281 Palmer, above n 245, [2-004], citing *East West Corp v DKBS AF 1912* [2003] QB 1509, [27], [38] and *Scottish and Newcastle International Ltd v Othon Ghalanos* [2008] 2 All ER 768, [46].

282 Ibid 1519–24 [29-013]–[29-019].

283 Ibid 1519–21 [29-013]–[29-017]. In Australia this might include, for example, statutes regulating the storage of human tissue and blood products.

through the application of work and skill, creating a new good (for example a cell line) capable of possession and transfer.

5.4.5 Parameters around the Use of Human Tissue: Consent and Ethics Obligations

In Chapter 1, we flagged the complexities associated with transfers of human tissue for research purposes. We recognised in an earlier section of this chapter that transfers of human tissue involve sufficient complexity that more detailed MTAs are warranted.[284] Ensuring the existence of consent over a particular transfer and resultant use is paramount.

Overwhelmingly, parties interviewed were cognisant of the importance of operating within the boundaries of consent, and of complying with ethics obligations over human tissue samples. Human tissue samples were seen as 'high risk' materials by many we spoke to. Scientists were especially aware of the importance of engaging with MTAs when complex materials such as human tissue samples were involved, with around 50 per cent of survey respondents recognising the importance of MTAs in cementing the fulfilment of ethics obligations. [285]

A significant number of TTO interviewees indicated that their institutions enter into MTAs for transfers of human tissue,[286] and that these transfers are always accompanied by an additional layer of negotiation and caution.[287] Acknowledgement by many of our interviewees of the need to track provenance is also reflective of a recognition that provenance is particularly important when human tissue samples are being transferred. This was reinforced by the inclusion in some 17 MTAs of terms relating to ethics. These terms varied in their content and level of specificity. While some referred specifically to the scope of consent provided by donors, others dealt with compliance with consent and ethics obligations only in general terms.[288] Overwhelmingly, the use of materials in a clinical context was prohibited or limited.[289]

One comment we would make is that obligations imposed by ethics committees were sometimes viewed as a proxy for the inclusion of terms

[284] See above 5.2.2.

[285] See above 3.4.6.

[286] See above 2.3.

[287] See above 2.3.3, *Specific Types of Materials: The Problems with Human Tissue Samples.*

[288] See above 4.6.4, *Ethics and Consent*.

[289] See above 4.6.4, *Exclusion of Clinical Uses*.

in MTAs dealing with consent and the terms of transfer over human tissue. Ideally, these requirements should be seen not as alternatives, but as necessary complements. In Chapter 3, in Section 3.4.6, we flagged the possibility that ethics committees may struggle to deal with the issues presented by cell lines (and perhaps other modified products), which may technically not be covered by ethics obligations relating to the original sample. This may be the case even where broad consent has been obtained (and is arguably especially important where broad consent has not been obtained). This is a different issue to that of ownership of a cell line and bolsters our argument that where human tissue is being transferred, specific terms should be included so that issues surrounding ownership, consent and ethics are left in no doubt. Relying solely on compliance with ethics approval and obligations under the *Declaration of Helsinki* may not, without more, provide sufficient protection to donors of human tissue samples.[290]

5.5 THE ISSUE OF GENOMIC AND OTHER DATA

Transfer of biological materials and data are inextricably linked, particularly in the context of genomic data.[291] The successful generation, collation and validation[292] of genomic data relies on obtaining appropriate tangible materials for analysis. Like materials, genomic data is a valuable resource. Data in the context of biological materials may take the form of confidential information.

Champions of the commons movement promote the open availability of data, asserting that '[u]ltimately, open access science will make industry more profitable and lead to the development of more medicines.'[293] In the context of human-related data, this sets up a conflict between

[290] World Medical Association, 'Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects', (18th WMA General Assembly, Helsinki, Finland, June 1964) <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>.

[291] Debra J H Mathews et al, 'Access to Stem Cells and Data: Persons, Property Rights, and Scientific Progress' (2011) 331 *Science* 725, 726.

[292] Paul N Schofield et al, 'Post-Publication Sharing of Data and Tools' (2009) 461(7261) *Nature* 171.

[293] Deborah Mascalzoni et al, 'International Charter of Principles for Sharing Bio-Specimens and Data' (2015) 23(6) *European Journal of Human Genetics* 721; A M Edwards et al, 'Open Access Chemical and Clinical Probes to Support Drug Discovery' (2009) 5(7) *Nature Chemical Biology* 436, 437; Tania Bubela et al, 'Managing Intellectual Property to Promote Pre-Competitive Research' (2012) 22(1) *Journal of Law, Information and Science* 98, 113–114.

requirements for release, and the necessity to comply with ethics obligations and privacy laws, and maintain confidentiality.[294] Our evidence revealed that, although many data transfers occur informally, more are transferred with a non-disclosure agreement (NDA) or confidentiality agreement in place. These agreements go some way toward protecting the privacy of personal genomic data. However, they are not designed to provide comprehensive coverage of the conditions of transfer. Conversely, data transferred under collaboration agreements will be subject to the same or similar conditions of transfer as materials under those same agreements. Those interviewees and survey respondents who indicated they used an MTA or data transfer agreement (DTA) when transferring data, would likewise transfer data under the same or similar terms as those under which material is transferred.

Yet, there is no doubt that data is different to tangible materials in a number of ways. The safety issues inherent in the use of biological materials are not present in the case of data. Further, it is non-rivalrous and infinite, unlike tangible materials that are a finite resource. Arguably (although not universally) data is easier to replicate and easier to transfer without authority. The ease with which data may be misused underscores the need for strict terms governing its transfer and use, whether the imposition of these terms be through ethics obligations or contractual provisions.

