

# Research governance of heritable genome editing rooted in salient value sharing

Mika Suzuki, MPH.

Uehiro Research Division for iPS Cell Ethics  
Center for iPS Cell Research and Application  
Kyoto University, Japan



# Disclaimer

- This presentation is merely from a personal view as a researcher.
- It does not express the opinions of CiRA or the Japanese government.

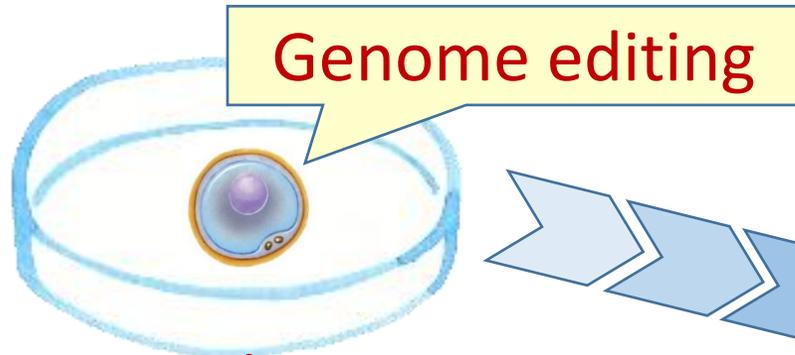
# Outline

- I. Introduction
- II. Commentary:  
Japanese and international setting
- III. Recommendations
- IV. Conclusion

# The needs for research governance that promotes responsible research globally

- In 2018, Jiankui He claimed he had genome-edited human embryos that led to the birth of twin girls
- Many international statements about the risks of heritable genome editing are not being implemented effectively  
e.g. Genome editing in human cells - initial joint statement. 2015.

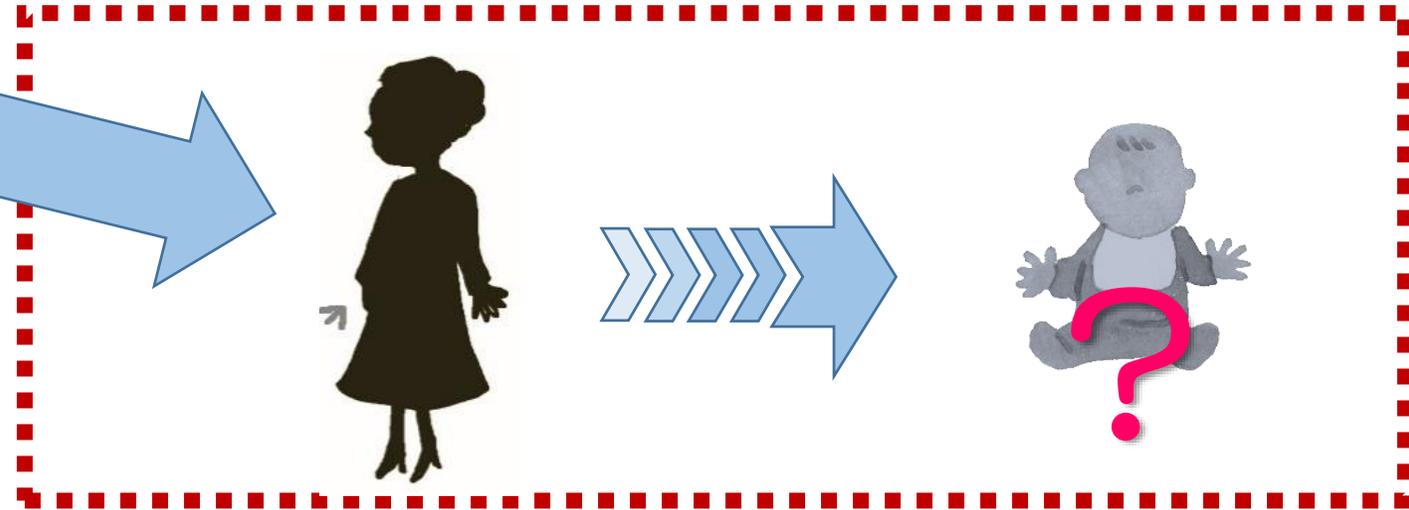
# This presentation focuses on heritable genome editing



