

NIH sIRB and GDS Policies:

Honoring the Exceptions, Limitations, and Alternatives

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What has history taught us?

- “[A] profound disconnect exists between common academic research practices and legitimate [AI/AN] community expectations, and justice requires that this gap be bridged.”

Goering, Holland, and Fryer-Edwards (2008) *HCR*

Beyond Belmont: Ensuring Respect for AI/AN Communities Through Tribal IRBs, Laws, and Policies

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We concur with Friesen and colleagues (2017) that it is timely to reflect on the history of the Belmont Report and its role in the development of research regulations, especially its failure to account for harms to communities and transparency in research. We would like to amplify the authors' comments about the relevance of these failures as they pertain to American Indian and Alaska Native (AI/AN) communities—and clarify a few important nuances. Transparency and trust are key issues that continue to beleaguer AI/AN communities and their perception of scientific research (Havasupai Tribe of the Havasupai Reservation v. Arizona Board of Regents and Therese Ann Markow 2008; American Journal of Medical Genetics [AJMG] 2010). It would have been fitting for the Belmont Report to address “respect for communities” in response to the harm caused to the African American community by the Public Health Service Tuskegee Syphilis Study,

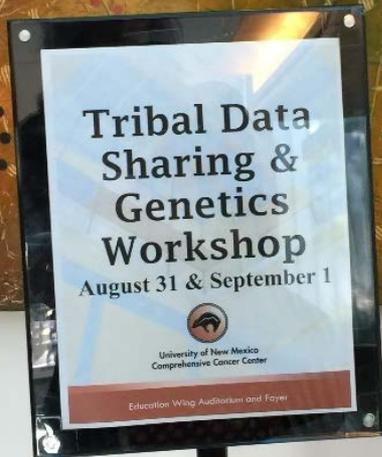
especially given that the study was an important catalyst in the establishment of both the National Research Act and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974. Realistically, however, it seems unlikely that the Belmont Report, a historical document that has stood intact for nearly 40 years, will be revised to formally incorporate a new principle that focuses on community respect and trust—which makes it all the more important to understand how the interests of AI/AN communities can be protected under the newly updated U.S. federal regulatory framework (“the final Common Rule”).

Friesen and colleagues (2017) acknowledge that the issue of community harms is relevant to AI/AN tribes through their inclusion of case examples and alluding to the sovereign authority that tribes have to establish research regulations. However, their concern that it is

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<http://206.192.150.42/tcs/#page:recordingList&pageNumber:1>

“American Indian and Alaska Native Cultural Wisdom Declaration”

Recommendations

- “Modify your requirements to fit the relevant traditional tribal paradigm or allow room for flexibility when evaluating proposals submitted by American Indian and Alaska Native tribal nations.”

<https://store.samhsa.gov/shin/content//PEP16-NTBH-AGENDA/PEP16-NTBH-AGENDA.pdf>

Key Question

- Are NIH policies flexible enough to permit collaborative research and data sharing to take place in partnership with sovereign nations?

NIH Policy Exceptions, Limitations, and Alternatives

- Single IRB (sIRB) Policy
 - Effective 1/25/18
- Genomic Data Sharing (GDS) Policy
 - Effective 1/25/2015

