

Introducing the Novel and Exceptional Technology and Research Advisory Committee “NExTRAC”

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Presentation to the NASEM Committee on Ethical, Legal and Regulatory Issues
Associated with Neural Chimeras and Organoids

November 13, 2020



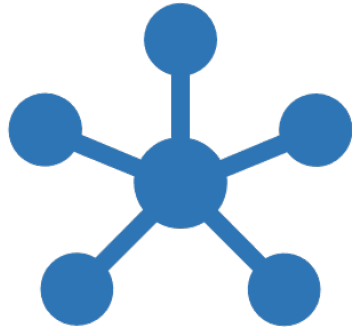
NExTRAC

- “Successor” to the RAC
- NIH FACA Committee
- Established in 2019
- The Committee makes recommendations on research involving the use of, and developments in, emerging biotechnologies. The Committee will address scientific, safety, ethical, and social issues associated with areas of emerging biotechnology research for which the NIH requests advice or guidance.

Two Working Groups formed in December 2019

- Working Group to Advise the Director on Gene Drives
- Working Group to Establish a NExTRAC Framework
 - Co-chaired by me and Gigi Gronvall, Ph.D (JHU)
- Working groups may add individuals who have expertise relevant to the working group charge
 - Gene drive working group includes two members of the NASEM committee that considered gene drives

The Working Group to Establish a NExTRAC Framework is charged with:



Describing effective approaches for prospectively identifying emerging biotechnologies or specific applications with reasonable potential to have important scientific, safety, or ethical considerations; and



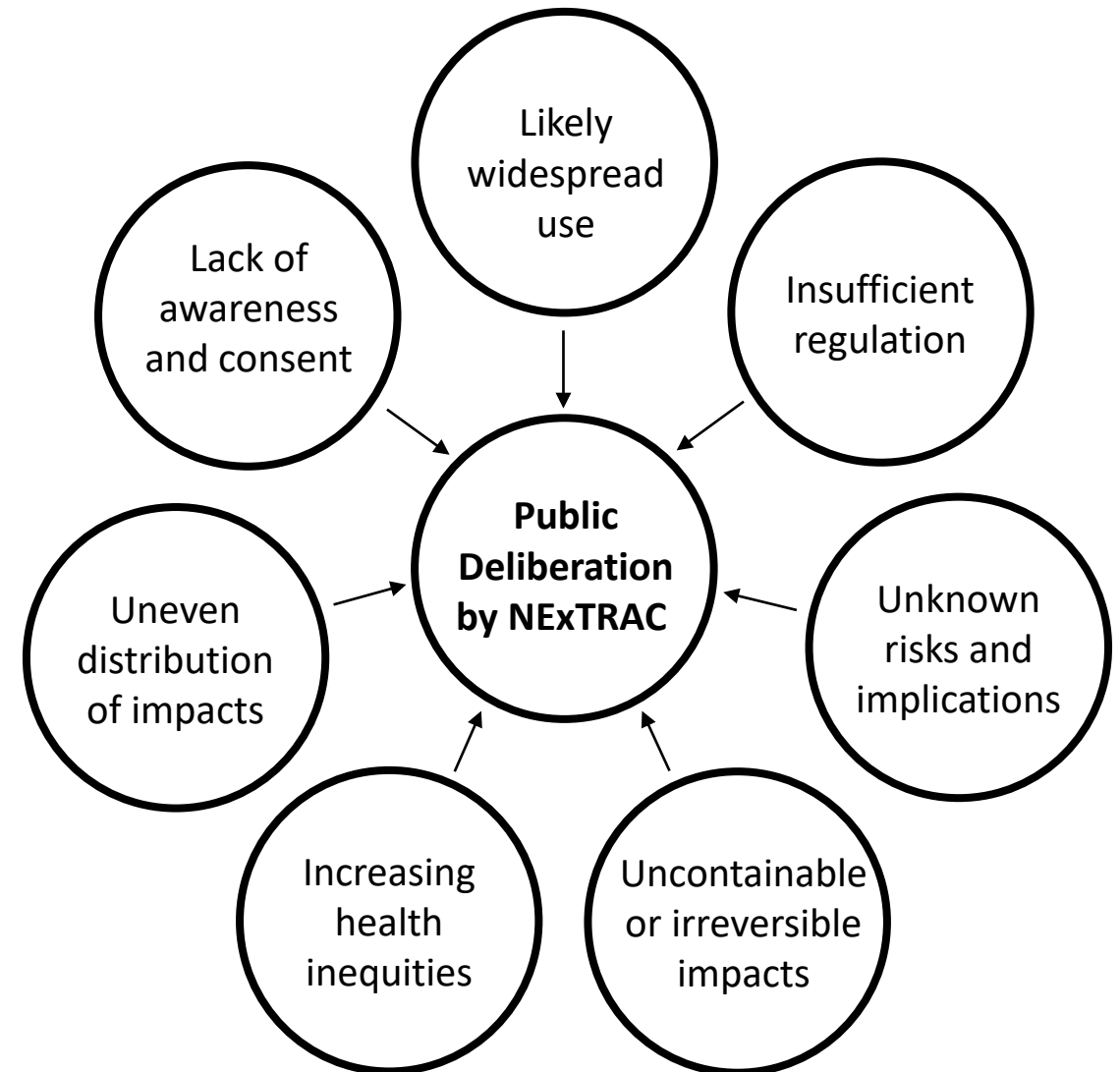
Conceptualizing a framework for NExTRAC deliberation of issues surrounding emerging biotechnologies and applications, including:

- Guiding principles for when an emerging biotechnology or its applications would significantly benefit from further public deliberation; and
- A potential process by which the NExTRAC will consider or evaluate any given emerging biotechnology or its applications.



Prompts for NExTRAC Deliberation

- Meant to bridge the gap to existing scientific, safety and bioethical principles, which still apply to this framework.
- Not meant to be all encompassing or in priority order.
- Not intended to be used as a checklist.



Prompts for public deliberation	Examples of relevant principles or values
Likely widespread use	Relevance and timeliness
Insufficient regulation	Oversight and transparency
Unknown risks and implications	Nonmaleficence and justice Safety and risk management
Uncontainable or irreversible impacts	Nonmaleficence Safety
Increasing health inequities	Equity and Justice
Uneven distribution of impacts	Fairness
Lack of awareness and consent	Autonomy and Respect for Personhood Nonmaleficence



Potential Process

NIH

**Horizon
scanning**

Informs

Identify charge

**Gather public input and/or convene
relevant fora, as needed**

Horizon scanning
input/feedback

Delivers
charge

Recommends
engagement

Provides support, as
needed

Presents
Report

NExTRAC

Factors:

- Scope of charge
- Timeline of charge
- Level that the technology/application has emerged

Deliberative Process for Consideration or Evaluation

Assess the type of
deliberation needed

Determine how public
engagement would be of benefit
and identify effective methods

Evaluate the scientific,
safety, and ethical
considerations

**Recommendations
and/or Report**