

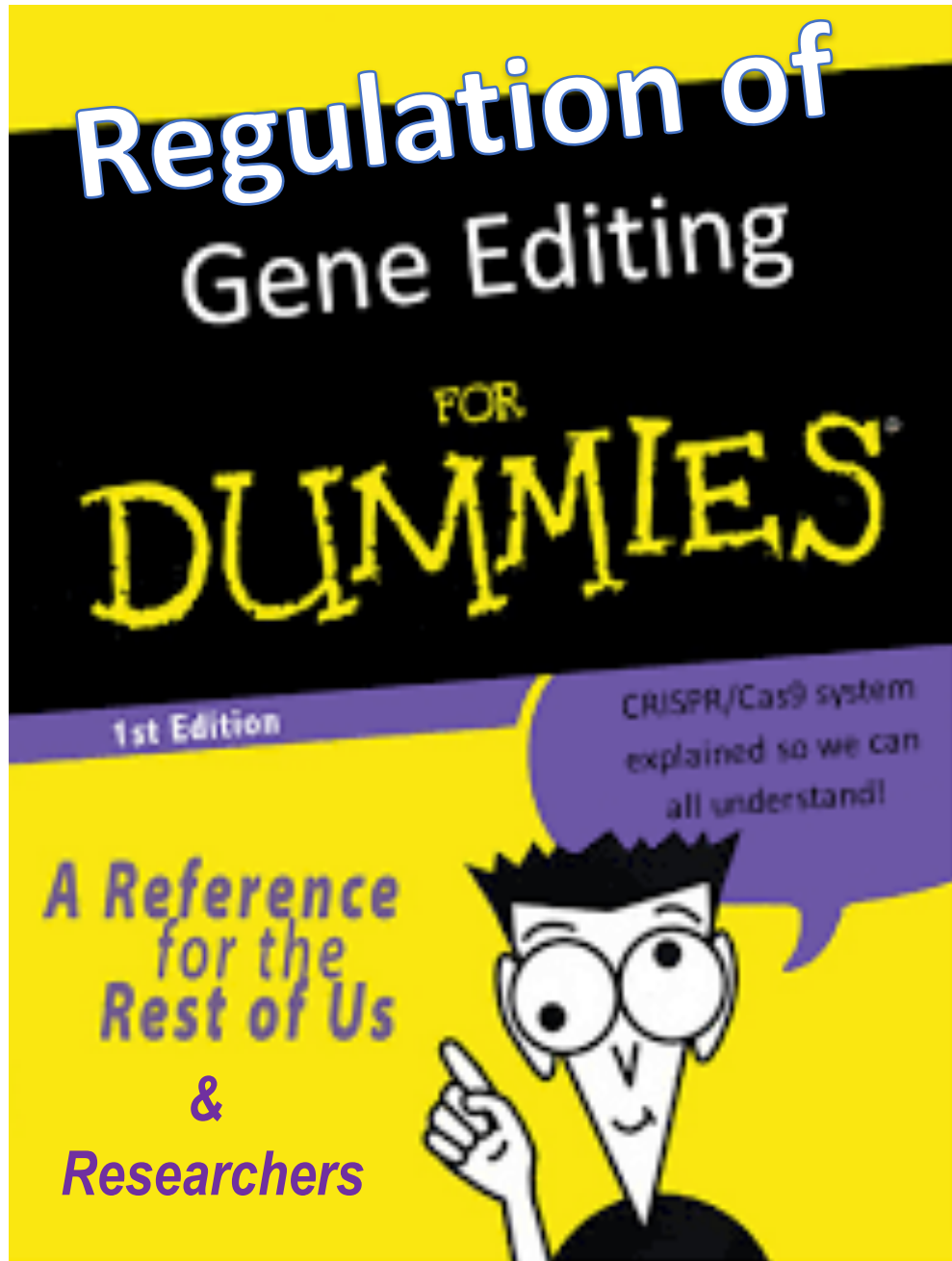
What to do about CRISPR? Views from the bench.

