Q&A FOR NACE/NIDA Webinar March 13, 2012

Q: Are there plans for Native American R03, R21, and R34 announcements? These also need special review committees familiar with Native research issues
A: At the current time there are no plans for these. We will be continually assessing what steps are needed to strengthen research in this area and will consider this and other suggestions.

Q: Would a project that includes a CBPR development of the intervention as well as testing of it be eligible?
A: The primary activity of the research project should involve tests of specific interventions. That said, the engagement of communities through CBPR and other collaborative models are important for the success of interventions. Thus, developmental research activities, such as a qualitative phase, designed to refine an intervention approach are permissible. Initial development of a partnership with a community should be done prior to submitting the application.

Q: Could you repeat the web site archive again please?
A: http://nace.samhsa.gov

Q: The Office of Minority Health also has wonderful resources for folks regarding funded proposals
A: OMH does have information on funded grants, but please note that they are not a partner of this Funding Opportunity Announcement.

Q: Can you please elaborate on how the research must adhere to 'trial standards.' In particular, could you provide any guidance to those of us considering a quasi-experimental, alternative to RCT design? Thank you!
A: For this FOA, adopting a RCT is not an explicit requirement. However, investigators should keep in mind that if possible, an RCT is highly desirable. If a quasi experimental design is proposed, a design that minimizes threats to internal validity as much as possible is important, and a one group before and after design is not permissible. When deciding what type of trial design to utilize, one should consider the relevant science and how to best address the specific aims and hypotheses of the study. Aspects of the design, such as what type of comparison group should be utilized, may vary depending on the type of science and the field of research, and the selection of a research approach must consider the needs to the tribes/communities. A strong justification should be provided for the type of trial adopted for the study.

Q: Is there a current PA or RFA at the R21 level that would be good mechanisms to consider for pilot work that might lead to this R01?
A: There is an “omnibus” or “parent” R21 PA, PA-11-261, that can be used: http://grants.nih.gov/grants/guide/pa-files/PA-11-261.html. In addition, some institutes have specific announcements that are relevant. Consider using PA-10-137:

http://grants.nih.gov/grants/guide/pa-files/PAR-10-137.html or NIDA's PA-11-312: http://grants.nih.gov/grants/guide/pa-files/PA-11-312.html.

Q: Getting a substantial population sample and decent power may be difficult in bush Alaska, especially for community nursing interventions (like home visiting with a tiny birth cohort). Is this the right FOA for this type of work?
A: We hope that the special review of these applications would allow for a proposal evaluation that balances the importance of a rigorous design with the realities of intervening in regions where it will be difficult to recruit the type of sample required for standard parametric statistical analyses. We encourage investigators to consider novel but robust approaches to address this concern such small sample methods. That said, an application should probably NOT propose to work in a single, small community. We encourage investigators to consider ways to enhance their potential sample such as through multi-community collaborations or technology-based interventions.

Q: What are the requirements for the control group? For native populations this can be challenging to find given the traditional interventions being studied. Can the control group be for a limited set of outcomes (e.g. service utilization and cost using)?
A: Control or comparison groups are expected. No treatment, wait-list, usual care, and alternative treatment comparison groups are all acceptable. Data should always be collected from the comparison group(s) on the primary variables of interest (i.e., those related to a particular health outcome or disease condition).

Q: What is the recommended number of PI's?
A: There is no recommended number of PIs. Each research project is expected to have unique needs and circumstances, and may benefit from a single PI or multiple PI arrangement. Note that if there is more than one PI, the investigators must prepare a multiple PI plan that justifies this decision and outlines the plan for project management and decision making. Each PI should have appropriate scientific credentials.

Q: Is it possible to add the contact information for those that have submitted successful applications?
A: The NIH Reporter is a search tool that lists the PIs and institutions that have received successful NIH applications: http://projectreporter.nih.gov/reporter.cfm. Please search this database to identify grants that are specific to your area of research.

Q: What is the letter of intent due date for May 15, 2012?
A: April 15, 2012 is the date by which those planning to submit an application by May 15 should notify the NIH. Submitting a letter of intent does not require one to submit an application. However, it helps NIH plan for the appropriate number of reviewers with specific areas of expertise.

Q: You have said, Dr Jobe, that the focus of this is on research - not services or demonstration projects - Is there a way of doing research that studies innovative health services or efforts that seek to demonstrate the value of an innovative approach?
A: Yes, but under certain circumstances. NIH provides funds for research, not for direct service delivery. However, NIH does fund research on the effectiveness of health services. This funding opportunity announcement is for health promotion and disease prevention, and certainly innovative preventive health services research would be welcome. If you have questions about what would be appropriate, please contact a program official from a participating institute.

Q: Could you write up an email announcement regarding this initiative and the technical assistance workshop dates and share? We can disseminate that information in via medical/tribal libraries and community based organizations working in the Indian country.
A: There is a website that provides this information. It is http://cancercontrol.cancer.gov/nativeamericanintervention/index.html. The link below provides information about future technical assistance workshops: http://cancercontrol.cancer.gov/nativeamericanintervention/webinar.html.

Q: If you submit in 5/2012, and need to resubmit a revision, do you have to wait until 5/2013 or will revisions be considered in rounds between May 2012 and May 2013? Thanks!
A: If you don't want to wait a year to resubmit your application, you can resubmit under a different funding opportunity announcement (note that it would have to be a R01 announcement). The disadvantage of doing this is that the application would not benefit from the special review panel—it would be assigned to a different study section. Before making this decision, it would be wise to discuss this with the program official who is assigned to your application.

Q: What is considered an adequate sample size?
A: This depends on a number of factors. We recommend that you work closely with a statistician who is experienced in working with clinical or behavioral intervention trials to determine the sample size given your unique situation. You should consider speaking with research colleagues or a program official if you need a recommendation. Each application should justify their sample size, in most cases, based on a power calculation.

Q: If you wanted to work in a CBPR and develop an intervention that you would then test, would that be an acceptable application?
A: Applications in response to this FOA must include an efficacy or effectiveness test of an intervention. If the application includes such a test as a primary focus, it would be acceptable.

Q: Can you speak about methods for doing an RCT using CBPR methods. Thanks!
A: There are researchers who have successfully conducted RCTs with Native American populations, and the way that CBPR is approached would depend on the context among other

factors. If you are unable to find examples in the literature, please contact a program official to discuss your unique circumstances.

Q: Who defines what is "culturally relevant" as relevance is different to each Tribal community.
A: We think that it is important to involve the community in every aspect of the research, because cultural relevance is dependent on the community. It is important that the individuals submitting applications come from the community and/or have a strong commitment to working with the community to produce strong science based on community perspectives.

Q: I'd like some more specific guidance on the Specific Aims section. Do you recommend that this be a list, or should there also be a narrative component? Thank you.
A: The Specific Aims section of the application can be no longer than one page and typically includes a narrative component providing a brief justification and description of the proposed work followed by a short list of research aims that highlight what the main objectives are of the the project. You may want to provide one or two explicitly stated hypotheses for each specific aim.