



Principles and Guidelines for Community-University Research Partnerships

Purpose: The principles and practices described here are intended to facilitate forming an enduring, collaborative and beneficial research relationship between the Community and University. We believe that implementation will allow for partnerships that reflect mutual respect and cooperation.

Background: A research partnership between the University and the Community is ideally part of a larger collaboration that includes the interests of each partner and spans a wide range of activities. The University and the Community recognize that they often embody different cultures and missions. Nonetheless, the University and Community realize that combining their unique resources and perspectives can further the goals of both parties. The Community contributes valuable in-depth understanding of community norms as well as concerns related to research participation held by members of the Community. The Community further brings knowledge of sources of data and potential applications of the research findings to community settings. The University brings research resources and expertise to the partnership as well as the potential to attract additional resources. The University also provides opportunities for the Community to gain experience and develop the capacity to plan and conduct research independently.

What follows is a statement of principles (not formal policy) that reflects the ideal of community-based participatory research. While in some community-based research, such as multi-site clinical trials, it will be difficult to embody all of these principles, all such studies should make every effort to embrace them. We believe that an evolution of research toward the participatory model will benefit both communities and researchers, and we hope that academic and community partners will increasingly follow as many of the principles as possible.

Definitions: The terms 'Community', 'Community Research' and 'Community Partner' are widely used and variably defined in both the professional and lay literature. For the purposes of this Statement we have chosen to create definitions that encompass their meanings as broadly as possible (Dunbar-Jacobs & Hipps, 2006).

- **Community:** The term may be applied to one or more of the following:
 - A. a defined geographic or political area such as a neighborhood, town or region;
 - B. a population that possess certain common characteristics such as its race, ethnicity, age or gender;
 - C. an entity that functions in society (and outside of the researcher's own institution) such as a business, civic organization, educational facility, religious group, or governmental agency.
- **Community-Based Research:** Research that draws upon the Community's (however variously defined above) resources in terms of subjects, data, personnel, material or other support.

- **Community-Based Participatory Research (CBPR):** This refers to a specific model of community-based research in which the researcher and individuals and/or entities in the Community create a partnership that identifies questions of mutual interest, conducts studies that reflect mutual input and derive outcomes that provide mutual benefit (Israel, Schulz, Parker, & Becker 1998).
- **Community Partner:** Individuals and/or entities within the Community who may fairly represent their interests, needs and/or concerns because they are both knowledgeable about and empowered to represent that Community. Community partners are sought for research based on this expertise and not simply because they control the resources to facilitate the desired study.

Ethical Principles: A foundational document in the research ethics literature is the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) which named three fundamental ethical principles applicable to human research: Respect for Persons, Beneficence and Justice. In this document, these ethical principles have been expanded to include their application not only to individual research subjects but also to interactions between the research partners, e.g. between a university and external collaborating institutions, agencies, and/or communities as follows:

- (1) **Respect** includes individuals and communities.
 - a. Respect for persons includes honoring the rights of all potential research subjects and taking measures to protect vulnerable individuals in the Community who may be potential research subjects (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).
 - b. Respect for community goes beyond honoring the rights of individuals to include considering the effects of the research on the Community itself - for example, by considering the effect of the research results on a community's self-perception or beliefs, on perceptions outside the community, or on health care delivery within the community (Working Group for the Study of Ethics in International Nursing Research, 2003).
- (2) **Beneficence** means that research will be designed to minimize harm or the potential for harm and to maximize benefits to the individual and/or the community.
- (3) **Justice** focuses on the equitable selection of subjects and sharing of results with the community.

Considerations in applying these principles

Integrating ethical principles into the research process to create a respectful, beneficial and sustainable Community-University Partnership requires a mutual commitment to Implementation Strategies. These should include the following:

Strategies:

- (1) Create an Ethical Framework: A set of operating principles must be agreed upon that define the ethical conduct of the research partnership.
- (2) Promote Diversity: Recognizing that the Community is diverse in multiple aspects, mechanisms should be identified to ensure that Community involvement is as broadly

representative as possible. The University also is recognized as representing a diverse community.

- (3) Share Decision-Making: Members of both the University and Community should participate in the planning, review and approval of community-based research.
- (4) Share Benefits: Given the legitimate contributions of both the University and the Community partners, the rewards derived from research should be shared in a way that reflect the needs and contributions of each member of the research partnership.
- (5) Train Research Partners: It is essential to train University and Community partners in the research endeavor, so that each develops an understanding and appreciation of the requirements of designing and conducting research, as well as the contributions of each partner to the endeavor. It is important to the success of this training that it be a joint process and that both partners periodically evaluate its effectiveness.

Implementation Strategies:

- (1) Create an Ethical Framework: Each partner has certain responsibilities. Among the most important of these is that each should recognize the other's needs and empower the other to assert its unique rights within the relationship. We recommend that as part of the development and implementation of any research project, Community and University partners sign a letter of understanding that specifies the agreed understanding and discloses any known or anticipated risks and benefits to the individual/institutional partners.