Tania Bubela

Professor



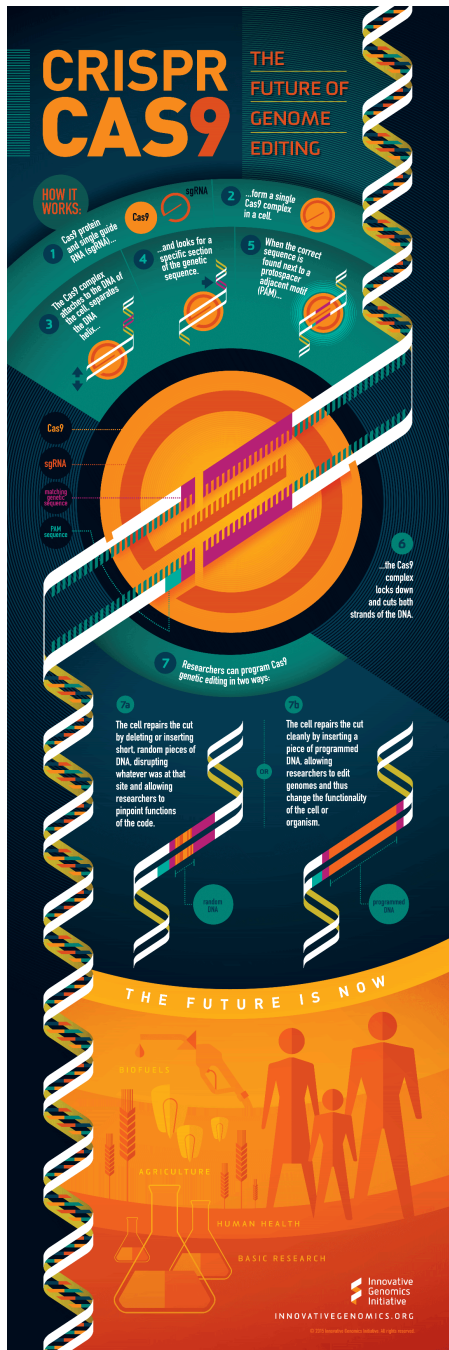
UNIVERSITY OF ALBERTA
SCHOOL OF PUBLIC HEALTH



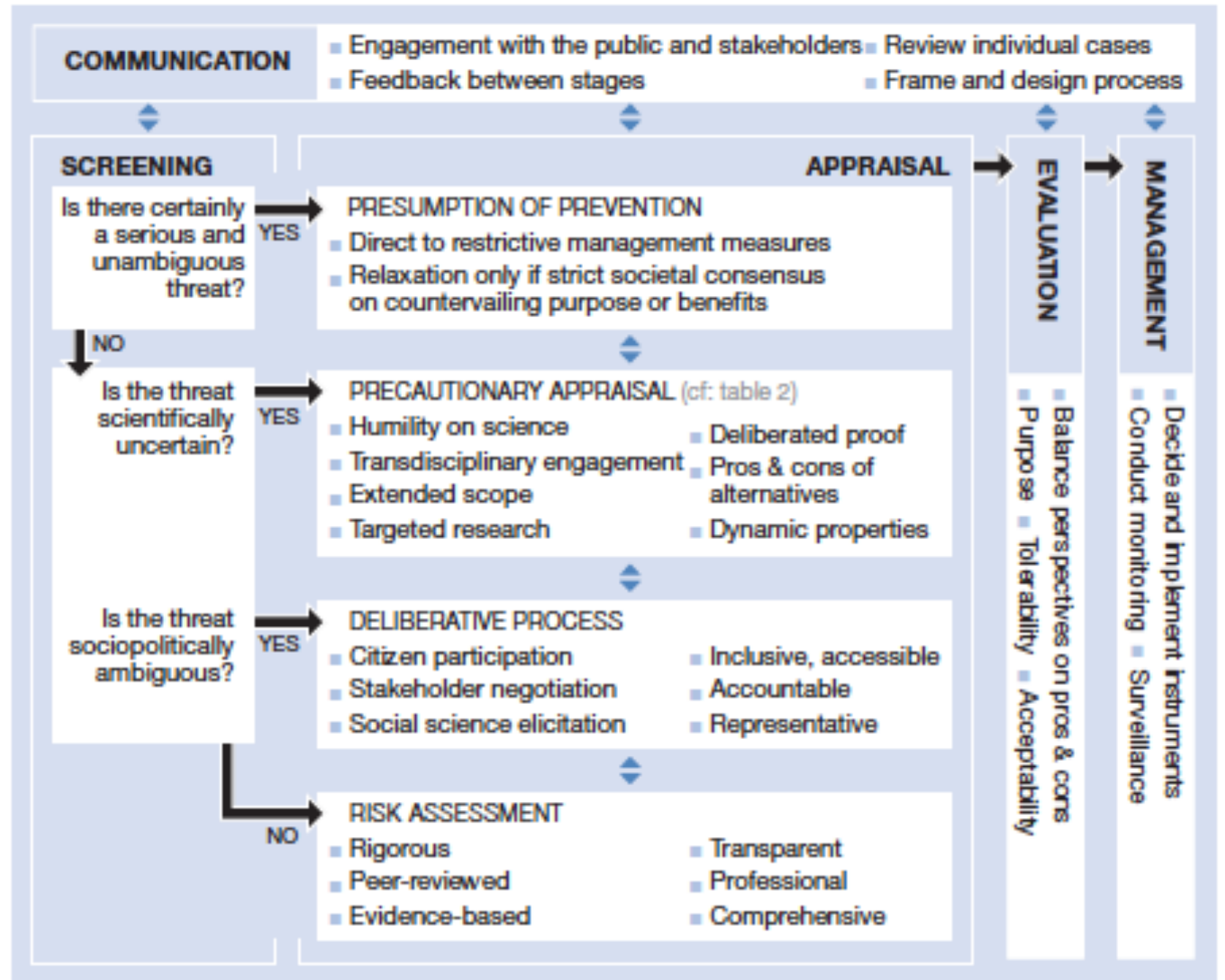
INTRODUCTION

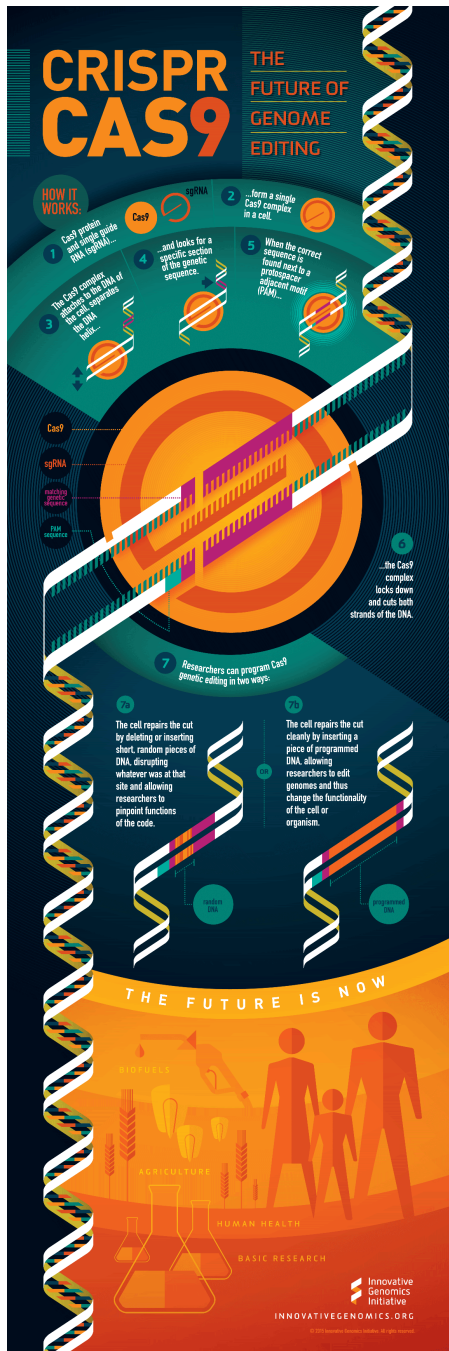
- Perspectives on regulating dual-use biotechnologies and associated R&D – a lesson in proportionality
- Lessons in developing proportionate regulatory responses:
 - Pre-clinical research
 - Clinical research
 - Germ-line editing
- Conclusions



