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Science Policy: The View from NIH

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Outline of Presentation

- NIH Office of Science Policy
- Data sharing and the NIH Genomic Data Sharing Policy
- Data Science initiatives
- Public-private partnerships
- COVID-19 initiatives



NIH Supports Texas Biomedical Research

• NIH Budget: \$41.7 billion

- 80% towards extramural research (50,000 grants, 300,000 researchers, 2,500 institutions)
- 10% towards intramural research (6,000 scientists)
- TX awards: \$1.37 billion (2019)
 - Private sector: \$38 million
- CPRIT: \$2.5 billion since 2008



NIH Office of Science Policy

- Advises the NIH Director on matters of significance to the agency, the research community, and the public by promoting progress in the biomedical research enterprise through the development of sound and comprehensive policies
 - Emerging issues associated with scientific and technological advances, often controversial
- Advocates for policy positions beneficial to the NIH mission
 - Ensure NIH's perspective is included in policy discussions and initiate discussions when needed
 - Make sure that NIH's mission and needs are accounted for when major changes are contemplated
 - Promote legal, regulatory, and policy frameworks conducive to science
 - Identify emerging issues that may impact NIH, formulate options to address those issues, and build consensus on the best options to address the issue



NIH Stakeholders and Modes of Engagement

- NIH Director testimony/hearings
- Responses to stakeholder inquiries
- Input on proposed regulation, legislation
- Technical assistance
- Public engagement: requests for Information (RFIs), town halls, workshops
- Develop NIH policies
- Issue reports, analyses, position statements
- Commission National Academies of Sciences (NAS) studies/reports
- Advisory Committee to the Director
- Interagency/White House working groups
- Public-private partnerships
- Blogs, social media, news releases

Selected Areas of Engagement

- Clinical and Healthcare Research Policy
 - Revised 45 CFR 46 (Common Rule)
 - Certificates of Confidentiality (mandated by 21st Century Cures Act)
 - Return of Individual-level research results (challenges with CLIA)
 - Digital health and privacy
- HOT TOPIC Neural organoids and chimeras
- Genomic medicine: regulation of vitro diagnostics, clinical utility
- Biosecurity and Biosafety
 - Novel and Exceptional Technology and Research Advisory Committee (NExTRAC)
 - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
 - New mouse model for COVID-19
- Tech Transfer and Innovation
- Data Sharing and Open Science







NIH's Culture of Data Sharing



The NIH Genomic Data Sharing (GDS)Policy

The greatest public benefit will be realized if large-scale genomic data are made available in a timely manner to the largest possible number of investigators. For human data, data are made available under terms and conditions consistent with the <u>informed consent</u> provided by individual participants.



GDS Policy in Brief

- Applies to all NIH-supported research generating "large-scale" genomic data
- Outlines principles for broad and responsible sharing of de-identified human data
- Genomic data is inherently identifiable and contains sensitive health information
- Establishes processes for data submission and access that protect the privacy and respect the wishes of research participants
- NIH expects researchers to have obtained informed consent for broad sharing and future research use



GDS Challenges and Future Directions

Challenges abound:

- Increased risk of **re-identification**, especially when combined with other types of sensitive data (e.g., medical imaging, EHRs)
- Public Trust at risk: Law enforcement use of genealogical databases, emerging phenotyping tools, data breaches
- **Streamlining** controlled-access process to ensure rapid access while still protecting participants
- **Data Science**: NIH investing in cloud infrastructure/ecosystem for storage and computation, standards, avoiding data silos

NIH Strategic Plan for Data Science



New cloud computing resource for NIH-funded institutions!

ng ded

NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability **(STRIDES)** Initiative

Genomic Data Sharing by the Numbers

Preliminary findings from forthcoming *Nature Genetics* paper demonstrate impact of the GDS Policy



- Investigators from 49 countries access NIH controlledaccess genomic data
- Secondary use publication analysis: 5000 publications using NIH genomic data

Texas is a major user of NIH human genomic data

investigators with approved data access requests



of approved data access requests



Let's Collaborate: Public-Private Partnerships

- Accelerating Medicines Partnership (AMP) (\$360 million)
 - NIH + FDA + multiple industry partners and non-profit organizations collaborate to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets for therapeutics
 - Alzheimer's Disease, diabetes type-2, RA/lupus, Parkinson's Disease
 - All partners have agreed to make the AMP **data and analyses publicly accessible** to the broad biomedical community (Knowledge Portal)



Major COVID-19 Initiatives



Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

- 1. Develop a collaborative, streamlined forum to identify preclinical treatments
- 2. Accelerate clinical testing of the most promising vaccines and treatments
- 3. Improve clinical trial capacity and effectiveness
- 4. Accelerate the evaluation of vaccine candidates to enable rapid authorization or approval

"To address what may be the greatest public health crisis of this generation, it is imperative that all sectors of society work together in unprecedented ways, with unprecedented speed."

NIH Director Francis S. Collins, MD, PhD, and Paul Stoffels, MD

Rapid Acceleration of Diagnostics (RADx) Initiative (\$1.5 billion)

- Support early innovative technologies ("shark tank")
- Move more advanced technologies swiftly through development pipeline to commercialization
- Point-of-care diagnostics are of particular interest
- NIH collaborating with its sibling agencies

"We need all innovators, from the basement to the boardroom, to come together to advance diagnostic technologies, no matter where they are in development."

Francis Collins, MD, PhD

Resources

Questions? Kristofor.langlais@nih.gov



- NIH COVID-19 Resources: https://www.nih.gov/health-information/coronavirus
- C Open-Access Data and Computational Resources to Address COVID-19: https://datascience.nih.gov/covid-19-open-access-resources
 - National Library of Medicine COVID-19 Resources: <u>https://www.nlm.nih.gov/index.html#Novel_Coronavirus</u>
 - ACTIV: <u>https://jamanetwork.com/journals/jama/fullarticle/2766371</u>
 - RADx: <u>https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics</u>
 - Advisory Committee to the Director: https://www.acd.od.nih.gov/
 - Funding opportunities: <u>https://nexus.od.nih.gov/all/2020/04/13/covid-19-funding-and-funding-opportunities/</u>
 - NIH Office of Science Policy: <u>https://osp.od.nih.gov/</u>; <u>SciencePolicy@od.nih.gov</u>
 - Genomic Data Sharing Policy: <u>https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/</u>
 - COVID-19 Biosafety FAQs/interim guidance: <u>https://osp.od.nih.gov/biotechnology/interim-lab-biosafety-guidance-for-research-with-sars-cov-2/</u>
 - Office of Data Science Strategy: <u>https://datascience.nih.gov/</u>
 - STRIDES Initiative: <u>https://datascience.nih.gov/strides</u>; <u>CIT_Cloud_Services@mail.nih.gov</u>
 - Accelerating Medicines Partnership: https://fnih.org/what-we-do/programs/amp; https://www.nature.com/articles/d41573-019-00033-8
 - NIH Strategic Plan for Data Science: https://datascience.nih.gov/sites/default/files/NIH Strategic Plan for Data Science Final 508.pdf
 - National Academies of Science (NAS) Organoids and Chimeras: <u>https://www.nationalacademies.org/our-work/ethical-legal-and-regulatory-issues-associated-with-neural-chimeras-and-organoids#sectionSponsors</u>