5.5.1 Data Transfer and HREC Requirements

Requirements imposed by ethics committees are a reliable avenue by which control over data (particularly data generated from human tissue samples) may be dealt with. However, as we noted in Chapter 3,[295] scientists are aware of the risk that obligations created pursuant to ethics approvals may lapse, resulting in data being transferred with no apparent authority from the subject from whom the data emanated. The same may be said of obligations created by MTAs or DTAs, effectively leaving researchers in possession of data in an obligation-free void.

This highlights two points. The first is the importance of ethics committees considering the breadth of data that might be generated through use of a tissue sample, some of which might not be foreseen at the time ethics approval is granted. The second is the significance of

[294] Dianne Nicol and Richard Gold, 'Standards for Biobank Access and Intellectual Property' in Matthew Rimmer and Alison McLennan (eds), *Intellectual Property and Emerging Technologies: The New Biology* (Edward Elgar, 2012) 133.

[295] See above 3.4.6.

formality in the process of transferring data; data accompanied by a DTA is less likely to be misused and more likely to be capable of being tracked from its point of generation. In short, ethics approvals are an essential part of the process of data generation, storage and use, but DTAs are just as critical in maintaining some degree of control over the future use of data. This is a particularly pertinent conclusion in relation to data created through the use of human tissue.

5.5.2 Data Transfers Under Agreement

In Chapter 2,[296] we presented evidence that indicated that approximately 60 per cent of interviewees had used formal agreements to transfer data. Of these, just under half had developed a distinct DTA, all of them being institutions conducting a high volume of transactions with well-entrenched processes for formalising the terms of exchange. This is reinforced by the fact that we managed to obtain just two DTAs for analysis during our study.[297] This is likely to be something that changes in due course, as the importance of tailoring agreements for data exchange is recognised. Certainly, a number of our TTO interviewees acknowledged as much during interviews.

It is clear from the evidence obtained during interviews and from the survey, however, that from the perspective of scientists, contracts accompanying the transfer of data are not yet in widespread use. Even TTO officers who were in favour of formalising the process of exchange conceded that many transfers of data probably occur without agreements in place. Some of these are likely under broader collaboration agreements, but many will not be.

The above comments relate, of course, to data transferred alone. Data transferred with materials is usually dealt with in some form (often in a piecemeal fashion) in MTAs. Our MTA terms analysis revealed that data is often included in the definition of material, so that general terms contained in MTAs may relate to data transferred with materials and also data arising from the use of materials.

Terms relating to confidential information (which might apply to data created from the use of samples) were often broad and lacked specificity,[298] and related to the duration of confidentiality obligations, and limitations on use of confidential information. There is some

[296] See above 2.3.6.

[297] Recall that eight institutions (of a total of 18 who employed formal processes for transferring data) indicated that they had developed specific DTAs.

[298] See above 4.6.5, *Confidential Information*.

ambiguity, however, as to whether all terms relating to confidential information would necessarily apply to all data that might require protection. Some terms referred to 'research or study data' while others defined confidential information differently.[299] In summary, it is not unequivocal that terms relating to confidential information would govern the transfer of data generated from use of a material. Given the importance of data to researchers, and the perpetual nature of data generated from the use of materials, we anticipate that we will begin to see increased consideration given to the treatment of data transfers in the future.

5.5.3 The Implications of Informality

As we have observed, data is frequently transferred without a formal agreement in place. Just as choses in action might be transferred under a bailment relationship, so too might other intangibles such as information. Particularly where information has some physical form (for example, if it is written in a document), it is capable of possession and hence, capable of being possessed.[300] In virtually every case where research data is transferred, it is likely to take some tangible form, so as to be capable of being viewed and used. Data is frequently transferred on physical storage devices, or stored and viewed on online storage platforms. This strengthens the argument that data is property, capable of possession and bailment, and of being subject to the attendant remedies accompanying such a relationship. This argument is further supported by overseas case law permitting an action in conversion for virtual data in the form of emails and other electronic records.[301] One difficulty with data is that there is often no absolute transfer; its non-rivalrous nature means that researchers are able to apply it in a research context simultaneously. Although not fatal, this does dampen the possibility that a bailment occurs upon its transfer.

Even where data has no tangible embodiment, there is an argument that it should be classified as property.[302] As noted earlier,[303] certain intellectual property rights (copyright and trademarks) have attained that status, as have other intangibles.[304] Hence, there may come a time when genomic research data transferred in an entirely intangible or digital form without any agreement in place, could also be argued to have

[299] Ibid.

[300] Palmer, above n 245, 1529 [30-002].

[301] See *Thyroff v Nationwide Mutual Insurance Co,* 8 NY 3d 284 (2007).

[302] Palmer, above n 245, 1547 [30-025].

[303] See above 5.3.2.

[304] Palmer, above n 245, 1534–8 [30-011]–[30-015].

been transferred under a bailment relationship. The relevance of this discussion relates to the extent of protection under other areas of law. Data of this nature is unlikely to qualify as a trade secret with the attendant remedies such a classification would afford.

5.6 THE FORM OF MTAS: WHAT DO MTAS LOOK LIKE? WHAT SHOULD MTAS LOOK LIKE?

5.6.1 Standardisation and its Prospects of Success

As we pointed out in Chapter 1,[305] standardisation is a much-mooted solution to the seemingly inevitable delays brought about by the use of MTAs. Much effort has been devoted to the development of template MTAs within the university setting in the US. Yet in Australia there has been no equivalent success. Simple template MTAs are certainly adequate in transactions involving low-risk, non-commercial transfers. In our view, the provision of a means for tracking provenance is (or should be) the primary mandate of MTAs.

Our interview evidence highlighted that there are many within the Australian research environment who view the possibility that MTAs might be standardised as remote. Certainly, the number of different MTAs in existence, along with evidence of institutional idiosyncrasies in MTA design and process, results in significant divergence in MTA structure, and the expenditure of a considerable amount of time on MTA negotiations. The reality is that standardisation might be achieved to some degree but it is unlikely to be universal. Nevertheless, there are some aspects of MTAs that lend themselves to standardisation, and should be considered.