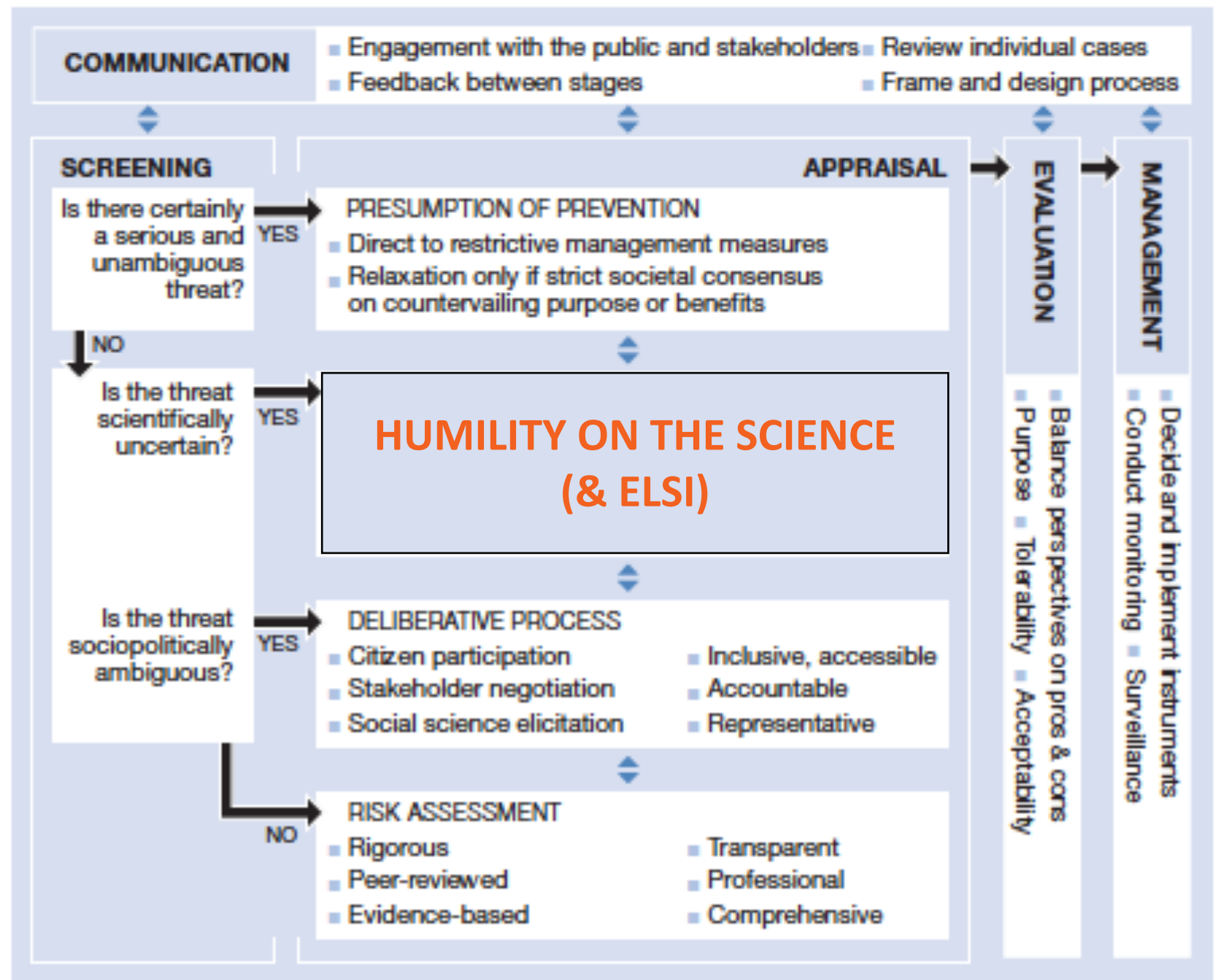


RISK ASSESSMENT & PRECAUTION FRAMEWORK

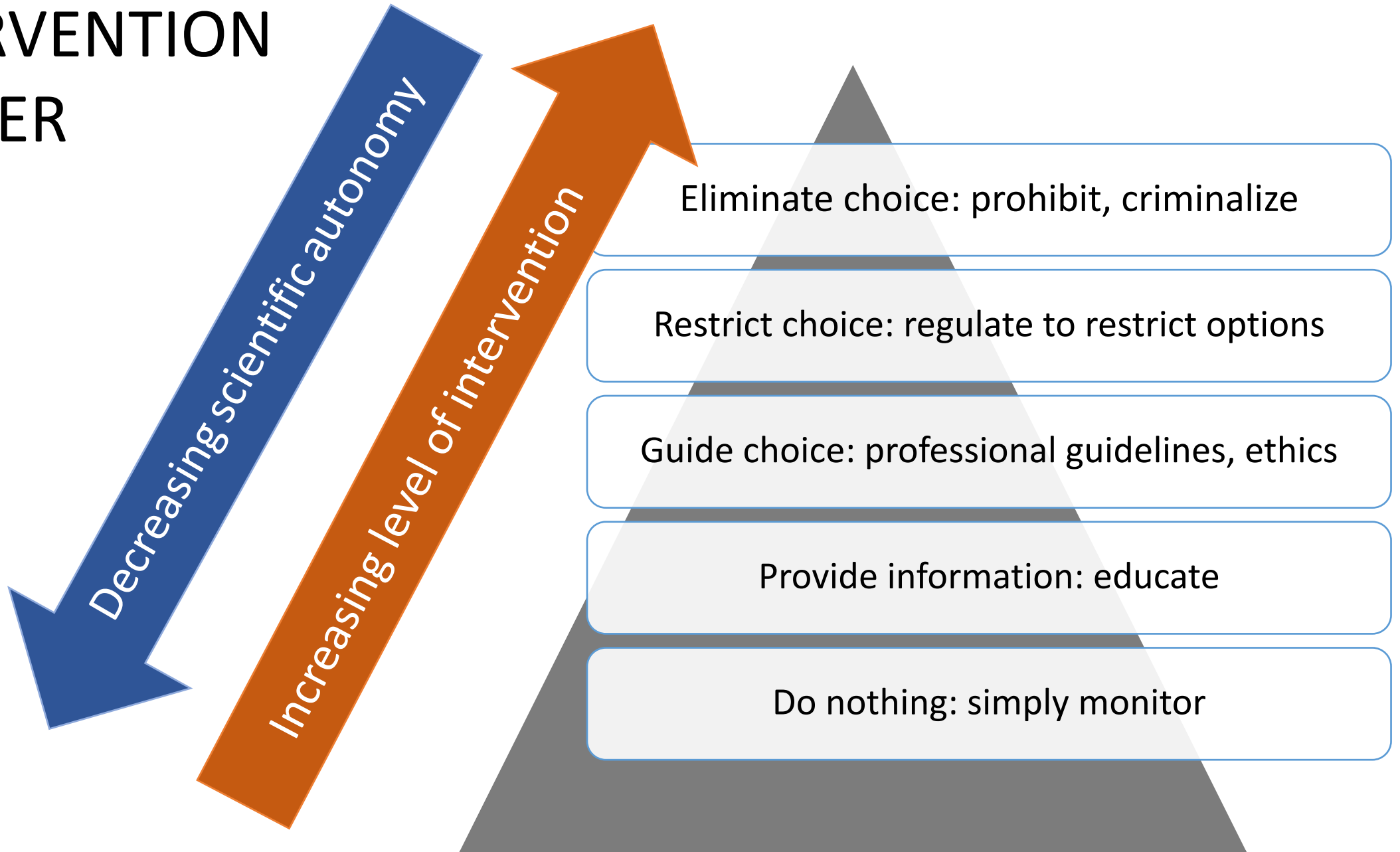




RISK ASSESSMENT & PRECAUTION FRAMEWORK



INTERVENTION LADDER





SELF-REGULATION

- “Summary Statement of the Asilomar Conference on Recombinant DNA Molecules”. *Proc. Natl. Acad. Sci.* Vol. 72, No. 6, pp. 1981-1984, (June 1975): 1981.
- Paul Berg and Maxine F. Singer. “The recombinant DNA controversy: Twenty years later”. *Proc. Natl. Acad. Sci.* Vol 92, pp. 9011-9013, (Sept. 1995): 9011.