Embryo/ Blastocyst

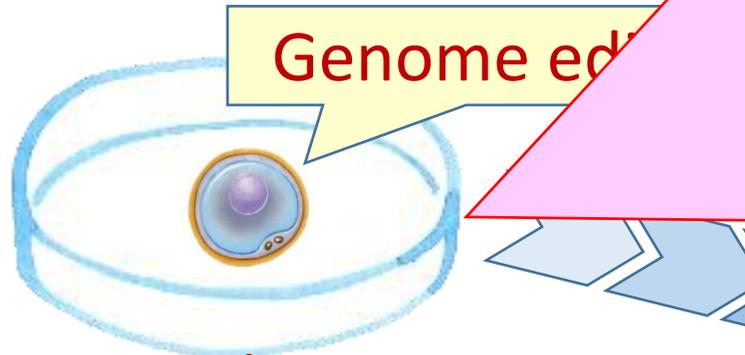
- Basic research  
e.g. only used in the laboratory

- Clinical use/application  
e.g. transplantation into a human womb



- ✓ Under research settings
- ✓ Provided as medical treatment

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Embryo/ Blastocyst

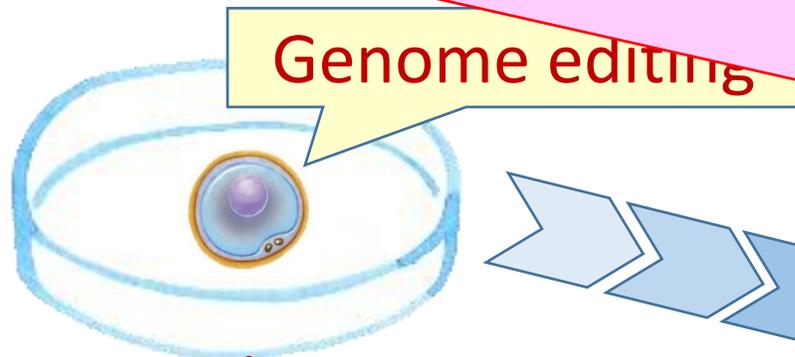
- **Basic research**  
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## Japanese National Guidelines for Research

- ✓ Only use surplus human blastocysts
- 1) understanding of embryo development/implantation
- 2) contributing to assisted reproduction technologies

# Japanese National Guidelines for Research

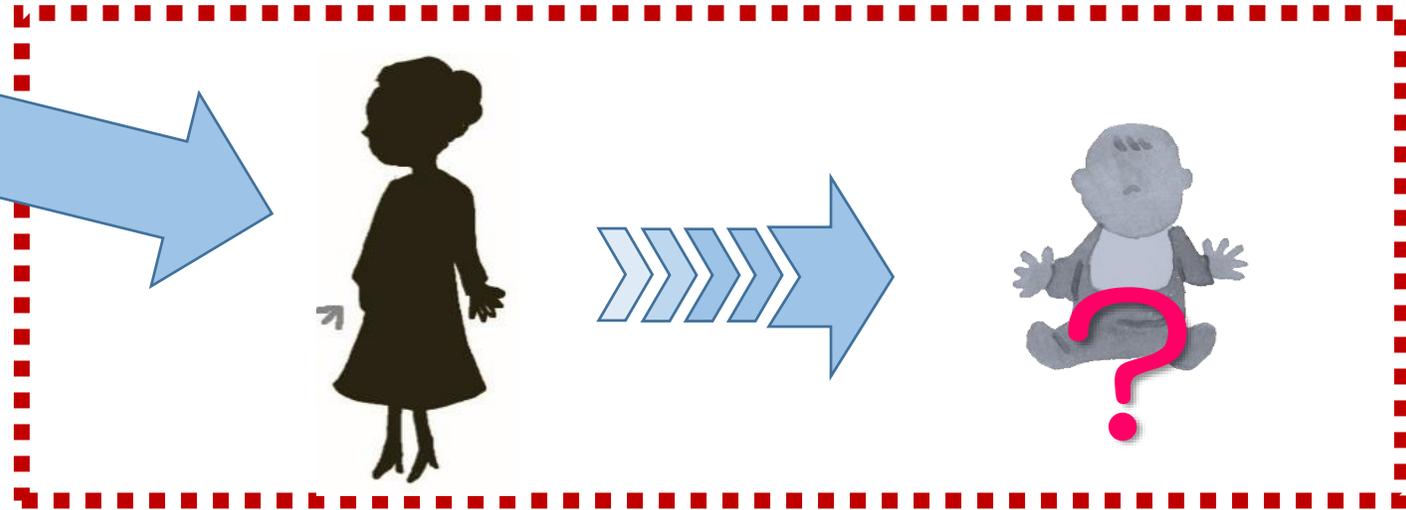
✓ Transplantation into a human womb is prohibited.