In Appendix 2, we list and briefly review the AUTM MTA Guiding Principles referred to in Chapter 4, noting that they form the backbone of the UBMTA. We do so with caution, given that our findings on MTA practice in Australia reveal a low degree of familiarity and conformity with the UBMTA. We follow with some recommendations as to how particular terms in MTAs might be dealt with uniformly in the Australian research environment. Our recommendations depart from the AUTM Principles and the UBMTA in some key respects.[306] In other ways we align

[305] See above 1.4.2.

[306] In particular we note our decision to recommend the inclusion of provisions restricting field of use and to refine other principles to respond to problems brought about by high levels of risk aversion. We suggest that risk aversion is the impetus for

our recommendations with key AUTM Principles echoed in the UBMTA, particularly with regards to tracking provenance. Although we do not propose to present a 'standard MTA', we are of the view that there is sufficient commonality between agreements and institutional practices to advocate adherence to the broad notions outlined in Table 50.

many institutions to insist on bespoke agreements. Our recommendations attempt to balance these key concerns and moderate the principles set by AUTM.

1	Definitions	
a.	**Materials**	Ideally, agreements will incorporate a general definition that: • covers the broad type of materials contemplated (including, if relevant, the broad category of materials (eg biologics/chemical/human); and • includes additional 'states' of the materials and their products. Clarity is increased via the incorporation of a *specified* reference to the material being transferred, preferably in a schedule.
b.	**Progeny**	If defined, progeny should mean unmodified descendants.
c.	**Derivatives and modifications**	Products created from use of the materials should be defined as either unmodified derivatives or modifications.
d.	**Derivatives**	A general definition of derivatives should be avoided unless there are no obligations attached to products, or unless definitions of unmodified derivatives and modifications are also included. MTAs should contain a separate definition of unmodified derivatives unless both material and modifications are defined. Definitions of unmodified derivatives should not include any reference to modifications, but may refer to synthetic or otherwise artificially created replicas of the material, different forms, states or bi-products made from the material. Unmodified derivatives may be incorporated into the definitional scope of materials but derivatives more generally should not.
e.	**Modifications**	Modifications should be a key definitional term. Modification should be defined as a substance (or product) created by the recipient which contains, incorporates or is otherwise created using the material. This definition should exclude unmodified derivatives. Provision might be made for jointly created modifications.

2	Provenance, Ownership and Title	
a.	**Provenance**	The provenance of a material (for the whole material or part of it) should be adequately recorded. It is preferable that permission to use materials be provided by the originator, or alternatively that the supplier warrant they have permission to transfer the material. If the supplier is not permitted to share the material, the receiver should seek an MTA with the originator. Many large consortia agreements make provision for data tracking, which would encompass recording of provenance.
b.	**Ownership of materials**	Generally speaking, suppliers of materials should retain ownership of those materials. There is a good argument that custodianship language be adopted for human tissue samples.
c.	**Ownership of derivatives, modifications and progeny**	Ideally, in any MTA provision will be made for: • Unmodified derivatives to be owned by the supplier (or originator), and; • Modifications to be owned by the receiver, unless there is evidence of joint-creation, in which case ownership should reflect the contribution of each party through a co-ownership relationship. Provision may be made for the supplier to retain ownership over materials embodied in the modifications. Progeny should be owned by the supplier or originator (unless that progeny falls within the definition of a modification).
d.	**Data**	Data ownership should be determined by level of contribution. Research data (data created during research conducted under an MTA) should be owned by the receiver unless there is evidence of joint creation, in which case the MTA should reflect the parties' contribution through co-ownership. The supplier may have the right to confidential information in information or data transferred to the receiver with the material. Consideration should be given to a term requiring the receiver to license to the supplier the rights (non-exclusive, royalty free) to use any know-how, data, results or invention for research or teaching.

3	Research Use and Publication	
a.	**Field of use**	MTAs should include a term specifying field of use. This term should be broad enough to enable changes to the particular project within the broad scope of the research, but narrow enough to accurately define the area of research. The field of use should not be so narrow as to unduly impede research.
b.	**Publication**	Provisions providing broad, unfettered power to delay or prevent publications should not be included in MTAs. Ideally, receivers should notify suppliers of their intention to publish research resulting from use of a material**.** Should suppliers elect to review publications, time frames for review should be reasonable in all the circumstances. Terms should take into account the fact that permission to publish should not be withheld unreasonably.
c.	**Attribution and authorship**	Authorship guidelines should stipulate the authorship of future publications, and that the supply of a material alone is an insufficient basis for authorship.
d.	**Ethics and consent**	It is prudent to include reference to relevant laws, guidelines and codes where dealing with human tissue (or other sensitive materials). Any additional encumbrances or protections necessary to ensure use is consistent with donor consent must be included in an MTA. We suggest that any particular, additional, or more than routine ethical conditions might be tracked in a schedule.
e.	**Nonhuman/ clinical use**	Provision should ordinarily be made that research conducted under MTAs excludes testing and/or treatment in humans**.** Clinical uses of materials require specific clauses or agreements, which should include a requirement for supplier consent.
f.	**Animals**	We consider that most implications from using animals in research should be adequately dealt with via provisions requiring compliance with ethics obligations.
g.	**On-sharing**	Generally speaking, agreements should provide for on-sharing where suppliers are content to agree to on-sharing with consent. Alternatively, a request to transfer on a material should trigger the operation of a provision for the negotiation of a new agreement, in order to encourage broad use of existing materials. It is also best practice for recipients to be allowed to share modifications without limitation by the supplier if limitations are imposed on the basis that the modification incorporates the material.