PERSPECTIVES

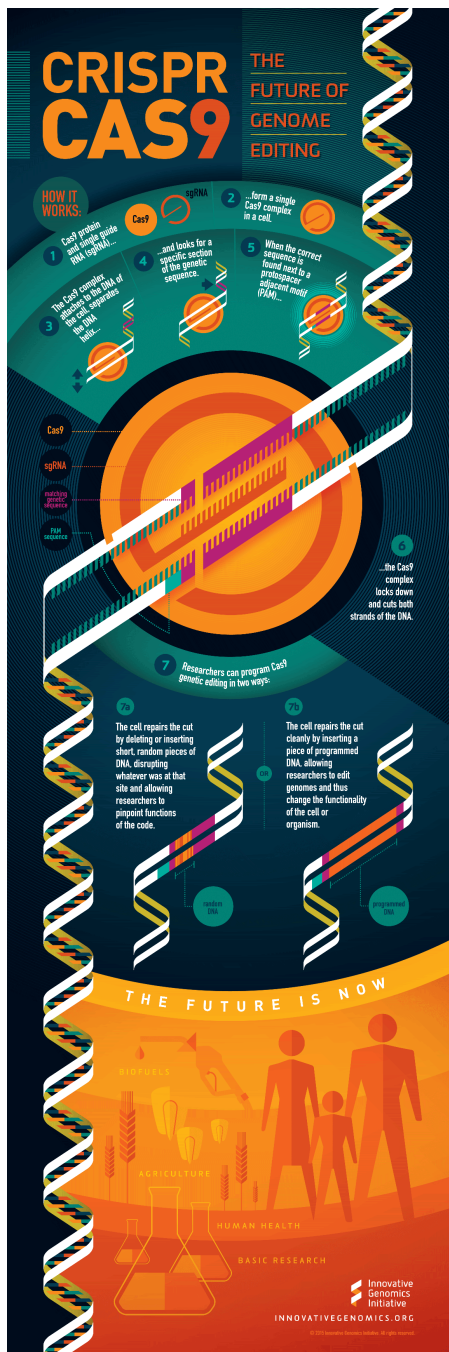
BIOTECHNOLOGY

A prudent path forward for genomic engineering and germline gene modification

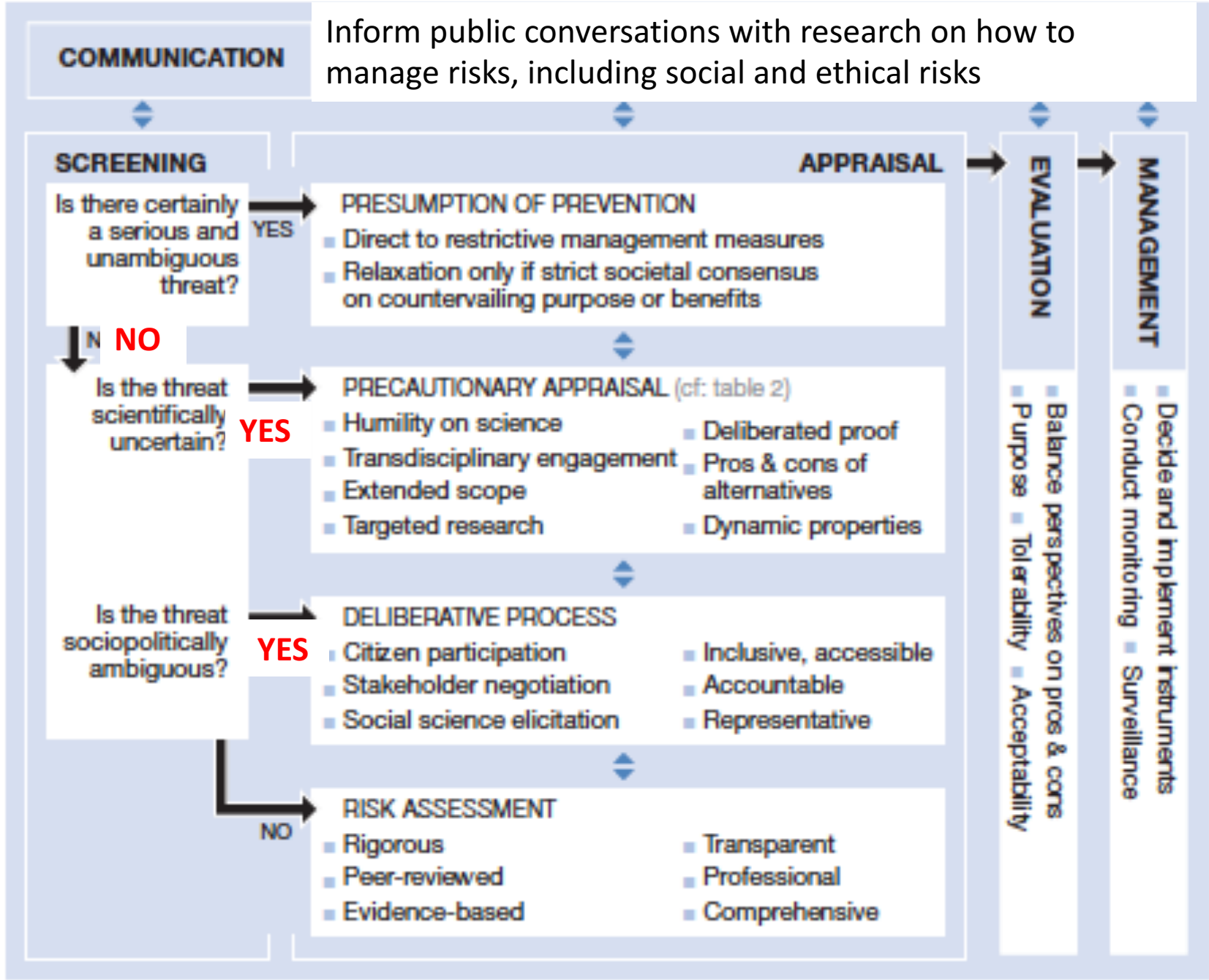
A framework for open discourse on the use of CRISPR-Cas9 technology to manipulate the human genome is urgently needed

