NIH Policy Updates: Single IRB and Data Sharing

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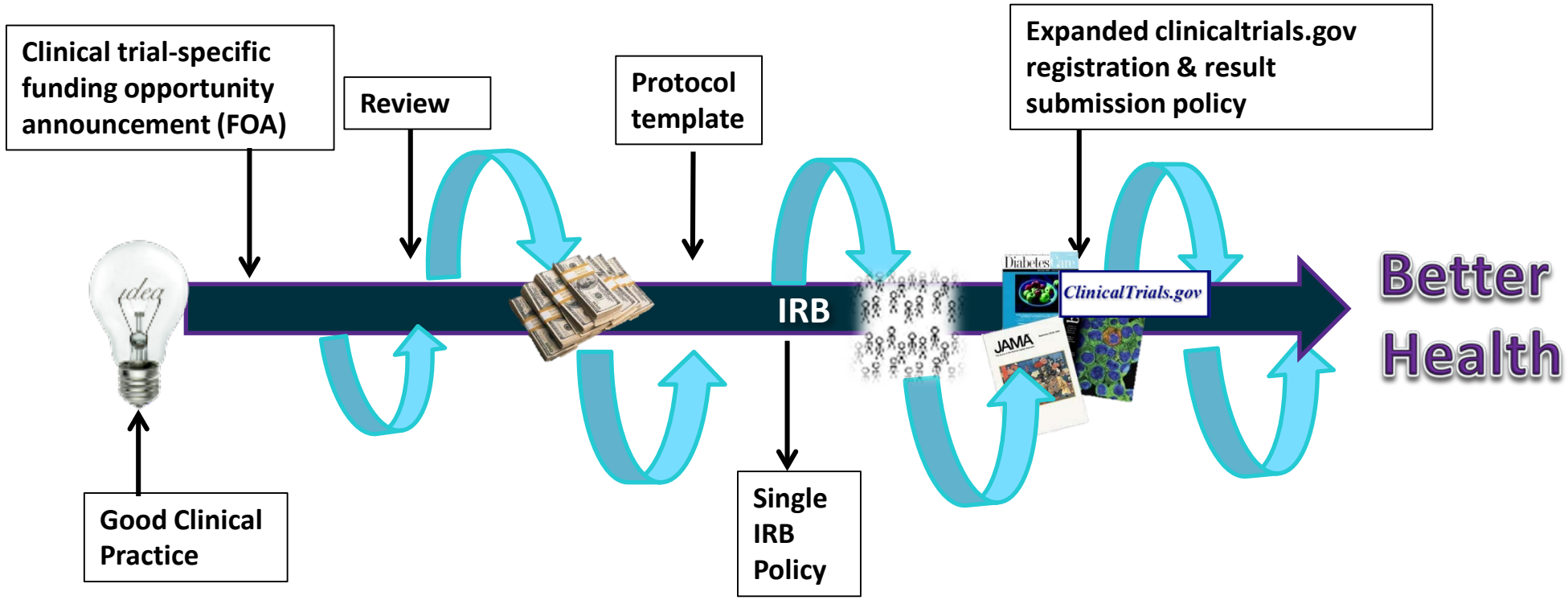
NIH Clinical Trials and Transparency Reforms



VIEWPOINT

Toward a New Era of Trust and Transparency in Clinical Trials

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National Institutes of Health, Bethesda, Maryland.

Michael S. Lauer, MD
National Institutes of Health, Bethesda, Maryland.

Francis S. Collins, MD, PhD
National Institutes of Health, Bethesda, Maryland.

"To realize the benefits of a clinical trial, the data must be broadly shared quickly. The DHHS has released a regulation for registration and summary results reporting. The NIH **will withhold clinical trial funding** if the agency is unable to verify adequate registration and results reporting…"

JAMA 2016 (online September 16, 2016)

Office of Science Policy (OSP) collaboration with the Tribal Health Research Office (THRO)

- When creating or updating policies, NIH is committed to communication and addressing tribal needs.
  - Development of a Fact Sheet and FAQs for Studies with Tribal Populations (with OER; in progress)

- OSP is in regular contact with THRO on issues affecting research with tribes and to consult with THRO
  - NIH Informational/Consultation Session on Tribal Interests in Research Involving Human Participants, February 23, 2017

NIH Policy on Use of a Single IRB for Multi-Site Research

NIH Policy on Use of a Single IRB for Multi-Site Research

Establishes expectation that domestic sites of NIH-funded multi-site studies will use a single IRB of record to conduct the ethical review of research

- Effective for grant applications submitted on/after Jan. 25, 2018

Public comments

- IHS: “Multi-site studies with central IRB approval should be required to seek IHS or Tribal IRB approval, as appropriate, for research conducted within the jurisdiction of federally recognized AI/AN Tribes”

- Cherokee Nation:

  Tribal IRBs ensure that research

  - is conducted in a community engaged manner
  - does not deplete or divert limited tribal resources away from direct patient care
  - findings are first shared with tribal leadership, tribal communities, and key stakeholders

NIH Policy on Use of a Single IRB for Multi-Site Research

The policy does not apply to tribal populations, including Tribal Colleges/Universities (TCUs)

- To show respect for tribal sovereignty and acknowledge the importance of firsthand knowledge of local tribal customs, cultural values, and tribal sensitivities

Exceptions:

- *Where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy*
- *If there is a compelling justification*

Benefits of Tribal and TCU reviews

- Allow for consistent research protections for tribal communities
- Allow for incorporation of tribe-specific values into research policies, including respect for sovereignty
- Create clear guidelines for collaborations between researchers and tribes
- Prevent research related-harms to individuals and communities and ensure that benefits are received by tribes (“return on investment”)
- Further the goal of having a robust process that ensures the conduct of culturally competent, ethical research.
  - Research is likely to benefit tribal nations, research scientists and institutions.

