UNC
THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

GUIDELINES FOR CONDUCTING PRACTICE-BASED RESEARCH

The goal of this document is to outline general recommendations for the conduct of clinical and translational research involving University faculty and community medical practices and other community partners.

General Principles

1. Research involving community medical practices or other community groups should be carried out as a partnership that is beneficial to and respectful of both parties. Such successful relationships will enhance the performance of high-quality community-based research, and continued involvement of these partners in research activities.

2. The research should address questions relevant to one or more of the following:

- improvement in the health of North Carolinians
- improved delivery of healthcare services
- better understanding and/or management of problems commonly encountered in primary care and/or
- other community-identified health care concerns including access to care.

Definitions, General Description and Organization

Practice-Based Research Networks (PBRNs) are groups of clinicians, practices and researchers who work together to answer community-based health care questions and translate research findings into practice. PBRNs engage clinicians in quality improvement activities and an evidence-based culture in primary care practice to improve the health of individuals and communities.

Community Engaged Research is the process of working collaboratively with groups affiliated by geographic proximity, special interest, or similar situations to address issues affecting their well-being or the well-being of their community. It is a powerful tool for bringing about changes that will improve the health of the community and its members, by engaging individuals in the development of the research questions, methods, interpretation of the findings and research dissemination.

Community Partners include churches, non-profit organizations, patient advisory boards, and other community groups committed to improving the health and healthcare of their constituents and who are interested in partnering with NC TraCS investigators in research.

NC TraCS Practice-Based Research Networks

Expanding Networks for Latinos through Community Engagement (ENLaCE)
Director: Dan Reuland, MD, MPH
Website: **www.tracs.unc.edu/index.php/enlace**

Goal: To foster the enhancement of the body of knowledge relevant to the health of NC Latino communities through translational research. We will do this through the conduct of engaged research projects involving our regional working group partners, as well as by offering a set of research services to scholars that are interested in Latino health research.

North Carolina Child Health Research Network (NCCHRN)
Director: Tamera Coyne-Beasley, MD, MPH

Goal: To build partnerships between community organizations, North Carolina community based and ambulatory practices, and research communities. Through collaborative research and dissemination this

network will maximize the translation of scientific discoveries into real world applications for the advancement of child and adolescent health and well-being through policy and practice.

North Carolina Network Consortium (NCNC) – a consortium of primary care research networks **Co-Directors:** Katrina Donahue, MD, MPH and Jacquie Halladay, MD, MPH
Associate Director: Madeline Mitchell, MURP
Website: **www.ncnc.unc.edu**

Goal: To address pressing questions related to the delivery of healthcare services, investigate the management of primary care problems, and to carry out statewide and national research related to the delivery of primary care services and the improvement of population health

Affiliated PBRNs:
E-CARE: Eastern Carolina Association for Research and Education (ECU)
MAPPR: Mecklenburg Partnership for Primary Care Research (Carolinas Medical Ctr)
NC-FM-RN: North Carolina Family Medicine Research Network (UNC)
PCRC: Primary Care Research Consortium (Duke University)
RCPCrN: Robeson County Primary Care Research Network (UNC)
NCCHRN: North Carolina Child Health Research Network (UNC)
NC MARCH: NC Multi-disciplinary Adolescent Research Consortium for Health (UNC)
UNCPN: UNC Physicians Network

Guidelines for Investigators Working with PBRNs Prior to Submission

1. Meet face to face with PBRN staff and investigators at least TWO to THREE months prior to submission. If you contact us with a short deadline, we may not be able to assist you or may only be able to provide limited assistance.
2. Discuss with the PBRN directors and staff their role in the project if funding is obtained.
3. Determine with PBRN Director(s) whether PBRN leadership and/or staff will be included in the proposal budget. If so, discuss the specifics and review the budget and budget justification with the PBRN leadership. If not, how will the PBRN effort be compensated or acknowledged? Budget discussions should also include compensation for practices and/or partners who will be engaged in the research.
4. If the PBRN has a role in the project after funding, expectations for PBRN leadership or staff with regard to manuscript development and authorship should be agreed upon before the proposal is submitted.
5. Discuss the project timeline and milestones.
6. Clarify the role of PBRN staff in practice recruitment.

Practice/Subject Recruitment Assistance

1. NCNC directors and staff have specific recruitment expertise in the medical practice setting and will assist investigators with this only when involved during the pre-award stage. In most cases this requires that PBRN staff members and/or Director(s) are included in the project's budget. This is a critical element to enhance the probability of successfully reaching study recruitment goals.
2. A separate meeting with PBRN Directors/staff and investigative teams interested in working with practices may be needed to clarify this key item as recruitment strategies are best handled at the proposal development stage and then altered as needed at the time of funding and study roll out.

Guidelines for Working with Practices and Patients

Before recruiting patients or practices, approval from your institutional review board (IRB) is required.