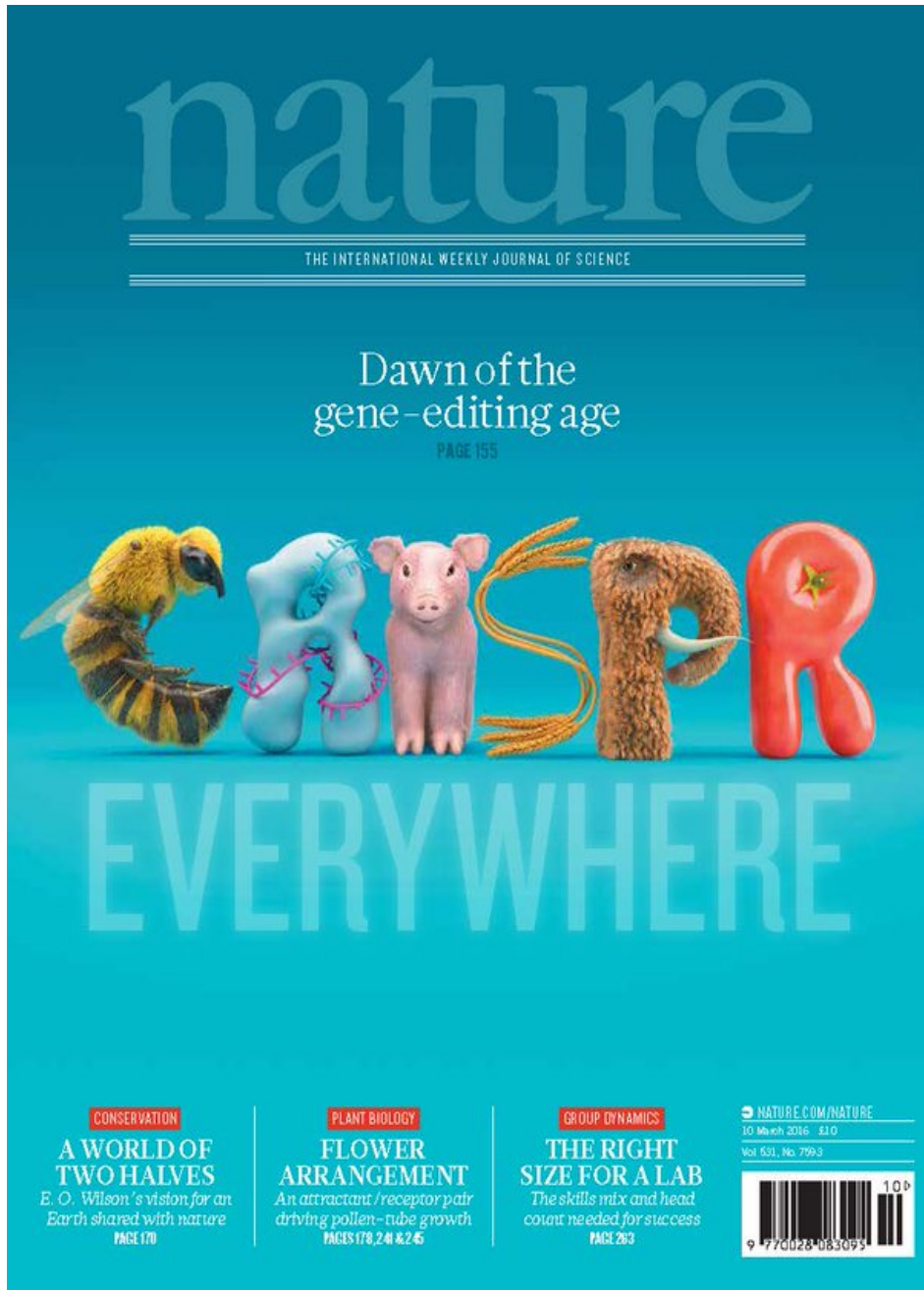
By David Baltimore,¹ Paul Berg,²
Michael Botchan,^{3,4} Dana Carroll,⁵
R. Alta Charo,⁶ George Church,⁷
Jacob E. Corn,⁴ George Q. Daley,^{8,9}
Jennifer A. Doudna,^{4,10*} Marsha Fenner,⁴
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Jonathan S. Weissman,^{4,17}
Keith R. Yamamoto^{4,18}