Embryo/ Blastocyst

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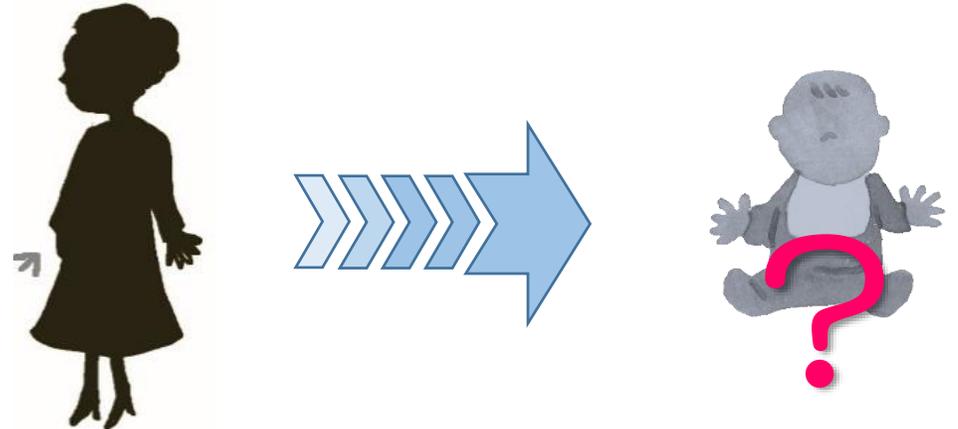
Currently, the National Committee in Japan is discussing whether to propose a new law that bans the use of genome editing technology as medical treatment.

✓ Only covered activities under research settings.

✓ Does not cover activities as medical treatment.

✓ Under research settings

✓ Provided as medical treatment



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# "how-to" or "conditions"

- “How to” includes establishing a law/guideline or review system such as a research ethics committee.
- “Conditions” include safety, researchers’ capacity building, social acceptance, and social welfare.
- There is the assumption that researchers and clinicians aim to conduct heritable genome editing clinically

Even if all the conditions are cleared,  
should society permit heritable genome editing?

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- i. rethinking quality of life, welfare, and health
- ii. developing a grand design
- iii. sharing salient values
- iv. deliberation independent of economic benefit.

## i. Rethinking quality of life, welfare, and health

The fundamental question to be deliberated is whether humans should use heritable genome editing in human reproduction.

- May be able to “cure” an anticipated disease or disability
- Quality of life (QOL) including mental and social aspects.
- QOL is affected by welfare, which is more than ‘good health’.
- ✓ Pay attention to other means that could also provide a higher QOL.

# What is a disease or disability?

- everyone has mutations in their genome
- mutations have the potential to benefit quality of life  
E.g. a heterozygous mutation in the CFTR gene may even protect against Typhoid Fever.

For some people in Japan

- a disease is simply part of their identity
- diseases are not something that should be removed
- treatment is for improving **quality of life**.

