Title Slide: Community-Based Participatory Research

Jared B Jobe, PhD, F A B M R (Cherokee)
Program Manager for Recruitment and Outreach
Division of Cancer Control and Population Sciences
National Cancer Institute, NIH
JobeJ@mail.nih.gov

Slide 2: Learning Objectives

- Describe current NIH Funding Opportunity Announcements for Community-Based Participatory Research
- Describe some approaches/perspectives on research in Indian Country
- Describe tips for constructing a viable CBPR application

Slide 3: New OBSSR Trans-NIH FOAs

- PA-10-136, "Behavioral and Social Science Research on Understanding and Reducing Health Disparities (R01)"
- PA-10-137, "Behavioral and Social Science Research on Understanding and Reducing Health Disparities (R21)"

Slide 4: Goals of the Announcements

- Encourage behavioral and social science research on the causes and solutions to health and disabilities disparities in the U. S. population.
- Emphasis is on research in and among three broad areas of action: 1) public policy, 2) health care, and 3) **disease/disability prevention.** Particular attention is given to reducing "health gaps" among groups.
- Applications that utilize an interdisciplinary approach, investigate multiple levels of analysis, incorporate a life-course perspective, and/or employ innovative methods such as system science or community-based participatory research are particularly encouraged.

Slide 5: Examples of Approaches to the Prevention Area - I

- Identification of modifiable risk and protective factors for diseases/disorders/injuries that may differ across populations;

- Development of population-appropriate methods for screening and identification of markers for those at risk for onset or progression of asymptomatic diseases/disorders, or at risk for adverse high-risk behaviors/injuries;
- Using behavioral and social science theory and findings to develop and evaluate individual- or group-level interventions to promote health of individuals or populations without recognized signs or symptoms of the target condition;

Slide 6: Examples of Approaches to the Prevention Area - II

- Translation of proven effective prevention interventions in the general population into practice among populations that experience health disparities;
- Effectiveness studies that explicate behavioral and social factors related to the organization, management, financing, and adoption of prevention services and practices; and
- Methodological and statistical procedures for assessing risk and measuring the differential effects of preventive interventions among populations experiencing health disparities.

Slide 7: Why Conduct Intervention Studies in Indian Country?

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

Slide 8: Trial Designs

- Between-Subject Designs
    - Randomize individuals or families
    - Randomize schools or communities
- Within-Subject Designs
    - Multiple-baseline approaches (requires no carry-over effects from prior phase)

Slide 9: Group-Randomized Design: Fits Well in Indian Country

- Also called group allocation design or cluster-randomized design.

- Clinics, hospitals, schools, or communities are randomized, so everyone in that unit is allocated to that group.
- The unit of randomization and hence the unit of analysis is the school or community.
- Individuals are nested within the school or community.
- Has large implications for required sample size.
- Pathways had 41 AI schools; TAAG had 36 schools.
- Need new statistical tools for analyzing the data and reducing sample size.

Slide 10: What is the Proper Control Group?

- Placebo concurrent control
- Active treatment concurrent control (superiority or equivalence trial)
    - Usual care or standard care
    - Attention control
    - Comparison group (alternate or weakened intervention or lower dose) (often preferred by AI/AN communities)
- Dose comparison concurrent control
- No-treatment control
- Delayed intervention or wait-list control
- Historical Control (almost never scientifically acceptable)

Slide 11: Beyond Cultural Competence: Viewing Culture as an Asset

- Community/tribal culture can be an important motivation for participation in research:
    - Importance of keeping the culture alive
    - Importance of children and elders
- Community/tribal culture should be an integral part of any intervention.

Slide 12: Inter-relationships of Health Conditions

- HIV/AIDS and other risky sexual behavior
- Drug, tobacco, and alcohol abuse
- 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.

Slide 13: The Good Red Road of Life

Tobacco is for ceremonial use only.
Traditional meats are low in fat: bison, deer, wild birds, and fish.
Traditional native crops are the Three Sisters: maize, climbing beans, and squash.
Gathered foods are berries, nuts, roots, and greens.
Native North Americans were the first to play many popular sports such as ice hockey and lacrosse.
Canoeing and traditional dances are good exercise.

Slide 14: Community Partnered Approaches

- Understand the differences among the terms:
    - CBPR, community research, community-based research.
- CBPR requires community involvement in **ALL** phases of the project.
- Don't claim in your application that you will conduct CBPR if the community doesn't partner in **ALL** of the areas.
- Go with one of the other terms, and explain why.
- OBSSR definition on CBPR:
    - http://obssr.od.nih.gov/scientific_areas/methodology/community_based_participatory_research/index.aspx

Slide 15: Suggestions for Community Partnerships - I

- Describe the scientific, logistic, and organizational responsibilities of each partner.
- Describe the history of partnership collaboration.
- Submit necessary clearances with the application:
    - Tribal or consortia resolution
    - IRB(s) concept clearance
    - IHS if their personnel or facilities are being used

Slide 16: Suggestions for Community Partnerships - II

- Submit evidence of strong scientific capabilities.
- Submit evidence of community involvement and support.
- Emphasize human subjects protections.
- Include a Data and Safety Monitoring Plan.
- Include a Community Advisory Board.
- Use community members as intervention staff and measurement staff—and remember that they must be different people.
- Use a qualitative phase to work with the community to develop the specifics of the intervention.

Slide 17: Suggestions for Community Partnerships - III

- Communities/tribes are entitled to ownership or control of research data and biological samples. Negotiate an agreement.
- Communities/tribes are entitled to review and approve research protocols, abstracts, and manuscripts.
- Regional IRBs should not be allowed to review and approve manuscripts, unless specifically requested by the community—this is paternalistic.
- Partners should negotiate a reasonable time period for approval; passive approval occurs if no response within agreed time limits.

Slide 18: Previous and Upcoming CBPR FOAs

- Community-responsive interventions to reduce cardiovascular risk in American Indians and Alaska Natives. RFA-HL-04-023.
- Primary and Secondary Prevention of Chronic Diseases in AI/AN (Working Title) PAR

Slide 19: Peer Review in CBPR

- Most applications will be assigned to the Community Level Health Promotion study section:
  - http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescriptionNew/HDMIRG/CLHP.htm
- Strict review of the science
- Strict review of the community partnerships
- Must be strong in both to fare well at peer review
- Some reviewers occasionally have issues with the community's rights to data ownership and review of documents. They are usually over-ruled by colleagues.