Intervention Research to Improve Native American Health

IRINAH

Update to TCAC – September 23, 2015
Participating Institutes

- 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
• 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

- 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

- 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

• 22 currently funded projects
• Next review of proposals September 30, 2015

• Website for IRINAH