



Intervention Research to Improve Native American Health

IRINAH

Update to TCAC – September 23, 2015

Participating Institutes

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- National Cancer Institute
- National Institute on Drug Abuse
- National Institute on Alcohol Abuse and Alcoholism
- National Institute of Environmental Health Sciences
- National Institute of Mental Health
- National Institute of Dental and Craniofacial Research
- National Institute on Nursing Research
- National Institute on Minority Health and Health Disparities
- Office of Behavioral and Social Sciences Research



Goals



- Focuses on health promotion and disease prevention
- Research to adapt, develop, and test interventions in American Indian, Alaskan Native and Native Hawaiian (NA) populations to improve risk profiles at individual, familial, and community levels
- Requires researchers to partner with communities to:
 - Incorporate concerns and issues of the community
 - Adopt methodologies that are relevant to NA populations
 - Implement appropriate study designs to address the complex and multi-layered causes of health inequities



Goals (continued)



- Tribal-Researcher Agreement
 - When needed – provide researcher-tribal agreement that recognizes tribal governance.
 - May include timeline for approval of manuscripts and abstracts
- May not need such agreements when working in urban areas

Though this is a R01 ...

- Does not require previous pilot studies/data from the current community/tribe
 - It is not always possible to do a pilot and provide that data in these small communities where they are now proposing a full scale intervention/prevention study
 - But can use similar/appropriate studies as a basis for the current project and provide justification
- Generalization is NOT a requirement. Not required to generalize to other communities across the US. May be difficult or inappropriate to generalize to other Native American tribes/communities – but can talk about lessons learned

Community-Based Participatory Research (CBPR) Approach

- Research plan to be consistent with community attitudes & account for community readiness for the intervention
 - Research should incorporate a CBPR approach
 - Focus on community/cultural strengths and resiliencies
- Applications should demonstrate a partnership between tribes/communities and researchers
 - If the application does not come from the community, then the research organization is encouraged to partner with the community
 - If the application comes from the tribes/communities they are encouraged to collaborate with research organizations

Recruitment of Individuals and Communities

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- Evidence of community support and capacity to recruit participants in every community involved in the study
 - implement measurement and intervention protocols in the target population
 - provide appropriate oversight
 - maintain appropriate levels of recruitment and retention throughout the intervention and follow-up period
- Individuals recruited as part of a pre-existing non-intervention study may be proposed for inclusion in the proposed study, with justification & parent study approval

Ownership of Data and Data and Safety Monitoring Plan/Board

- Issues of ownership, control, and storage of data and biological samples should be addressed in the application
- Tribes/Communities may wish to retain ownership or control of data and biological samples and this is allowed
 - Partners can negotiate a formal and written data and biological sample agreement after the award
- Studies need to discuss a Data Safety Monitoring Plan. If needed the application may discuss establishing a Data Safety Monitoring Board

Innovation and Dissemination

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- Innovation/Novel nature of the application may be because they are adapting or developing interventions in these small populations and not necessarily a “new” or “novel” intervention
- Provide potential of the intervention to be incorporated into the medical care systems, public-health system, and/or community structure of Native communities
- Show how the intervention may be disseminated & the scale of the study expanded for implementation in the communities in which the study was conducted

Update

- Formation of IRINAH network of PIs to encourage:
 - Cross-collaboration on projects
 - Publications – Eg: *“The adaptation and implementation of a community-based participatory research curriculum to build tribal research capacity.”* [Jernigan VB¹](#), [Jacob T](#); [Tribal Community Research Team](#), [Styne D](#). Am J of Public Health 2015. Available at <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2015.302674>
- 22 currently funded projects
- Next review of proposals September 30, 2015
- Website for IRINAH
<http://cancercontrol.cancer.gov/nativeamericanintervention/index.html>