4	Intellectual Property, Commercialisation and Confidential Information	
a.	**IP ownership**	**Background IP** Providers should inform receivers of any IP they have in the material, and provide a licence to use the material subject to the MTA. Specific licences can be included in the MTA. Suppliers should advise receivers of IP over the materials held by other parties, of which they are or should be aware. **Future IP** Broad terms claiming rights to future IP developed through use of a material should not be included in MTAs. There are very few circumstances where suppliers should claim any rights to IP over modifications. In some instances, it might be appropriate for supplier rights to IP over unmodified derivatives to be built into an MTA. Receivers should have the right to claim IP over modifications (although exploitation may be subject to commercialisation decisions).
b.	**Indemnification for IP infringement**	Receivers should not be unconditionally required to indemnify suppliers for IP infringement. It is best practice for receivers to be liable for their own actions in infringing IP through use of the material.
c.	**Future commercialisation**	Rights to commercialise should be subject to future agreement, proportionate to contribution. Commercialisation decisions should not restrict sharing for academic (research and teaching) purposes.
d.	**Confidential information**	Confidential information should not include data created under the MTA (unless it is sensitive in nature, eg personal identifiable information). Research data should generally be published and accessible. Protection of confidential information must not be used as a basis to prevent publication of research.
e.	**Reporting requirements**	It makes sense to require the receiver to report to the supplier upon completion of a project, although we note that enforcement of such a provision is difficult. Reporting requirements during the life of a project should be proportionate in all cases.

5	**Boilerplate Terms**	
a.	**Costs and fees**	Costs associated with material transfer should generally be borne by the receiver.
b.	**Obligations on completion**	It is not best practice to require destruction or return of modifications. Ideally, parties should agree on destruction or return of a material on completion, taking into account ongoing research requirements and value in the material. If return is not possible or it is unclear if the supplier will accept return of the material, it is appropriate for the agreement to provide an option for the receiver to remain the physical custodian of the material. In this case it would not be prudent for them to use that material for further research without an additional agreement. In this case, the receiver should be able to on-share the materials, provided the restrictions are consistent with the original contract and provenance is tracked.
c.	**Governing law**	For research MTAs where the aim is to expedite research, it is not best practice to include a term mandating state or country-specific governing law unless both parties are located in the same jurisdiction. It is appropriate to either include a term where the governing law is the jurisdiction of the party not bringing proceedings under the MTA, or to remain silent on jurisdiction and provide that jurisdiction will be determined in the event of a disagreement.
d.	**Dispute resolution**	Dispute resolution clauses are a common standard term and should be included in an MTA.
e.	**Liability**	It is best practice for each party to be liable for their own actions. Limiting the field of use should assist to define the scope of potential legal action.
f.	**Licencing back**	There is a good argument that the supplier should be entitled to have a research-only license to use modifications created by the receiver. The terms of any agreement in respect of licensing back materials and associated data should be the same or as similar as possible to the agreement between the parties in respect of the original material.
g.	**Termination**	It is not best practice to facilitate unilateral termination without basis. It is appropriate that any serious and unremedied breaches of terms relating to ethics obligations (eg dealings with human tissue inconsistent with consent) should be grounds for termination.

Table 50: Best practice recommendations for Australian MTAs

We recognise that, despite the fact that there is significant commonality between terms contained in the MTAs of various institutions, realistically it may not be feasible to reduce the number of standard agreements in circulation. We encourage the adoption of the recommendations set out above in drafting and negotiating MTAs, but are cognisant of the fact that standardisation may be unattainable. We reiterate that a better approach is to consider ways in which the processes surrounding MTAs might be reshaped in order to expedite transfers, as discussed above in section 5.2.2. We reiterate that this may mean educating both TTO officers and scientists as to the function of MTAs, and taking steps to alter processes around MTA negotiations.

5.7 CONCLUSION

The mixed methodology of this study allowed detailed exploration of the intricacies of materials transfer in Australian publicly funded research organisations. Chapters 2, 3 and 4 presented evidence that made it clear that a number of issues that have been identified in earlier international and Australian studies examining MTA practice remain prevalent in the Australian research environment. However, it also unearthed issues that have not previously been articulated. This chapter has further elaborated on these issues and their legal ramifications. Based on this analysis, and the findings presented in previous chapters, we conclude that:

- although MTAs are viewed by many of those individuals involved in the research chain as documents to record provenance and facilitate collaboration, a significant number continue to view them as being vital to indemnify, and to secure future indemnification and intellectual property rights;
- this trend to use MTAs as devices to protect against liability or solidify rights to intellectual property can be largely attributed to risk aversion. It is this central issue of risk aversion that must be addressed in order to reform inefficient and unwieldy MTA practices;
- while the number of parties engaging in formal MTA exchanges (and the number of MTAs in circulation) has expanded dramatically, a residual inclination to transfer materials informally is evident, particularly amongst parties with a collaborative history. Although informal transfers generally present few problems for researchers, the analysis in this chapter highlights a degree of uncertainty as to their legal status;

- the appetite for adoption of a standardised MTA is lacking in Australian research organisations. While a number of parties indicated support for an Australian 'standard' MTA, a considerable number of other parties were less enthusiastic. Risk aversion militates against the universal adoption of a uniform standard, but as we have pointed out, there is significant scope for alignment in key MTA terms; and
- there is a marked tendency to transfer data (unaccompanied by materials) informally. There are a number of reasons why this might be the case, but the ethical and legal ramifications of informal data transfer are likely to mean that data transfer becomes typified by increasing levels of formalisation.

These conclusions are not a comprehensive summary of the study findings. Our study was ambitious in its scope in that it sought to triangulate evidence to paint a broad picture of MTA use in Australia. For us, the critical message is simple: MTAs are an important tool to track provenance and facilitate collaboration, and in a vast majority of cases they need do little more than this. From this perspective, formalisation is a positive development in the materials transfer environment, and increased formalisation of data transfer in line with this fundamental tenet should be encouraged. If adhered to, standardisation (in relation to transfer of materials and data) should be simple to achieve. In pursuit of 'alignment' of MTA terms, the real challenge lies in reducing risk aversion and encouraging the streamlining of institutional processes. We hope that this Occasional Paper is a useful step in raising awareness that in materials transfer, efficiency and simplicity are key.