# The patient perspective



Kirin Kiki in March 2014 (Asahi Shimbun file photo)

**Ms. Kirin Kiki**  
Japanese veteran actress

- “There’s no point in comparing myself now to my old healthy self and feeling miserable. . . . Rather than fighting reality, I choose to accept what’s in front of me and go with the flow.” (The Japan times, September 16, 2018.)
- "Life would be unbearably boring if you thought of sickness as simply bad and health as simply good." (The Asahi Shimbun, December 14, 2018)

# The perspective of a clinical geneticist



**Dr. Kiyotaka Tomiwa**

Director of Todaiji Ryoiku  
Hospital for Children

Pediatrician, Clinical geneticist,  
Genetic consultant

<http://twf.or.jp/info/info2.html>

- “For those who want to ‘autonomously’ choose giving birth to a ‘healthy child’ and not ‘unhealthy child’, humans are not equipped to accept unexpected results because of deviate from natural providence.”
- “Even if a born child is healthy, there is no end to parental concerns such as illness, accidents, developmental disabilities, and so on. “
- “Being a parent means taking on worries and distress with the joy brought by the child. “

*“Prenatal Diagnosis. Who is the decision-maker whether to be diagnosed or not?.”, 2017. in Japanese.  
(My translation) 15*

## ii. Developing a grand design

Almost all existing discussions relate to hardware and software.

### Hardware

Research institute,  
Instruments,  
Foundation etc.

### Heart-ware

Professionalism,  
Motivations,  
Morality, motions,

### Software

Law/Guideline,  
Policy, Education  
etc.

✓ How guidelines incorporate ethical challenges

# e.g. Standard of Conduct for Researchers regarding Regenerative Medicine (The Japanese Society for Regenerative Medicine)

Government: Governance and management



Government

Researchers shall \*\*\*, shall not \*\*\*.



Guideline

Researchers



General public

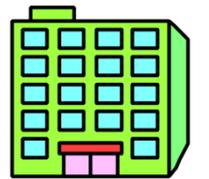
Researchers conduct research by following the guidelines.

Researcher: Governance  
Government: Management

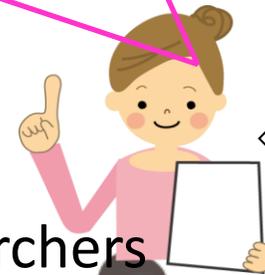
We endeavor \*\*\*,  
We behave \*\*\*.

