

# **Accelerated Review of Research Amidst a Pandemic**

Alaska Indigenous Research Program

May 20, 2021



ALASKA NATIVE  
TRIBAL HEALTH  
CONSORTIUM

# Perspectives Considered



Institutional  
Review Board  
(IRB)



Tribal Research  
Review



Researcher



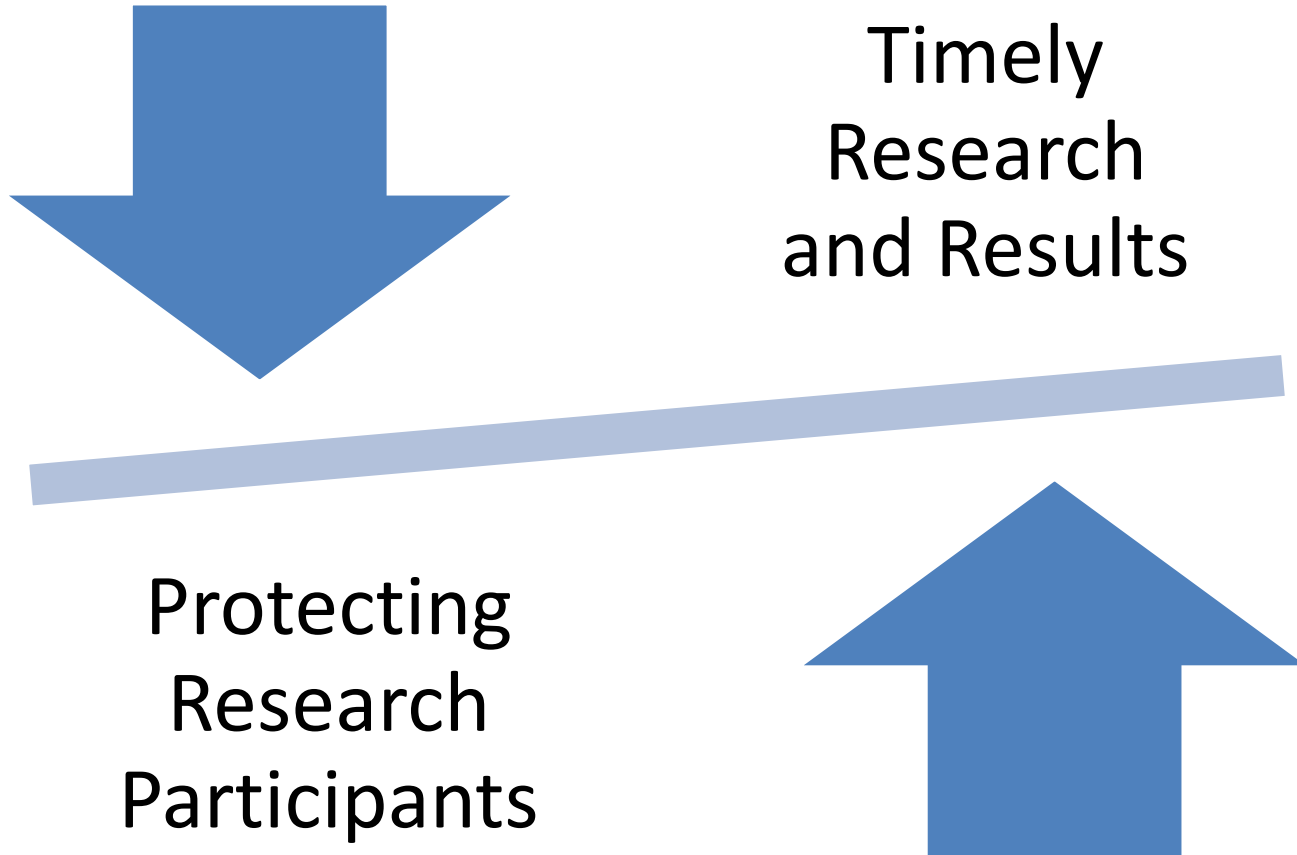
ALASKA NATIVE  
TRIBAL HEALTH  
CONSORTIUM

# Ethical Principles

- Federal Regulations
  - Revised Common Rule 45 CFR 46
  - FDA 21 CFR 50 and 56
  - HIPAA
- Tribal Research Review Policies