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APPENDIX 1

SCIENTIST SURVEY INSTRUMENT

Centre for Law and Genetics, University of Tasmania

This survey is being undertaken by Professor Dianne Nicol, Professor Don Chalmers and Dr Jane Nielsen from the University of Tasmania. It is a component of a project funded by the Australian Research Council (DP140100301). In part, this survey is an adaptation of a survey of Monash University researchers by Professor Ann Monotti (with her permission).

The aim of this survey is to identify and assess the strengths and weaknesses of Material Transfer Agreements (MTAs) in facilitating exchange of biological materials between researchers. This survey is designed to create an empirical dataset regarding this issue. It will be used in law reform debates, government inquiries and in academic publications.

Invitations to participate in the survey are being sent to Australian biomedical researchers who have been identified through Scopus searches.The survey should take approximately 10-20 minutes to complete, depending on your responses to various questions. You can exit the survey at any time. The survey will remain open until Friday 16th September.

All data will be treated as strictly confidential. Electronic identifiers will only be used for administrative purposes (e.g. sending reminders). After completion of the survey all electronic identifiers will be destroyed and anonymity safeguarded. Data will be aggregated and no individual results will be reported when results are analysed and reported. Submission of this survey implies your consent to the information you provide being used anonymously in the research project.

We are most grateful for your participation in this research. If you have any questions regarding this survey please contact Dr Jane Nielsen, Senior Research Fellow at Jane.Nielsen@utas.edu.au or on 03 6226 2322.

This project has received ethics approval from the Social Sciences Human Research Ethics Committee (Tasmania) (Approval No. H0013753). If you have any concerns of an ethical nature or complaints about the manner in which the project is conducted, you may contact the Executive Officer of the Human Research Ethics Committee (Tasmania) on 03 6226 7479, or human.ethics@utas.edu.au

* 1. Do you wish to proceed?

- ◯ Yes
- ◯ No

Preliminary Questions

This section asks some preliminary questions. Please note that throughout the survey questions that require an answer are clearly marked with an asterisk (*). Some questions do not require an answer. Please read the instructions for each question carefully. Depending on your answers the survey may skip some questions.

* 2. Do you use any of the following research materials/data in your research? If YES, please indicate ALL materials you use.

- ☐ I don't use research materials/data
- ☐ antibodies
- ☐ cell lines
- ☐ vectors
- ☐ genes
- ☐ genetically modified animals
- ☐ plasmids
- ☐ fluids - animal
- ☐ fluids - human
- ☐ tissue - animal
- ☐ tissue - human
- ☐ genomic data

other materials or data (please specify)

Preliminary Questions

* 3. Have you received any of the following materials/data from other researchers and/or from third party providers outside your institution? If YES, please indicate which materials you have received

- [ ] no, I haven't received any
- [ ] antibodies
- [ ] cell lines
- [ ] vectors
- [ ] genes
- [ ] genetically modified animals
- [ ] plasmids
- [ ] fluids - animal
- [ ] fluids - human
- [ ] tissue - animal
- [ ] tissue - human
- [ ] genomic data

other materials or data (please specify)

* 4. Have you supplied any of the following research materials/data to other researchers outside your institution? if YES, please indicate which materials you have supplied.

- [ ] no, I haven't supplied any
- [ ] antibodies
- [ ] cell lines
- [ ] vectors
- [ ] genes
- [ ] genetically modifed animals
- [ ] plasmids
- [ ] fluids - animal
- [ ] fluids - human
- [ ] tissue - animal
- [ ] tissue - human
- [ ] genomic data

other materials and data (please specify)

* 5. what is your field of research?

* 6. What is your research environment?

- [ ] CSIRO
- [ ] CRC
- [ ] Laboratory - University
- [ ] Laboratory - Research Institute
- [ ] Laboratory - Hospital Based
- [ ] Clinical Rooms
- [ ] other (please specify)

* 7. What type of appointment do you hold?

Material Transfers: Receiving Materials

In this part of the survey we are interested in your experiences and views on receipt of materials for your research. In the second section you will be asked similar question with regard to supply of materials, as many people have different experiences in respect of each.

Materials include antibodies, cell lines, vectors, genes, genetically modified animals, plasmids, fluids (human and animal), tissue (human and animal) and other research materials.

Material Transfer Agreement (MTA) refers to a written agreement under which the owner of materials supplies that material to another person.

Informal exchange refers to exchange without the use of an MTA.

* 8. Have you ever received *materials* for research purposes?

Material Transfers: Receiving Materials

* 9. When you receive material, is it by way of: (please select all that apply)

	always	frequently	sometimes	rarely	never
an MTA that is specific to that material	○	○	○	○	○
an MTA that is part of a formal research collaboration	○	○	○	○	○
an MTA that is part of a formal large scale research consortium	○	○	○	○	○
an MTA through an intermediary distributor (eg Jackson Laboratories or Addgene)	○	○	○	○	○
an informal exchange (exchange without an MTA)	○	○	○	○	○
I don't know where the materials come from	○	○	○	○	○

* 10. Where a MTA for receipt of materials has to be negotiated, who do you work with at your institution (indicate all that apply)?