Government

Support/  
Co-work



Researchers



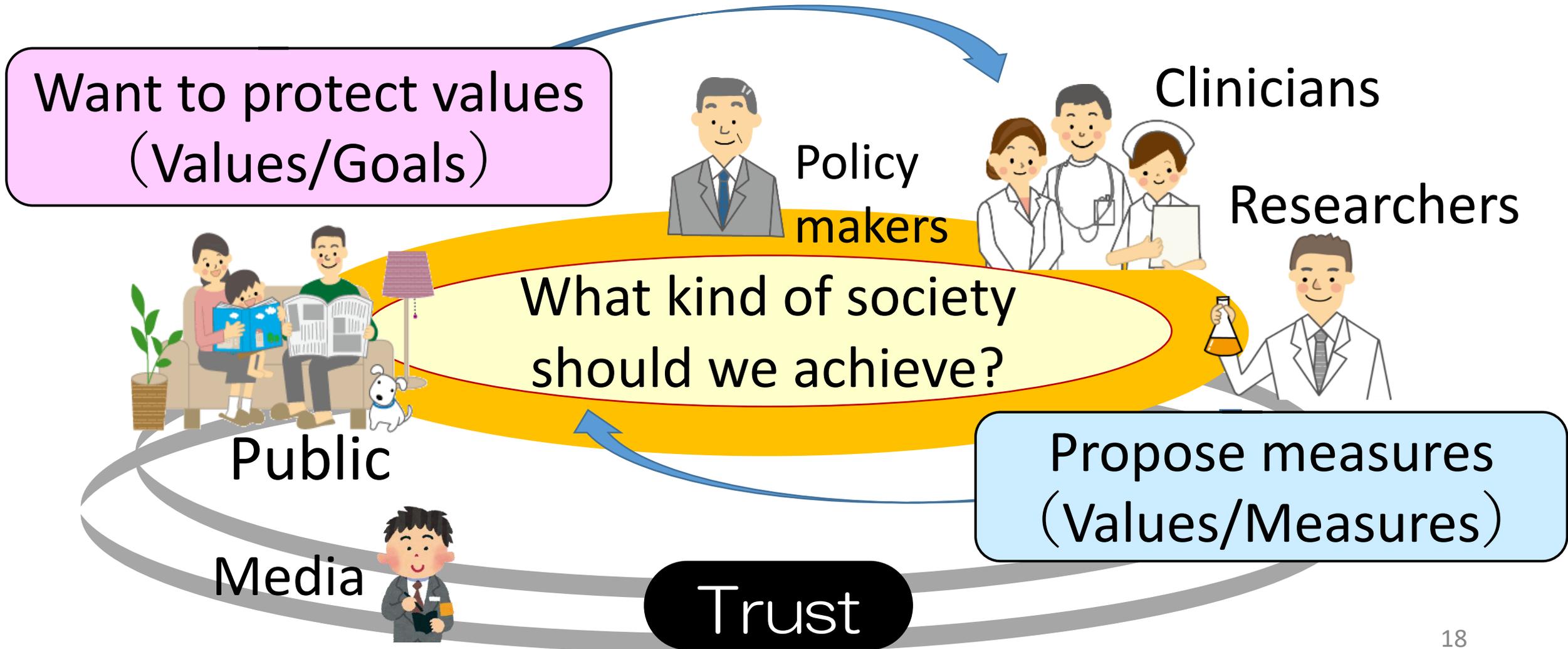
Guideline



General public

Researchers conduct research using their own principles.

- iii. Deliberation based on sharing salient values
- iv. Independent of economic benefit



# The justification should be considered

Informed consent from the patient is not sufficient justification. It is a precondition.

If researchers decide to use a cutting-edge technology based on only public needs and preferences, then they are merely technology providers.

Researchers have to consider the conflict between curing the patient and preserving the diversity of the human genome.

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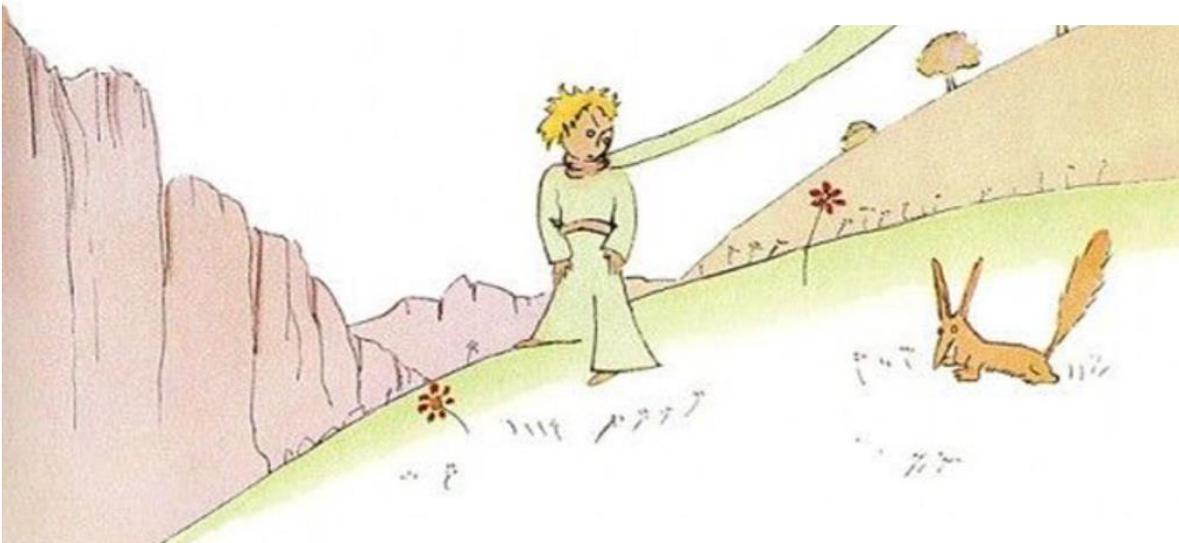
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The needs for research governance that promotes responsible research globally

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"You mustn't forget it.  
You become responsible forever for  
what you've tamed."



*The Little Prince* by Antoine de Saint-Exupéry  
<https://www.openrightslibrary.com/the-little-prince-quotes/>

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