Roles of the University in the Partnership

- a. The University should be familiar with the important issues facing the Community that would be appropriate for a research study, and should familiarize themselves with the potential partners in the Community who might be in a position to collaborate in research projects and/or to represent its interests.
- b. The University should ensure that potential Community partners are educated about the process of research development, approval, implementation, analysis, and dissemination and the time lines over which each of these occurs so that they can participate meaningfully in each step.
- c. The University should ensure that potential Community partners are capable of thoroughly assessing the potential risks and benefits of their participation in research studies and determining whether their participation meets the standards of a true partnership. Where potential Community partners lack a formal review mechanism, a model process should be developed in cooperation with the Community for such use.
- d. University Researchers should ensure that the individuals within the Community groups or agencies with whom they are negotiating fully understand the purpose and the implications of the proposed research and the research partnership so as to make informed decisions about their participation.
- e. University Researchers should have and provide proof of liability coverage for any negligent acts arising from activities performed in the course of the research partnership in amounts and scope adequate to provide coverage for negligent injury to patients, subjects and Community partners arising from the research.

- f. University Researchers should involve Community partners in the planning of studies as early as possible so that they can contribute to each step of the research process.
- g. University Researchers should involve Community partners as early as possible in discussions about the potential uses of all data to be collected, including a dissemination plan for the sharing of the research findings with the wider Community, and should develop a process for handling findings that may reflect negatively and thus cause harm to one or both partners.
- h. University Researchers should involve Community partners during planning for funding of the study, acknowledging and budgeting for activities commonly funded in research grants that are performed by the Community agents or groups during the course of the study.
- i. University Researchers should be willing in the early stages of planning the research to (a) add research questions to data collection instruments that are important to the Community agency or group and are relevant to the study and (b) include the findings from these additional questions in their data analyses.
- j. University Researchers should appropriately acknowledge the contributions of Community partners and their key staff in any publications and presentations resulting from or related to the research and should, whenever possible, encourage participation by interested staff of the Community partner in the preparation of those publications and presentations; staff should be named as authors when their contributions are at the level expected for authors of scientific publications.

Roles of the Community in the Partnership

- a. Potential Community Partners, in anticipation of committing to participate in the research process, should ensure that they are educated in the various steps of a study's development, approval, implementation, analysis, and dissemination of findings as well as the time lines over which each of these steps occurs by availing themselves of individual and/or organizational training opportunities.
- b. Potential Community Partners, in anticipation of committing to participate in the research process, should establish a process of internal review and approval to ensure that any proposed studies are appropriate for the Community Partners' involvement and will not impair their ability to meet their organizations' missions.
- c. Potential Community Partners, in anticipation of committing to participate in the research process, must establish an infrastructure to ensure that they will meet all ethical and regulatory standards, including Human Subject Protection standards and policies, and must agree to undergo relevant training equivalent to that required of their University collaborators.
- d. Community Partners must accept the authority and requirements of the Institutional Review Board approving any research protocol in which they plan to participate.
- e. Community Partners must adhere to the same Conflict of Interest standards that are required of their University collaborators.
- f. Community Partners must adhere to the same conditions for the use, maintenance, security and disposal of research data that are required of their University collaborators.
- g. Community Partners should review and comment on drafts of any research participant information sheets and data collection forms prior to their use to ensure

that the final forms are acceptable to the Community participants from a social, cultural, linguistic and literacy viewpoint.

- h. Community Partners should, to the greatest extent possible, look beyond their own immediate needs and take steps to maximize the benefit of the research they are partnering in to the larger Community.

(2) **Promote Diversity:** A true partnership requires that the University and the Community recognize and appreciate each other's diversity, and understand the importance of this diversity to the long term success of the partnership. To realize the goal of true community engagement, therefore, a Community-University partnership should:

- a. Develop a thorough baseline knowledge of the community - its history, its demographics, its resources, its weaknesses, and the relationships that exist within it.
- b. Assess the Community's needs and identify priority issues by a process that seeks the broadest possible representation and strives to reach the greatest possible consensus. Needs and issues identified in this manner should be shared with interested members of the University so that they may be included in other University research agendas.
- c. Identify potential partners and determine their capacities to collaborate in various studies. All reasonable efforts should be made to offer opportunities equitably so that as many partners as possible participate in as many studies as possible given their abilities and interest to meaningfully contribute to them.
- d. Ensure that beneficiaries of the research reflect the diversity of the community as broadly as possible.

(3) **Share Decision-Making:** For the Community and its various constituencies to have confidence that research is not only appropriate but also beneficial, the Community should be involved in the research approval process sufficiently early to allow meaningful influence on a study's design where appropriate to improve benefits and reduce risks. How this sharing in the approval process will be implemented may vary from community to community.

