

# NACE Technical Assistance Webinar



## NIH PAR-11-346: Interventions for Health Promotion & Disease Prevention in Native American Populations

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# Interventions for Health Promotion & Disease Prevention in Native American Populations

## I. Overview



# Technical Assistance Workshops Tentative Schedule\*

- Tucson – January 26, 2012
- Honolulu – March 1-2, 2012
- Oklahoma City – October 25, 2012
- Minneapolis – June 14, 2012
- Seattle – July 17, 2012 (NRN)
- Anchorage, AK – August 1 or 2, 2012 (AAIP)
- Fairbanks, AK – August 4, 2012

\*<http://cancercontrol.cancer.gov/nativeamericanintervention/>

# Focus of the Funding Announcement

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- Develop, adapt, and test the effectiveness of health promotion and disease prevention interventions in Native American (NA) populations.
- Native Americans include the following populations:
  - ▣ Alaska Native
  - ▣ American Indian
  - ▣ and Native Hawaiian\*

\*The term 'Native Hawaiian' means any individual any of whose ancestors were natives, prior to 1778, of the area which now comprises the State of Hawaii.

# NIH Partners\*



- National Cancer Institute
- National Heart, Lung, and Blood Institute
- National Institute on Alcohol Abuse and Alcoholism
- National Institute on Drug Abuse
- National Institute of Environmental Health Sciences
- National Institute of Mental Health
- National Institute of Nursing Research

\*This TAW focuses on substance abuse. If you are interested in one of the other institutes' programs, please talk with one of the contacts listed in the PAR.

# Application Due Dates



- PAR-11-346 : Interventions for Health Promotion and Disease Prevention in Native American Populations (R01)
  
- Application Due Dates:
  - May 15, 2012
  - May 15, 2013
  - May 15, 2014
  
- <http://grants.nih.gov/grants/guide/pa-files/PAR-11-346.html>

# R01 – Research Project Grants

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- ❑ Investigator-initiated
- ❑ Discrete, specified research
- ❑ 12 page limit for research strategy
- ❑ Awards renewable
- ❑ Up to 5 years (usually 3–5 years)
- ❑ 2 submissions—initial and 1 amended
- ❑ If > \$500K/year, must request NIH Center for Scientific Review (CSR)/Institute Program Director approval to submit

# Why Conduct Intervention Studies in Native Communities?

- Many research studies have been conducted in Native Communities, but very few of them are intervention studies.
- Communities have repeatedly said that they are tired of being studied and want intervention studies.
- Of those few intervention studies in Native Communities, many have been characterized by poor designs, and poor adherence to the standards of randomized controlled trials (ITT analysis, randomization, control groups).
- Although issues exist in conducting trials in Native Communities, trial standards should be met.



# Inter-relationships of Health Conditions

- ❑ HIV/AIDS and other risky sexual behavior
- ❑ Abuse of tobacco, alcohol, and other drugs
- ❑ Suicide
- ❑ Obesity, diabetes, cardiovascular disease
- ❑ Cancer
- ❑ These issues all have some basis in disease of the spirit.
- ❑ We should not just treat the symptoms, but address the underlying issues.

# Research Need in Native Communities



- Prevent and reduce risk factors (primordial and primary prevention);
- Increase screening rates for early detection of disease (secondary prevention);
- Partner with communities to:
  - Incorporate their concerns and issues;
  - Adopt methodologies that are relevant to AI/AN/NH populations; and
  - Design intervention studies to address the complex and multi-layered causes of health inequities.

# Goals of the Program - I



- Focus on multilevel design to target:
  - ▣ Individual behaviors; and
  - ▣ Social and institutional levels (familial and tribal)
- Interventions should incorporate community values, and may include traditional health, medical, and/or cultural practices.
- Adopt an ecological approach to the design, so interventions can be sustained.
- Intervene on at least TWO levels simultaneously:
  - ▣ individual/familial ; and
  - ▣ institutional/structural levels

# Goals of the Program - II

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- ❑ The intervention should not be so time-consuming that it exceeds the ability of people to participate
- ❑ Culturally appropriate and relevant
- ❑ Demonstrate community support & collaboration in research design - Strongly encourage using the community based participatory research philosophy
- ❑ Plans for recruitment & retention of subjects
- ❑ Propose a reasonable budget & timeframe
- ❑ Ensure adequate protection of humans and environment
- ❑ Include Tribal resolution or equivalent letter of support from the community

# Goals of the Program - III



- Coordinate activities across NIH.
- Have a special review with AI/AN/NH research experts.
- Dissemination of the Scientific Results to:
  - ▣ The involved Native communities
  - ▣ Scientific journals
  - ▣ Scientific conferences
- Disseminate successful interventions throughout Indian Country, Alaska, and Hawaii for adoption in other Native communities.