- ☐ I haven't had to negotiate an MTA
- ☐ the technology transfer office
- ☐ the legal office
- ☐ the research office
- ☐ a lab manager
- ☐ I do it myself
- ☐ I don't know

other (please specify)

11. What do you see as the main purpose(s) of an MTA when you receive materials (indicate all that apply)?

	extremely important	somewhat important	neutral	not very important	not important at all
it's standard procedure to use an MTA	○	○	○	○	○
to clarify ownership of material	○	○	○	○	○
to clarify terms of exchange	○	○	○	○	○
to ensure you and/or the supplier are legally protected	○	○	○	○	○
for permission to use existing IP	○	○	○	○	○
to clarify permissible uses of material	○	○	○	○	○
to clarify publication arrangements (permission to publish, authorship, attribution)	○	○	○	○	○
to clarify rights to IP generated through use of the material	○	○	○	○	○
for human material, to ensure compliance with ethical and legal obligations	○	○	○	○	○

other (please specify)

12. Indicate the extent to which you find MTAs beneficial when receiving materials.

very beneficial	somewhat beneficial	neutral	somewhat useless	useless	n/a
○	○	○	○	○	○

Please explain

* 13. Think about materials you have received by way of MTA over the past 12 months. Has your research been adversely affected by an MTA during this period?

always	frequently	sometimes	rarely	never
○	○	○	○	○

Material Transfers: Receiving Materials

14. What was the nature of that adverse effect?

- [ ] delay in research
- [ ] cessation of research
- [ ] breakdown in collaborative relationship
- [ ] restricted ability to publish my research results
- [ ] restricted field of research use
- [ ] requirement to transfer IP to/share IP with the supplier of the materials
- [ ] requirement to report my results to the supplier of the materials
- [ ] restricted ability to clinically develop

other (please specify)

15. When you experienced an adverse effect, who was the supplier of those materials?

- [ ] Australian private organisation
- [ ] International private organisation
- [ ] an intermediary distributor (eg Jackson Laboratories or Addgene)
- [ ] Australian university
- [ ] International university
- [ ] Australian research institute/hospital
- [ ] International research institute/hospital

other (please specify)

Material Transfers: Receiving Materials

* 16. If you *received* materials by way of *informal exchange*, what was the reason for this?

- [ ] long-term research collaboration
- [ ] standard practice
- [ ] formalised MTAs are too difficult
- [ ] never receive materials informally
- [ ] don't know
- [ ] other (please specify)

Material Transfers: Receiving Materials

* 17. Has your research been adversely affected by an informal receipt of materials?

always	often	sometimes	rarely	never
○	○	○	○	○

Material Transfers: Receiving Materials

18. Below are some implications of engaging in informal transfers for the receipt of materials. Please indicate which (if any) of these implications you have encountered.

- ☐ uncertain provenance of material
- ☐ position in relation to liability uncertain
- ☐ position in relation to IP uncertain
- ☐ position in relation to publication uncertain

other (please specify)

Material Transfers: Supply of Materials

In this part of the survey we are interested in your experiences and views on supply of *materials* to other researchers.

* 19. Have you *supplied* materials to other researchers in Australia or overseas?

Material Transfers: Receiving Transfers

* 20. Do you (personally) negotiate transfers of materials where you are supplying them?

always	often	sometimes	rarely	never
○	○	○	○	○

Material Transfers: Receiving Materials

* 21. Where an MTA for the supply of materials needs to be negotiated, who do you usually work with at your institution (please indication all that apply)?

- [ ] I haven't had to negotiate an MTA
- [ ] the technology transfer office
- [ ] the legal office
- [ ] the research office
- [ ] lab manager
- [ ] I do it myself
- [ ] I don't know

Material Transfers: Receiving Materials

* 22. When supplying material, is it by way of

	always	often	neutral	sometimes	never
a formal MTA that is specific to that material	○	○	○	○	○
an MTA that is part of a formal research collaboration	○	○	○	○	○
an MTA that is part of a large-scale research consortium	○	○	○	○	○
an MTA through an intermediary distributor (eg Jackson Laboratories or Addgene)	○	○	○	○	○
an informal exchange (without a written MTA)	○	○	○	○	○

other (please specify)

23. If you have supplied material subject to an MTA, what do you see as the main purpose(s) of an MTA (please select all that apply)?

	extremely important	somewhat important	neutral	not very important	not important at all
clarify ownership	○	○	○	○	○
clarify terms of exchange	○	○	○	○	○
to ensure you and/or the receiver are legally protected	○	○	○	○	○
permission to use existing IP	○	○	○	○	○
clarify permissible uses of material	○	○	○	○	○
specify requirements for return or destruction of material	○	○	○	○	○
clarify publication arrangements (permission to publish, authorship, attribution)	○	○	○	○	○
clarify rights to IP generated from use of the material	○	○	○	○	○
for human material, to ensure compliance with ethical and legal obligations	○	○	○	○	○

other (please specify)

Material Transfers: Supplying Materials

* 24. If you have *supplied material informally*, what is the reason for this?

- ☐ long-term research collaboration
- ☐ standard practice
- ☐ formalised exchanges too difficult
- ☐ never transfer informally
- ☐ don't know

other (please specify)

25. Below is a list of possible implications of engaging in informal transfers for the supply of materials. Please indicate on the scale provided the extent to which you believe each implication is a positive or negative aspect of conducting an informal transfer.

	very positive	somewhat positive	neutral	somewhat negative	very negative
lack of clarity in relation to right to publish	○	○	○	○	○
lack of clarity in relation to IP rights	○	○	○	○	○
lack of clarity in relation to use of the material	○	○	○	○	○
no restrictions on the use of material	○	○	○	○	○
legal risks arising from use of the material	○	○	○	○	○
Other implications (please specify these implications in the space provided below)	○	○	○	○	○

other

* 26. Overall, do you consider MTAs to be beneficial when supplying materials? Indicate the extent to which you find them beneficial.

	very beneficial	somewhat beneficial	neutral	rarely beneficial	never beneficial	n/a
Are MTAs beneficial when supplying Materials?	○	○	○	○	○	○

please explain your answer to this question

Transfers of Data

In this part of the survey we are interested in your experiences and views on receipt and supply of *data* (independent of the transfer of research materials)

Data includes genomic and other data which may be transferred independent of the transfer of research materials