SCIENCE 2015



RISK ASSESSMENT & PRECAUTION FRAMEWORK





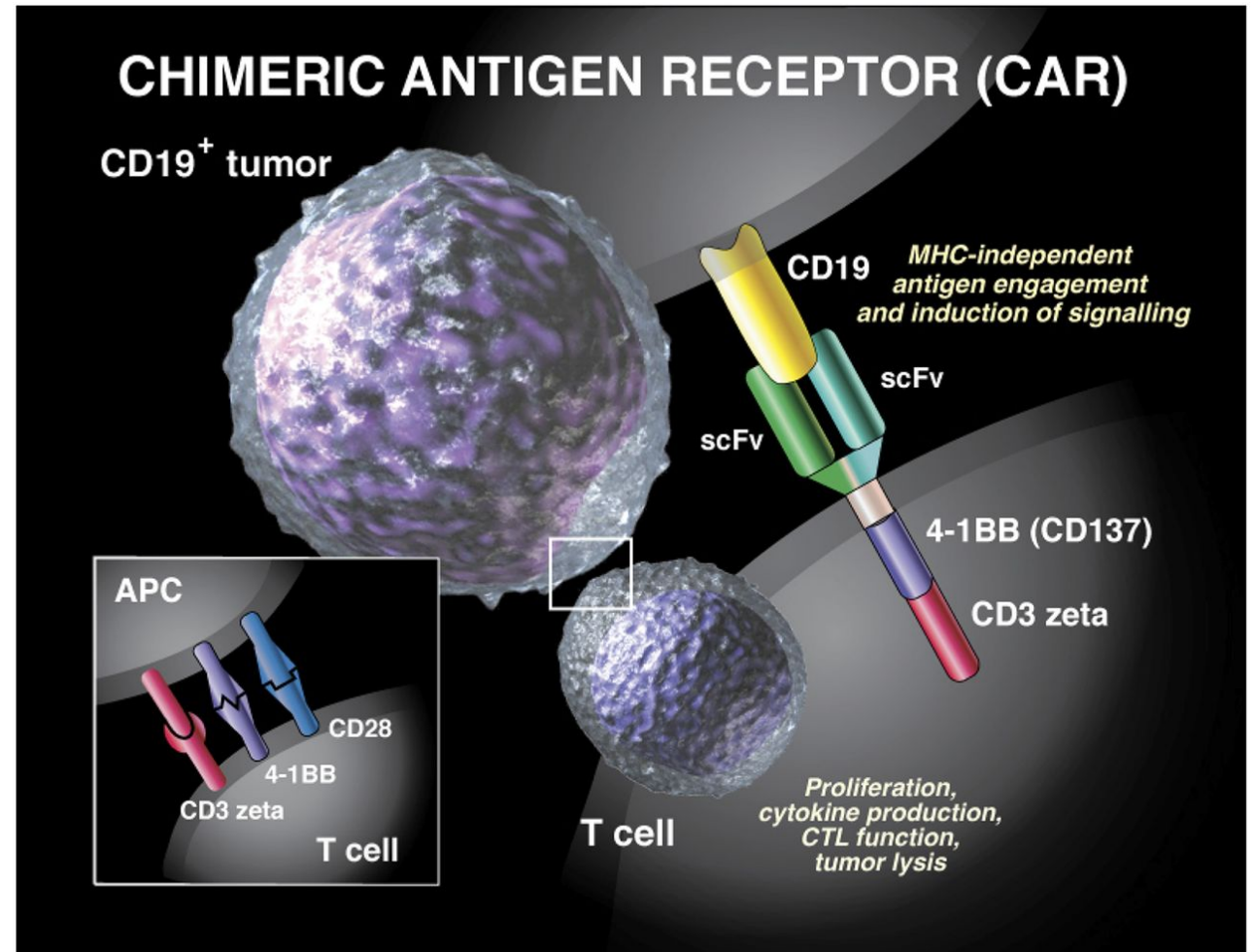
EXISTING REGULATION

- Simple systems for genome editing
- Broad application
- Accelerates genomic alteration
- Safety concerns with off-target effects
- Already regulated
 - Biosafety
 - Environmental regulations for GMOs
 - Animal care/ethics
 - Food and drug regulations
 - Research ethics





CLINICAL CONTEXT EXAMPLE





Editing humanity

The prospect of genetic enhancement



PURE HUBRIS

Gene-editing research in human embryos gains momentum – *Nature* 2016
Experiments are now approved in Sweden, China and the United Kingdom.



STATUTORY PROHIBITION: A FAILURE OF PUBLIC TRUST

- **Assisted Human Reproduction Act 2004**

No person shall knowingly:

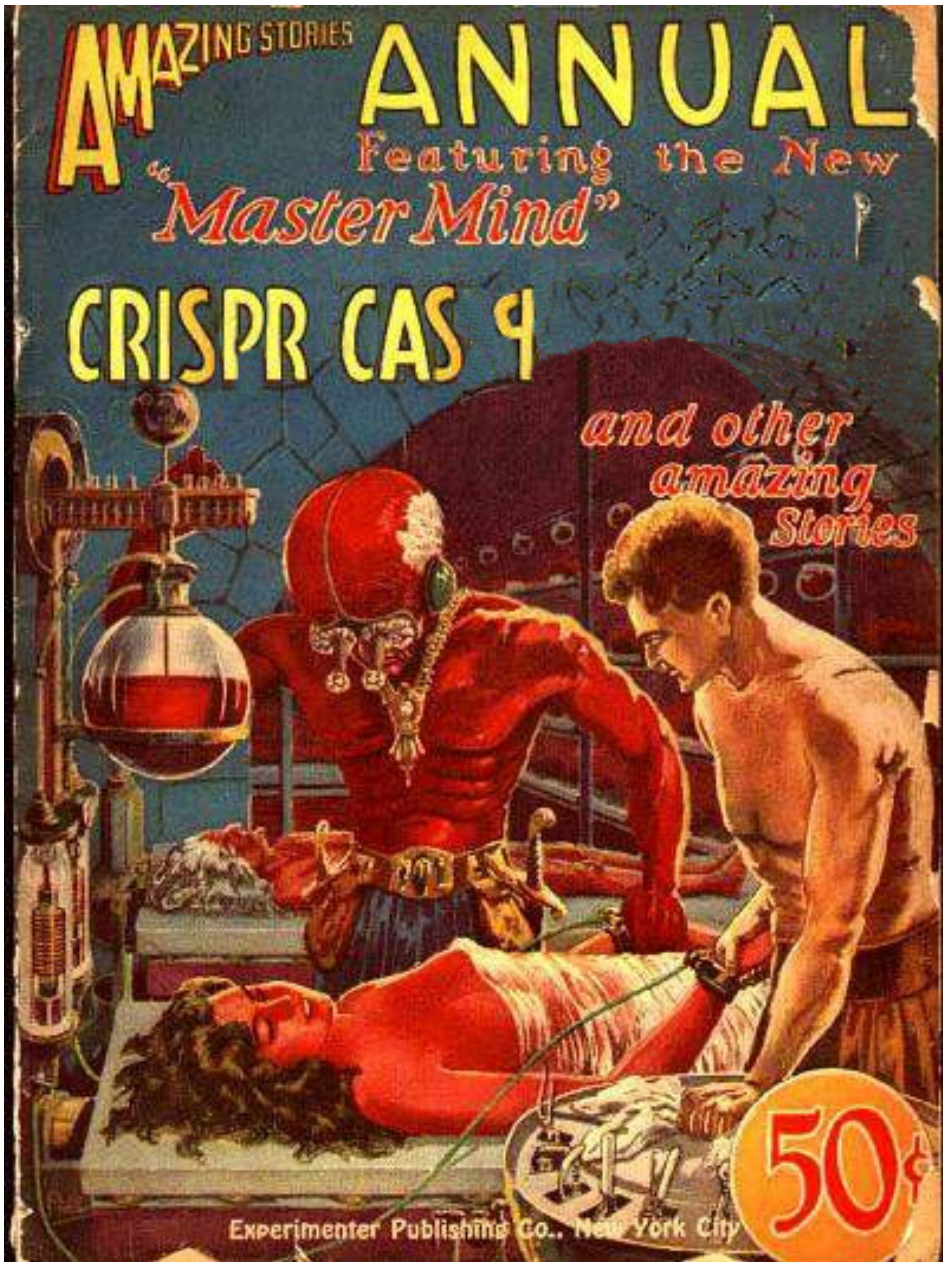
(f) alter the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants;

(c) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or foetus or transplant an embryo so created into a human being

3-Parent Babies

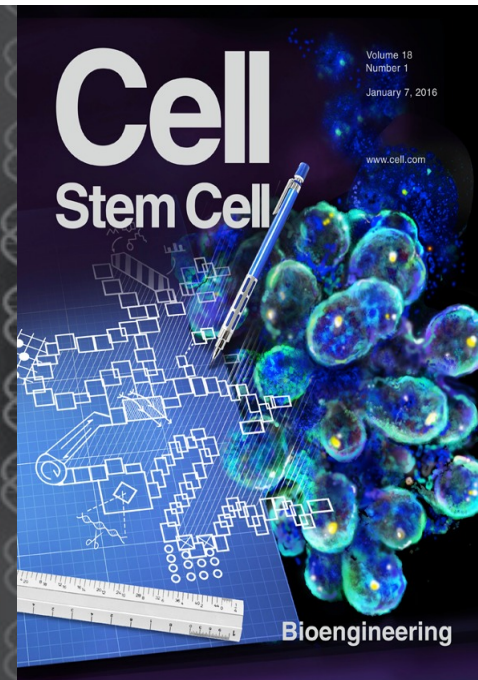
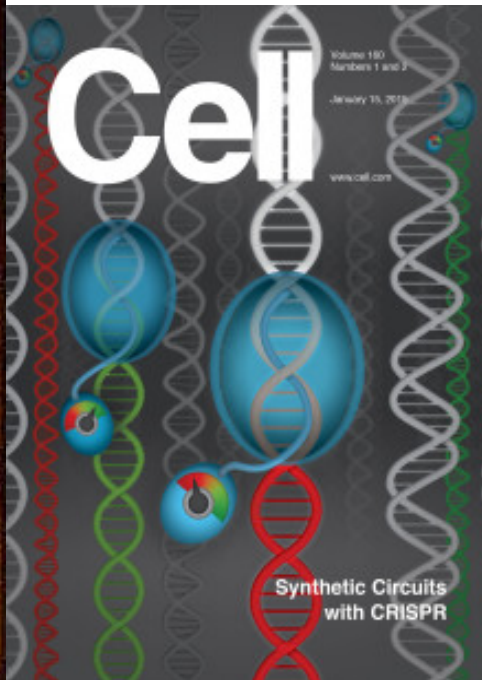
Controversial IVF
procedure set to be
legalised in the UK





CONCLUSIONS

- Imperative to maintain public trust for social license
- Address scientific, ethical and societal risks and benefits
- Deliberative mechanisms that account for global diversity
- Adaptive regulatory responses proportionate to risks





THANK YOU

Funders

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Mansour, Jaclyn Hutchinson



international
BARCODE
OF LIFE