Practices

1. In general, it is expected that the project's PI attend an on-site visit to each practice or practice organization during proposal development. Recommended procedures for practice recruitment include the following:
   a) If the practice is part of a larger organization, a representative from the governing organization should be included in all discussions. Often, a meeting with the organization's representative is the first step.
   b) Practice recruitment visits should include a lead provider and the practice manager.
   c) Whenever possible provide food appropriate for the time of day of the meeting.
   d) Prepare a 1-page document that briefly summarizes the project goals and specifies what each party (the practice staff and the research team) is expected to do.
   e) Explain exactly what compensation will be provided to the practice including a timeline for payment.
2. When, how, and how much to involve practices in research conceptualization and design should depend on the project. In general, consultation with primary care physicians is highly recommended as part of research development. The degree of involvement of specific practitioners and practices will, however, depend on the interest of providers in research, and should balance the value of provider involvement with the time burden incurred.
3. Asking practices for letters of support for grant proposals may be considered an unnecessary burden on practices, if the research is being proposed in partnership with a PBRN or other entity that has a track record of working successfully with practices (and can cite that success), especially if selection of practices would be better done after funding than at the proposal stage. On the other hand, if one or more practices has been involved in conceptualization and development of the proposal, then a letter of support is appropriate.
4. When initiating a study, practice staff should be actively involved in decisions regarding the process of data collection in their practice.
5. Practices should be paid for involvement in research to compensate for provider and staff time required for meeting participation, assistance with subject identification and enrollment, participation in data collection, and other research-related tasks. The time and effort of practice staff involved in a study should be reimbursed in a manner that adequately reflects the effort required, as is true for any research involving community groups. The minimum amount recommended for a very "low touch" project is $1000/practice.
6. For any given project, each practice should have one or two key contact persons (project leaders) with whom the research study has primary communication.
7. Any practice participating in a study should have the opportunity to receive the study results. The optimal way to present results is in person; however, if that is not feasible, a written report and copies of any published manuscripts should be provided to the practices. Practices also may be interested in knowing if results will be presented at a conference or meeting.

Please understand that UNC, NCNC Directors, and affiliated investigators and staff have spent over 10 years developing and nurturing our relationships with practices and community members. All practices should receive a thank you note, letter, and/or certificate of participation after (or, in the case of a certificate, during) participation in a site visit or study**.**

Patients

1. All patient participants should be reimbursed commensurate to the amount of time and effort required for participation. If you have questions about reimbursement, we would be glad to provide guidance about the amount and timing.

2. All studies should follow Federal guidelines for the protection of the rights of human subjects and be

reviewed and approved by the appropriate Institutional Review Board (IRB) prior to initiation of data collection.

3. Consider providing signs/brochures to be placed in waiting rooms to inform patients about the study and to thank them for their participation.

Acknowledgement of Funding Source

Each funding agency may have its own acknowledgment requirements.

Examples

This publication was made possible by Grant Number from NIAMS/NIH.' or 'The project described was supported by Grant Number_____ from NIAMS/NIH.

This research was supported by Grant XXXXXXXXX from the Agency for Healthcare Research and Quality.

For TraCS Supported Projects, include the following acknowledgement:

This project was supported by Award Number 1UL1TR001111 from the National Center for Research Resources. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health.

Manuscript Development

It is the responsibility of each project principal investigator(s) to ensure that: manuscripts are of the highest quality; study designs are described consistently across manuscripts; variables defining the same constructs are measured consistently across analyses; appropriate authorship credit is given to those contributing to various aspects of the work, and that appropriate stakeholders and PBRNs are acknowledged.

Authorship

Each manuscript will have a lead author. Typically, this will be a study team member who puts forth substantial effort on the project and drafts the majority of the manuscript. Not all members of a study team need be included on every publication. Instead, authorship and the order of authorship will be determined by the lead author, based on the amount of the effort put forth on a specific paper. It is the responsibility of the lead author to ascertain that all authors meet the criteria outlined below.

All authors on a paper must make substantial contributions to the manuscript, including matters related to conceptualization, formulation of analysis plans, synthesis of results and/or drafting subsections of the manuscript. The specified manner of participation will be determined in consultation with the lead author and principal investigator(s). It is expected that co-authors will be active, regular participants in discussions pertaining to manuscript design and the analysis and interpretation of data. Also, to facilitate timely completion of manuscripts and to make the best use of the group's diverse expertise, responsibility for writing different aspects of the manuscript will typically be shared among co-authors so that all authors contribute significantly to the finished work.

Following guidelines on authors' professional and ethical responsibilities (Annals of Internal Medicine, Vol. 127, No. 10, 1997), authors should meet all of the following criteria:

1. Conceived and planned the work that led to the paper and/or interpreted the evidence it presents.
2. Drafted the paper or reviewed successive versions and took part in the revision process.
3. Approved the final version.

Practice-based Research Toolkit

A website with tools for practice-based research: http://www.researchtoolkit.org/