- a. The engagement of the Community in the approval process should be enhanced through one or more mechanisms:
 - strengthening the role of the Community membership in the current IRB process
 - creating a Community Advisory Board
 - requiring a specific and detailed letter of support and understanding of roles and responsibilities from planned Community partners
- b. In addition to enhancing Community participation in the approval of specific studies, a mechanism such as a Community Advisory Board should be created to provide ongoing Community input into the larger research agenda and the University-Community partnership.

(4) **Share Benefits:** The potential benefits accrued through participation in research are many and vary according to the participant or the community at large. Within the academic setting, salary support, reputation, tenure, and increased chances for further funding are but a few of the individual benefits, while the University garners prestige,

funding for its research mission, and an enhanced ability to recruit other faculty and to attract additional resources. Community partners can similarly benefit through database development, program evaluation, and acquisition of data that will support additional projects, programs or grants, the creation of patient education materials, staff training/mentoring - all of which can provide both programmatic support and build capacity for independent research. Opportunities for benefit to the research partners and the populations recruited into the study should be built into each research project to the fullest extent feasible.

- a. University and Community partners should develop a plan for dissemination of research findings within the Community. Elements of a comprehensive dissemination plan can be found in the Yale Center for Clinical Investigation/Community Alliance for Research and Engagement publication, "Beyond Scientific Publication: Strategies for Disseminating Research Findings".
- b. University researchers should help to educate the Community to recognize which contributions to the research endeavor represent legitimate costs in the eyes of funding agencies so that Community partners have realistic expectations when negotiating a budget for a given study.
- c. University researchers should recognize and design studies with respect for the essential missions of most of their potential Community partners which are patient care and/or client services, not research.
- d. University researchers should work collaboratively with each partner to identify and maximize collateral benefits that might reasonably accrue to the Community partner during the conduct of the planned research.
- e. The University should facilitate access to key resources such as skilled epidemiologists, data analysts and IRB staff, who can work with Community agents and groups to enable them to participate in University studies.
- f. The University should encourage and be willing to partner with Community agents or groups that wish to take the lead in research studies.

Train Research Partners: It is essential to train both partners in the research endeavor, so that each develops an understanding of the requirements and the contributions of each partner to the conduct of research. Training also promotes acceptance and advocacy for the priorities of community research by both Community and University partners and empowers the Community to pursue research opportunities. Training takes many forms including formal training materials as well as informal interactions between research partners. These educational interactions should strive to meet the goals outlined below.

Training for All Partners

- a. Educate all researchers regarding the principles and the importance of Community-University research partnerships, so that no matter where they may subsequently work, they will continue to use and disseminate these principles whenever opportunities for Community-University partnerships arise.
- b. Identify key values and other components of each partner's culture and ensure that each research partner understands and respects the differing perspectives and priorities of the other. All researchers should be informed that this process for

developing understanding and respect is a necessary step whenever one is engaging in research with new partners.

- c. Create mentoring partnerships by identifying interested Academic and Community members which help the latter to develop basic research skills and acquire experience by participating in actual studies while also providing the former with the opportunity to learn about Community values and resources.

Training for University Partners

- a. Educate researchers about issues of significant interest to the Community to identify and facilitate studies of value to the Community.
- b. Inform researchers about potential Community partners whose work overlaps with the area of their studies to facilitate the establishment of working relationships.
- c. Inform University researchers about potential sources of data within the Community that could be used to support the development and/or the conduct of research studies.
- d. Educate University researchers about how to design research projects to reflect Community conditions, capacity and constraints so as to enhance the quality of the studies.
- e. Educate all IRB members about the principles and the importance of Community-University research partnerships.

Training for Community Partners

- a. Create opportunities for Community members to receive training in the various aspects of the research process.
- b. Inform the Community about potential academic partners whose work overlaps with their interests or organizational missions to facilitate the establishment of working relationships.
- c. Inform the Community about sources of data and other evidence-based information that would be of value to the Community.
- d. Educate the Community in the grant writing process to better enable Community partners to respond to funding opportunities in a timely and competitive fashion.
- e. Familiarize the Community with the process of identifying potential sources of funding for research projects and capacity building.

References

- Dunbar-Jacobs, J. & Hips, L. (2006). *CTSI Community Partners Program*. University of Pittsburgh Clinical and Translational Science Award Proposal, National Institutes of Health: S. Reis, Principal Investigator.
- Israel, B., Schulz, A.J., Parker, E.A. & Becker, A. (1998). Review of community-based research. *Annual Review of Public Health, 19*, 173-202.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. OPRR Reports. Appendix 6, A6-7-A6-14.

Working Group for the Study of Ethics in International Nursing Research (2003). Ethical considerations in international nursing research: A report from the International Centre for Nursing Ethics. *Nursing Ethics*, 10, 122-137.

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