NEW ACD WORKING GROUP

CATALYZING THE DEVELOPMENT AND USE OF ALTERNATIVE METHODS TO ADVANCE BIOMEDICAL RESEARCH

Howard Chang
Virginia and D.K. Ludwig Professor of Cancer Research and Professor of Dermatology and Genetics, Stanford University

Lyric Jorgenson
Acting NIH Associate Director for Science Policy & Acting Director of the Office of Science Policy National Institutes of Health

November Ad Hoc ACD Meeting
November 3, 2022
INNOVATIVE TECHNOLOGIES CREATE TREMENDOUS SCIENTIFIC OPPORTUNITY

Research using brains-in-a-dish forces a radical rethinking of Huntington's disease

SARS-CoV-2 Can Infect Human Brain Organoids
The results are a proof-of-concept that the novel coronavirus can replicate in neurons, but it's too soon to say whether this occurs in people with COVID-19.

NIH to Invest $130M in Biomedical, Behavioral AI Projects

NASA-SpaceX launches will boost science research on the space station
NIH INVESTMENTS IN ALTERNATIVES
COMPLEMENTARY AND NOT REPLACEMENT APPROACHES

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<th>In Chemico</th>
<th>In Vitro</th>
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<td>• Cell-free methods</td>
<td>• Cultured cell methods</td>
<td>• Computational methods</td>
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<td>• Epigenetics</td>
<td>• Induced Pluripotent Stem Cells (iPSC)</td>
<td>• Artificial Intelligence, Deep Learning, and Machine Learning</td>
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<td>• Biochemical pathways</td>
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EXPERIMENT DETERMINES THE APPROACH

WHEN ARE ALTERNATIVE METHODS MOST VALUABLE?

Toxicology
- Uses more standardized approaches
- Availability of historical data
- Consistency of aims

Research dependent on animal models
- Reliance on animal models in some research areas
- Studies of biological differences
- Alternatives can lead to need for use of animal models

Rigor, Transparency, and Translatability
- Development of new methods outpaces standards
- Authentication of cell lines
- Validation of computer simulations

Regulatory considerations
- Animal Rule
- Public trust
- Scientific limitations
WHAT IS NEEDED

An Honest Assessment of Scientific Opportunity

• Enhance the rigor and translatability of animal studies (ACD rec)
• Identify where alternatives can have the biggest scientific impact

Proactive & Strategic Shaping of NIH Portfolio

• Where use of alternatives can catalyze new scientific discoveries
• Areas for ripe for innovation to spur new research approaches
Articulate high-priority areas for NIH investment in the use and development of novel alternative methods to:

- Advance progress into understanding specific biological processes or states
- Augment the tools and capabilities for biomedical research to complement and/or potentially replace traditional models
NOVEL ALTERNATIVE METHODS WORKING GROUP
PROPOSED ROSTER

Co-Chairs

Howard Chang  Lyric Jorgenson

Executive Secretaries

• Brittany Chao
• Jessica Creery

WG Members

• Researchers with expertise in:
  ▪ Alternative models (e.g., in chemico, in vitro, in silico)
  ▪ Creating benchmarks for alternatives
  ▪ Developing benchmarks for community efforts

• Representation from:
  ▪ Across sectors
  ▪ Across disciplines
  ▪ Ex officio members from federal agencies

Full roster in progress—stay tuned!
NOVEL ALTERNATIVE METHODS WORKING GROUP
PROPOSED NEXT STEPS

- Finalize charge and roster (November 2022)
- Update ACD and discuss workplan (December 2022)
- Work! (January–May 2023)
- Present preliminary findings to ACD (June 2023)
- Stakeholder engagement (June-November 2023)
- Final report with recommendations (December 2023)