# For More Information:



- NIH grants process:

[http://grants.nih.gov/grants/grants\\_process.htm](http://grants.nih.gov/grants/grants_process.htm)

- NIH grant eligibility:

[http://grants.nih.gov/grants/grant\\_basics.htm](http://grants.nih.gov/grants/grant_basics.htm)

- New NIH Peer Review System

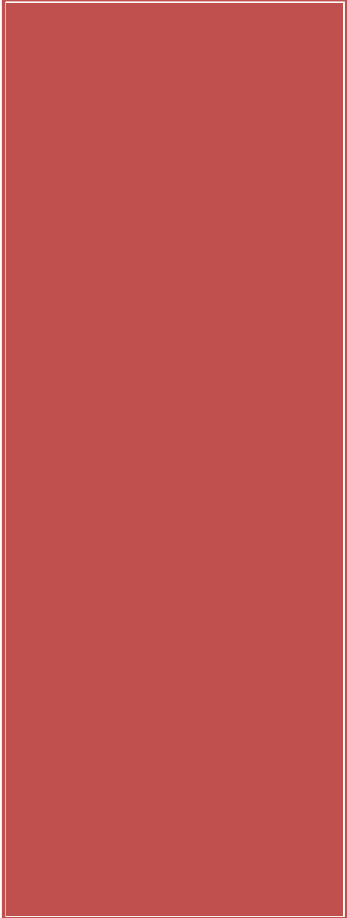
<http://enhancing-peer-review.nih.gov>

- Grants.gov help:

[http://grants.gov/agencies/grantors\\_help\\_resou.jsp](http://grants.gov/agencies/grantors_help_resou.jsp)

# Thank You for Your Attention!



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- Please visit the PAR's website:
    - ▣ <http://cancercontrol.cancer.gov/nativeamericanintervention/index.html>



# Interventions for Health Promotion & Disease Prevention in Native American Populations

## II. Preparing a Competitive Application





# Getting Started

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YOU HAVE A  
GREAT IDEA!



IS THIS THE  
RIGHT FOA?



# Understanding the FOA

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## □ Benefits

- Specific focus on Native American populations
- Three submission dates
- Special review
- Multiple NIH IC Participation

## □ Limitations

- Focus on research – not on services or demonstration projects
- R01 grant mechanism expectations
- FOA requirements for eligibility and responsiveness

# Partnerships: Community and Scientific

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- ❑ Buy-in of tribal or community leadership
- ❑ Selection of at least one PI with a strong scientific background
- ❑ Identification of consultants and staff to develop and execute the research plan
- ❑ Partnerships established prior to application preparation and submission
- ❑ Serious commitment to working together (and preferably a history of doing so)

# Specific Aims & Research Strategy

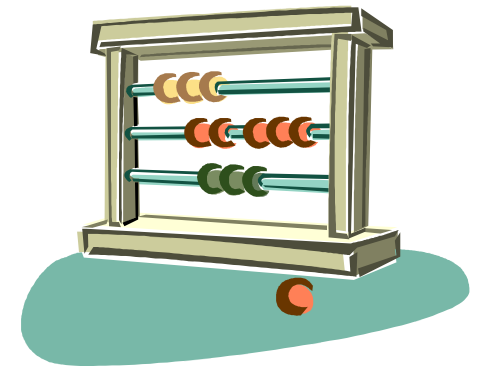
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- Specific Aims section of application should...
  - ▣ List the broad, long-term objectives and what the proposed research is designed to accomplish
  - ▣ State the main hypotheses to be tested
- Research Strategy section of application should...
  - ▣ Provide sub-sections on significance, innovation, and approach
  - ▣ Emphasize the study's potential impact based on the novelty and feasibility of the research and strength of the evidence to be produced and disseminated

# Measures and Data Analysis

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- Measures
  - ▣ Justify selection of measures and provide psychometric data when applicable
  - ▣ Explain the selection of any non-standard measures
- Data Analysis
  - ▣ Work closely with a statistician experienced in the analysis of behavioral trial data
  - ▣ Be certain to include a power analysis



# Pilot Data

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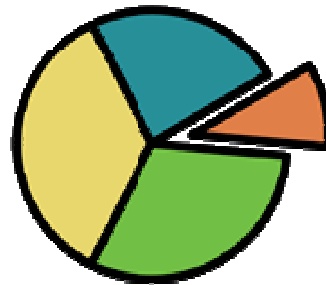
- A pilot study is a small, preliminary test or trial run of an intervention or of an evaluation activity such as an instrument or sampling procedure. The results of the pilot are used to improve the program before it is used on a larger scale\*
- Be certain to include pilot data
- Pilot data can take many forms; in some cases it may be necessary to take pilot data from a different community

\*National Science Foundation

# Important Additional Information

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- ❑ Human Subjects section
- ❑ Data and Safety Monitoring Plan
- ❑ Inclusion of minorities, women and children
- ❑ Appropriate use of appendices (e.g., letters of support)
- ❑ Information about investigators and environment



# Tips for Success

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- Follow directions carefully and present a logical, coherent explanation of the proposed project
- Use charts and graphs to your advantage
- Never assume reviewers will “know what you mean”
- Provide a timeline for the study and curb any tendencies to be too ambitious
- Submit a letter of intent



# Review of Grants

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- Special Committee with topical expertise
- Standard NIH Review Criteria
  - ▣ Significance
  - ▣ Investigator
  - ▣ Innovation
  - ▣ Approach
  - ▣ Environment
- All applicants receive a summary statement, which contains substantive feedback on the merits of their application



# Steps in Planning to Submit

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- ❑ Read FOA carefully and completely
- ❑ Get to know your authorized institutional official and be certain that your institution is prepared for electronic submission to NIH
- ❑ Prepare a 1-2 page concept paper and discuss it with a NIH program director
- ❑ Construct a timeline that includes getting feedback from tribal and scientific collaborators, securing letters of agreement, and allowing sufficient time for your institution to review and submit the grant

# Final Thoughts

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- Discuss ideas, concerns, and questions with a NIH program director/program official
- Work closely with study partners and peers throughout the process; seek to enlist the help of individuals who have had successful experiences with NIH grants
- Patience and perseverance are a necessity