# Conflicts



# Pandemic Effect

- Need for rapid research to drive management of pandemic
- Need to include diverse populations, including those at high risk
- Still need protections in place
- Many competing demands on reviewers



**COVID-19: How HRPPs are  
Preparing and Responding  
A Discussion Forum**



**ALASKA NATIVE  
TRIBAL HEALTH  
CONSORTIUM**

# Institutional Review Board Requirements §46.107

- At least 5 members with varying backgrounds
- Diverse membership
- Scientific and non-scientific background
- Community member representation
- Recuse if conflict of interest
  
- Volunteers



# Challenges for IRBs in Pandemic

- Volunteer members and other roles
- Remote meeting format
- Setting review priorities
- Capacity for expedited review
- Protocol deviations for safety of participants



# Expedited Review of Research

- Revised Common Rule allows expedited review of research by IRBs in specific cases
  - Minimal risk
  - List of 8 categories of expedited research
  - Minor changes to existing studies
  - Continuing review of existing studies
- Expedited reviewers have authority of full IRB except they may not disapprove

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>



ALASKA NATIVE  
TRIBAL HEALTH  
CONSORTIUM



IDEAS AND OPINIONS

Annals of Internal Medicine

## Desperate Times: Protecting the Public From Research Without Consent or Oversight During Public Health Emergencies

Mary Catherine Beach, MD, MPH; Howard M. Lederman, MD, PhD; Megan Singleton, JD; Roy G. Brower, MD; Joseph Carrese, MD, MPH; Daniel E. Ford, MD, MPH; Bhakti Hansoti, MBChB, MPH, PhD; Craig W. Hendrix, MD; Ellen Verena Jorgensen, MD; Richard D. Moore, MD, MHS; Philip Rocca, JD, MAT; and Jonathan M. Zenilman, MD

Beach MC, et al. Ann Intern Med 2020; 173:926-928



ALASKA NATIVE  
TRIBAL HEALTH  
CONSORTIUM

# Public Health Activities

- Not research according to 45 CFR 46 § 102:
  - (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).



# Consequences of Public Health Surveillance Exception

- No specific requirements for oversight, consent, protection of participants
- Requests may include long-term storage of specimens
- Editorial authors' concerns
  - Public health surveillance evolving into research
  - Prior examples of harm
- Tribal review of non-research vs. research



# Tribal Review of Research

The Board of Directors of the Alaska Native Tribal Health Consortium (ANTHC) established the Health Research Review Committee (HRRC) to review health research proposals and related manuscripts and abstracts prior to submission for publication to determine whether they merit approval based on their consideration and respect for the dignity and cultural perspective of the Alaska Native People, scientific merit, and consistency with the Mission, Vision and Values of the ANTHC.



# ANTHC Accelerated Research Review Procedure

- ANTHC had an existing Human Subjects Research Policy and the HRRC had a Charter
- There was a need for accelerated review.
  - History – cancer clinical trials as impetus
  - Proposals in 2016
  - Pandemic led to more changes / implementation
  - *Manuscripts, 2021 pending*



# Criteria for Accelerated Review

- Focus on an Alaska Native or other relevant patient populations and may yield urgently needed information or other health benefits
- Have been identified as potentially beneficial by a provider with appropriate privileges at the Alaska Native Medical Center (ANMC) or another provider treating a patient of ANMC or another AHS provider for one or more specific patients whose health care needs exceed the capabilities of ANMC and other providers
- Have so short a window that the opportunity to participate may be closed before a proposal could be reviewed and approved through the ordinary process.



# Researcher Perspective

- Give a brief description of the project you had and why it was time sensitive
- What worked well? What did not go as expected?
- What advice would you give researchers who may need to seek accelerated review?



# Future

- Implementation of new Accelerated Review Procedure is in its infancy at ANTHC.
- Researchers going through the process can help shape the future of Accelerated Review.
- Charter and Procedure revisions are continuously updated and implemented





# Thank you

- Elizabeth Ferucci, [edferucci@anthc.org](mailto:edferucci@anthc.org)
- Abbie Willetto, [alwilletto@anthc.org](mailto:alwilletto@anthc.org)
- Laura Eichelberger, [lpichelberger@anthc.org](mailto:lpichelberger@anthc.org)