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

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*

PRIMR Webinar

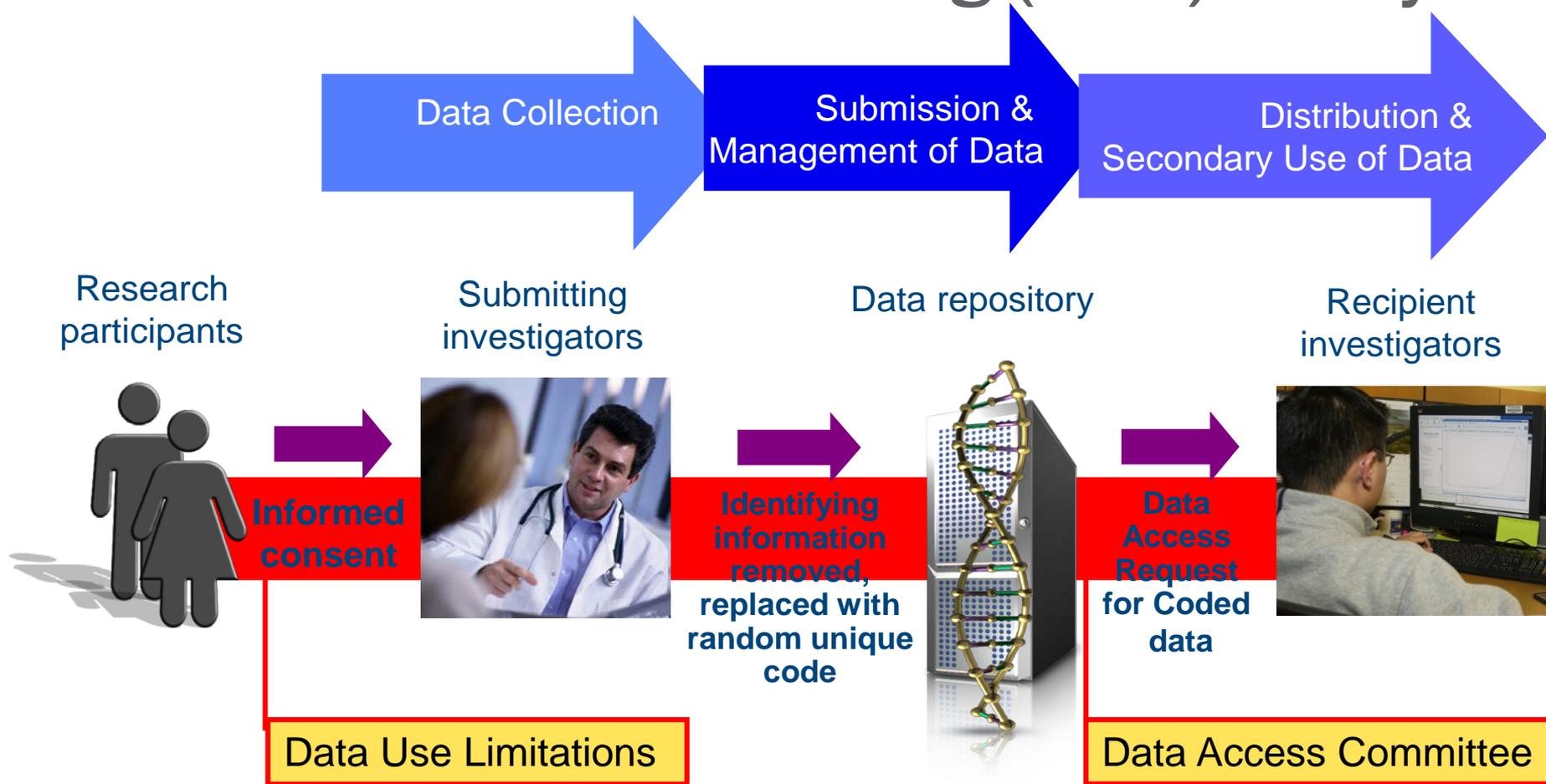
Preserving a Role for Tribal Review of Research in the Context of Single IRB Policies

Tuesday, September 20 • 1:00-2:30 PM ET



<http://www.primr.org/webinars/sept2016/>

NIH Genomic Data Sharing (GDS) Policy



Public Comments on GDS Policy: *Lack of Community Input*

- “Once data are submitted to the repository there is no opportunity for a community, tribal leadership, or a local IRB to be involved in decisions regarding data use.”
- “...contradicts the practices of collaborative research based on a partnership ethic between tribal governments and researchers.”
- “...tribal and other minority communities are wary of delegating assessment of cultural or other harms to federal employees assigned to Data Access Committees.”

NIH GDS Policy Flexibilities

- Institutional certification/IRB should assure that:
 - “The data submission is consistent, as appropriate, with applicable national, **tribal**, and state laws and regulations as well as with relevant institutional policies”
 - “Any **limitations on the research use of the data**, as expressed in informed consent documents, are delineated”
 - “To the extent relevant and possible, consideration was given to **risks to groups or populations** associated with submitting data to NIH-designated data repositories and subsequent sharing”

NIH GDS Policy Flexibilities

- Limited exceptions “in cases where data submission to an NIH-designated data repository is not appropriate”
 - Requires alternate plan to share data through other mechanisms

How might this work?

- Data Use Limitations
 - Genetics of sickle cell disease variation/African American populations
 - Used for SCD research only
- Described in consent forms

How might this work?

- Alternative Data Sharing Plans
 - Genetics of T2D and NCDs/Sub-Saharan Africa
 - Oversight committee to consider researcher track record, ethical considerations, relatedness to non-communicable disorders
 - “Data/samples will be shared with co-investigators and other IRB approved investigators in collaboration with [original investigator] to facilitate biomedical research as approved by the participants on the signed informed consent form.”

How to Facilitate Community Input for Tribal Data Sharing?

- Data Use Limitations
 - Would AI/AN representation on NIH Data Access Committees (DACs) help to safeguard tribal data held in NIH repositories?
- Alternative Data Sharing Plans
 - Are different governance models needed to ensure appropriate stewardship of tribal genomic data?

Key Question

- Are NIH policies flexible enough to permit collaborative research and data sharing to take place in partnership with sovereign nations?
 - Yes
 - Tribal oversight of research
 - Data Use Limitations
 - Alternative Data Sharing Plans
 - Details will depend on community and study

Thank you!

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