



NATIONAL INSTITUTES OF HEALTH
**Novel and Exceptional Technology and
Research Advisory Committee (NExTRAC)**



The John Edward Porter Neuroscience Research Center
NIH Campus, Building 35A, Room 620/630
December 5-6, 2019

AGENDA – DECEMBER 5

- 11:00 AM – 11:30 AM** **Welcome and Ushering in a New Era of Responsible Innovation**
Francis S. Collins, MD, PhD
- 11:30 AM – 11:45 AM** **Introduction of Committee Members**
Richard Whitley, MD

SESSION I: PATHWAYS FOR RESPONSIBLE INNOVATION IN EMERGING BIOTECHNOLOGY
Discuss successes and challenges of different approaches to governance, oversight, and public engagement.

- 11:45 AM – 12:30 PM** **Panel Discussion**
Moderator: Carrie D. Wolinetz, PhD
- Gary Marchant, JD, PhD and Larisa Rudenko, PhD, DABT
- *What lessons have been learned from previous experiences with oversight, and public engagement for earlier emerging biotechnologies (e.g., RAC with rDNA)?*
 - *What approaches should be considered for current emerging biotechnologies and their applications?*
 - *How can approaches be developed that evolve to adapt to future emerging biotechnologies and their applications?*
- 12:30 PM – 1:30 PM** **Lunch Break**

SESSION II: IDENTIFYING AN “EMERGING” BIOTECHNOLOGY

Define key features of novel and/or exceptional technologies in biomedical science and discuss potential strategies for proactively scanning the research landscape to anticipate their development and application.

1:30 PM – 2:00 PM

The Case for Horizon Scanning

Richard M. Murray, PhD

2:00 PM – 3:15 PM

Lessons from Current Technologies

- Gene Editing in the Clinic – Matthew Porteus, MD, PhD
- Gene Drives – James P. Collins, PhD
- Neurotechnology – Kafui Dzirasa, MD, PhD
- Synthetic Biology – Christina Smolke, PhD

3:15 PM – 3:30 PM

Break

3:30 PM – 4:45 PM

Panel Discussion with Presenters

Moderator: Alan I. Leshner, PhD

- *Are there defining scientific or technical characteristics of an emerging biotechnology? Are these characteristics similar for biotechnologies across disciplines?*
- *What features of emerging biotechnologies make them scientifically transformative? Are the new capabilities of emerging biotechnologies game changers or do they represent an incremental advance in our capabilities?*
- *What are potential strategies for identifying new biotechnologies and their applications on the horizon, and how can we anticipate these new developments?*
- *When has a biotechnology “emerged”?*

4:45 PM

Adjournment

AGENDA - DECEMBER 6

SESSION III: FORECASTING IMPLICATIONS OF EMERGING BIOTECHNOLOGIES

Define the specific risks, benefits, and implications of emerging biotechnologies and discuss strategies for anticipating and addressing these issues proactively.

- | | |
|----------------------------|---|
| 9:00 AM – 9:30 AM | The Case for Proactive and Adaptive Consideration of Risks and Benefits
Kenneth Oye, PhD |
| 9:30 AM – 10:00 AM | Weighing Risks and Benefits: Lessons from Biosafety
Zach N. Adelman, PhD |
| 10:00 AM – 10:30 AM | Stakeholder Engagement
Cinnamon Bloss, PhD |
| 10:30 AM – 10:45 AM | Break |
| 10:45 AM – 12:00 PM | Panel Discussion with Presenters
Moderator: Margaret F. Riley, JD <ul style="list-style-type: none"><i>What ethical and social issues do emerging biotechnologies and their applications have in common with established technologies? What issues are different?</i><i>How can we identify emerging biotechnologies that may pose novel risks, benefits, and oversight challenges?</i><i>How do we engage the public effectively in discourse, especially at early stages when specific applications or safety challenges may not be known?</i> |
| 12:00 PM – 12:15 PM | Public Comments |
| 12:15 PM – 12:30PM | Charge to the NExTRAC
Francis S. Collins, MD, PhD |
| 12:30 PM – 1:00 PM | Discussion and Next Steps
Carrie D. Wolinetz, PhD and Richard Whitley, MD |
| 1:00 PM | Adjournment |