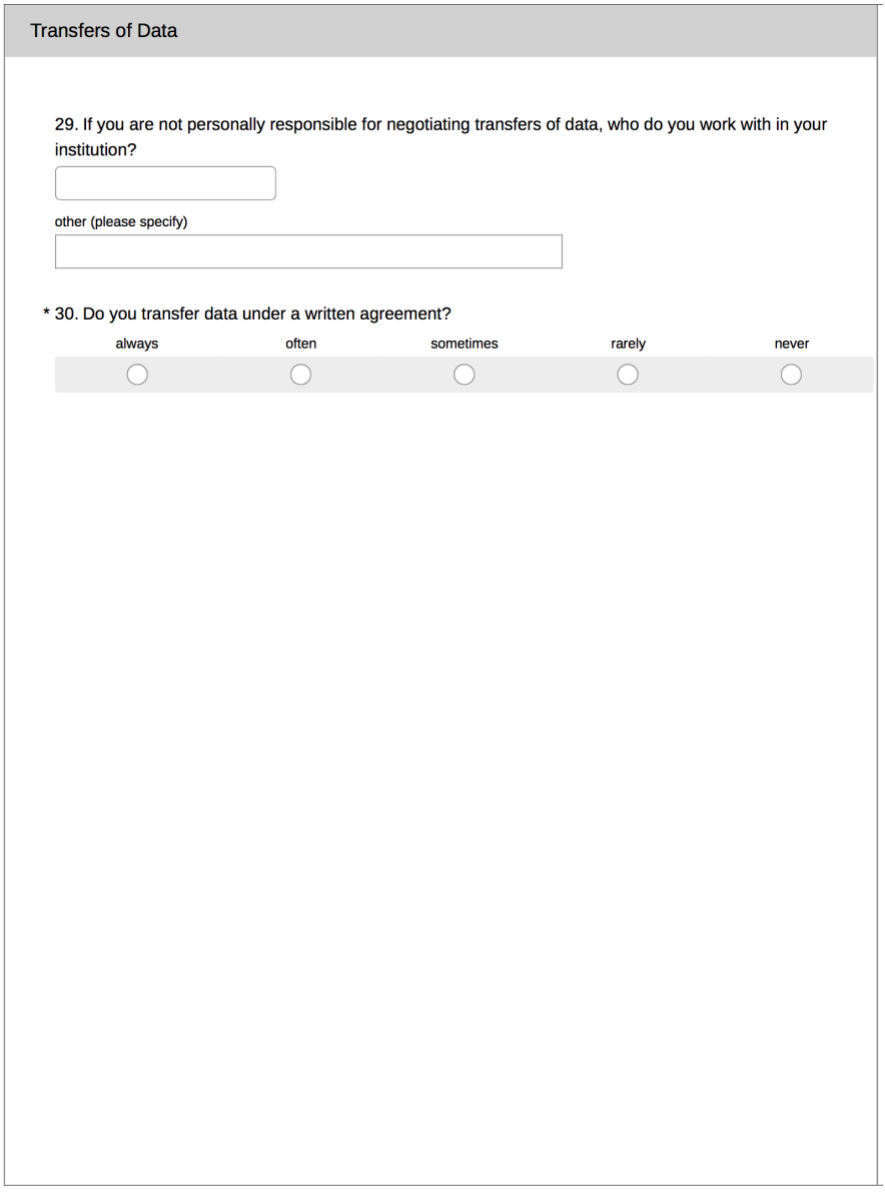
* 27. Do you *share/transfer data*, either in conjunction with the exchange of materials, or independently?

- ☐ yes, I provide my data to other researchers
- ☐ yes, I receive data from other researchers
- ☐ no, I do not share data with other researchers

Transfers of Data

* 28. Are you (personally) responsible for negotiating transfers of data?

always	often	sometimes	rarely	never
○	○	○	○	○



Transfers of Data

29. If you are not personally responsible for negotiating transfers of data, who do you work with in your institution?

other (please specify)

* 30. Do you transfer data under a written agreement?

always	often	sometimes	rarely	never
○	○	○	○	○

Transfers of Data

31. If you do use a written agreement is it the same agreement you would use for transfer of materials (ie an MTA)?

Transfers of Data

32. Why do you *transfer data informally*?

- [ ] I always have
- [ ] no established procedure to use a formal agreement
- [ ] collaboration agreement
- [ ] I trust the other party
- [ ] I'm not using the data myself
- [ ] there is no value in data
- [ ] the institution I work for encourages 'openness'

other/explain

33. Do you encounter any difficulties when you transfer data informally?

always	often	sometimes	rarely	never
○	○	○	○	○

explain (please specify)

CRISPR Technology

This part of the survey asks specific questions about use of clustered regularly interspaced short palindromic repeats (CRISPR) gene editing technology. Please answer this part even if your answers to previous questions related to your use of CRISPR technology.

* 34. Do you use CRISPR technology in your research?

- ☐ yes
- ☐ no

CRISPR Technology

35. Did you acquire CRISPR technology by way of:

- [ ] Addgene
- [ ] other intermediary distributor
- [ ] commercial provider
- [ ] we created our own
- [ ] informal transfer
- [ ] I don't know

other (please specify)

36. Do you intend using CRISPR techniques to produce a clinical outcome for use in humans?

- ○ yes, and I have permission to use CRISPR in a clinical setting
- ○ yes, but I do not yet have permission to use CRISPR in a clinical setting
- ○ yes, but I have not thought about whether I need permission
- ○ no, I don't intend using CRISPR in a clinical setting
- ○ no, I know I'm not allowed by my agreement
- ○ I don't know

Please add any further comments you may have

37. Do you have any other comments?

Thank you for participating in this survey. Submission of this survey implies your consent to the information you provide being used anonymously in the research project. If you have any questions relating to the survey please contact Jane Nielsen, Senior Research Fellow at Jane.Nielsen@utas.edu.au.