Resources for investigators conducting research involving tribes

- NIH Tribal Health Research Office (THRO): Responsible for ensuring meaningful input from and collaboration with tribal Nations on NIH programs and policies
- CRCAIH toolkit : a resource for American Indian Tribal nations or other Indigenous Nations developing IRBs or other committees responsible for the ethical review and monitoring of research on Tribal land.

OSP collaboration with THRO

The NIH Office of Science Policy (OSP) is in regular contact with THRO on issues affecting research with tribes

- Development of a Fact Sheet and FAQs for Studies with Tribal Populations (with OER; in progress)
- NIH Informational/Consultation Session on Tribal Interests in Research Involving Human Participants, February 23, 2017
- OSP, OER, and THRO will be discussing the concerns about Tribal member information and the requirement for clinical trial result submission.

NIH Data Sharing Policies

NIH Longstanding Policy

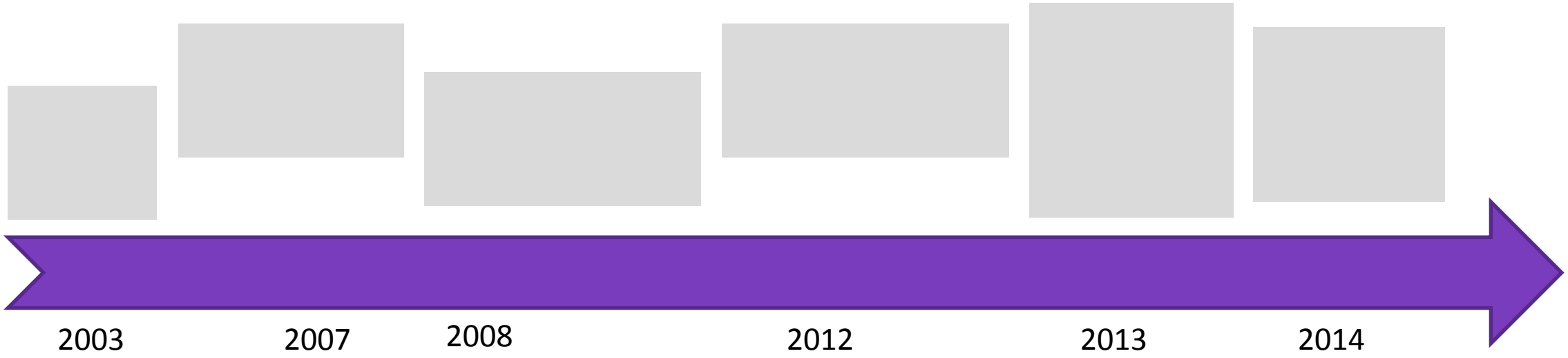
NIH expects the results and accomplishments of the activities that it funds be made available to the public.

CONSISTENT WITH INFORMED CONSENT

Data Sharing: Why the Interest?

- Science increasingly digital, generating vast amounts of data
- Data collected can be used for multiple purposes (e.g., patient care data)
- Advances in IT and bioinformatics make it easier to collect, organize, access, and analyze data
- Changing scientific ethos and practice – more open and transparent
- U.S. Government Initiatives
  - February 2013 White House initiative to increase access to the results of federally funded scientific research, including publications and data
  - NIH Big Data to Knowledge Initiative (BD2K) supports the broad use of digital assets and resources to enhance the utility of biomedical big data and accelerate discovery
  - Common Rule revisions supports consent to maximize utility of biospecimens and data

A Culture of Sharing



Points to Consider for IRBs for Human Genomic Data under the GDS Policy

- The Points to Consider for Institutions and Institutional Review Boards (IRBs) is a document created to assist IRBs in their review of, and institutions in their certification of, investigator applications and proposals involving the submission and access of human genomic data under the GDS Policy.

- The document indicates that if the research involves tribal populations, the Authorized Institutional Official(s) should consider tribal laws and regulations, and whether consultation with tribal communities may be appropriate. Additional information about the GDS Policy and related documents is available on the NIH Office of Science Policy website.

Considerations for Broader Data Sharing Policy Development:

- **Scope and Applicability, and existing NIH data sharing policies**
- **Requirements**
  - **—Data Management and Sharing Plans**
    - Evaluate during peer review (e.g., Additional Review Criteria)
    - Machine-readable, updateable, publicly available (e.g., RePORTER)
  - **—Require data sharing (e.g., 21st Century Cures Act)**
    - **Ability to provide a justification in Data Management and Sharing Plans for why certain data cannot be shared**

End