If you would be happy to be contacted to participate in an interview by phone we would be pleased to hear from you. Please provide your email address. This address will not be associated with your survey results. Alternatively, you may email us directly at Jane.Nielsen@utas.edu.au

APPENDIX 2

ANALYSIS OF THE APPLICABILITY OF AUTM PRINCIPLES IN AUSTRALIA

AUTM Principle	Explanation	Our Alignment with Principle
Provider should maintain ownership of Materials.	Includes any Material that has been incorporated into substances generated by Recipient. Provider should not seek ownership of substances generated by Recipient unless such substances are progeny or unmodified derivatives (unmodified subunits or expression products) of the originally provided material. Use of undefined terms to establish ownership of products of Recipient's research, such as "derivatives," should be avoided.	We agree with this principle and consider it should be included in Australian MTA templates.
Recipient should not transfer Materials to third parties.	Recipient should not be allowed to transfer the Material beyond researchers working under the direction of the Recipient PI. However, Recipient should have the right to make new substances generated by Recipient containing the Material available to other investigators in non-profit research institutions for research purposes only, under terms no more restrictive than those found in the UBMTA.	We agree generally with the reasons for this principle but are of the view it should be qualified. In some cases, researchers may wish to on-transfer materials in a manner which is unlikely to be detrimental.
Provider should make Material available to other non-profit institutions.	If Material is a unique resource Provider should commit to making Material available to other investigators for basic research under terms no more restrictive than the UBMTA to satisfy a need to reproduce published data and build upon published results. This is only to the degree that there are	We agree with this principle and consider it should be included in Australian MTA templates.

	sufficient quantities available, and that the Material is not otherwise available commercially or easily manufactured by the requestor.	
The Provider should not place restrictions on the funding sources the Recipient may use.	If the Recipient is using the Material for its non-profit research purposes, there should be no restrictions on the funding sources used by the Recipient. In particular, the use of funds from industry should be permitted, as long as the Material is not used for commercial purposes and the Material is not transferred to the industry sponsor. If the industry sponsor wishes to use the Material in its facilities, it should discuss terms with the Provider	We agree with this principle and consider it should be included in Australian MTA templates.
Other than research use rights, the Provider should have no rights to inventions made by the Recipient in the use of the Material.	Consistent with the NIH Research Tools Guidelines and the Nine Points to Consider, the Provider (and all other non-profit research institutions) should have the right to use for its own internal research and education purposes inventions made by the Recipient in the use of the Material. While the Provider can appropriately restrict the Recipient's further transfer of the original Material provided, the Provider should place no restrictions on what the Recipient does with inventions created solely by Recipient scientists. However, Recipient should notify Provider if Recipient files a patent application claiming a method of manufacture of Material, or claiming a substance that contains the Material.	We agree with this principle, except in cases where parties have conducted collaborative work.
Recipient does not receive any commercial	Recipient rights should not include the right to sell, lease, or license the Material to third	We support this principle. We suggest, however, that

rights from the Provider.	parties unless otherwise authorized by the Provider. The Provider may prohibit use of the Material by the Recipient for commercially-oriented activities such as fee-for-service work.	provision be made for commercial rights to be negotiated when commercialisation opportunities or potential arise.
Provider should not require a Statement of Work from the Recipient.	For published materials, consistent with the freedom of academic research, the Provider should not require the Recipient to provide a detailed Statement of Work.	We suggest that current practice supports a change to allow statement of work or a field of use provision. We posit that this will assist with some liability concerns and actually promote sharing.
The Provider should not require pre-review or copies of publications.	The Provider should not require a copy of any publication involving use of the Material, since such publication will be publicly available already, nor should the Provider require a pre-review period.	We agree with this principle but suggest that its implementation is problematic. We suggest that notification may be allowed, and a small amount of delay tolerated for specified reasons but veto-like provisions impermissible.
The Providing scientist should not require authorship.	Provider should not require Provider scientist to be listed as an author in Recipient publications, except as scientifically appropriate, but may require that the Recipient acknowledge the source of the Material in any scientific publication. Similarly, the Provider should not require a collaboration as a condition of providing the Material.	We agree with this principle and consider it should be included in Australian MTA templates.
There should be no requirement for Recipient to treat research results or the	Recipient shall not be restricted in any way from disclosing the results of its research. In addition, because the Material has been published, there should be no restriction on	While we support this principle, it appears contrary to our evidence. Yet we have limited evidence to suggest this is a

Material as confidential.	disclosing the composition or structure of Material. Moreover, maintaining confidentiality of information received from Provider is generally inconsistent with these open transfers of published materials for Recipient's research that is intended to be published. However, if Provider chooses to provide unpublished information, it may ask that such information be held in confidence, pursuant to a standard confidentiality provision in which the information is transferred in writing, marked as such, and with the customary exceptions.	problem. We suggest a practical way to support this principle is to include a term requiring notification but not pre-review of publications.
Each party should accept liability for its own actions.	To the extent it is legally able to do so, Recipient should accept liability for Recipient's use, and Provider should accept liability for losses due to Provider's gross negligence or wilful misconduct. No indemnification of Provider by Recipient should be required.	While we support this principle, we suggest that this will be the most difficult principle to implement as Australian intuitions are highly risk adverse.
Provider may specify disposal of Material on termination, but Recipient should be permitted to continue research use of new substances.	A termination date should be specified. Upon termination, Material should be returned or destroyed, at Provider's direction. Destruction of Recipient's new substances containing Material should not be required, but Recipient should be allowed to transfer such new substances to other investigators for research purposes only.	We agree with this. We also suggest that it is best practice to facilitate ongoing custodianship of the material for research purposes – although this does not extend to use without permission.
Provider should include export control language only if the Material is known by the	If the Provider is aware of any export control restrictions associated with the Material, it should provide that information to the Recipient. The parties should assist each other in	We make no recommendations in this respect.

Provider to be subject to export control restrictions.	complying with export control regulations.	
Institutions, rather than individual investigators, should assume responsibility for insuring that Materials are transferred under terms consistent with these principles.		We support this principle and also suggest that more effort should be placed on informing scientists of their obligations under their agreements to promote safe and fair use, particularly contemplating additional requirements of human tissue.