Conducting Research in Healthcare Settings
NC TraCS Guidelines

Research in healthcare settings with patients and the providers and staff who care for them can produce profound and lasting improvements in health and healthcare.

> *Do you want to conduct practice-based research, but you don't have access to clinics?*
> *How do you begin to build relationships with practices?*
> *How do you earn trust and avoid over-burdening clinical personnel?*

This document outlines recommendations for researchers interested in conducting clinical and translational research involving medical practices and other community partners.

General Principles

1. Practice-Based Research should be conducted as a partnership between researchers and practices that is beneficial to and respectful of both entities. This model helps to ensure successful, high-quality research while promoting strong and sustainable relationships.
2. Research should address questions relevant to one or more of the following:
   - Improving the delivery of healthcare services
   - Improving our understanding and/or management of problems commonly encountered in primary care and other clinical settings
   - Improving the health of North Carolinians

Definitions, General Description and Organization

Practice-Based Research Networks (PBRNs) are groups of clinicians, practices, and researchers who work together to address pressing health care questions and translate research findings into practice. PBRNs engage clinicians in quality improvement and research activities and promote the use of evidence in primary care practice to improve the health of individuals and communities.
Community Engaged Research is the process of conducting collaborative research with various stakeholders (including local clinics, businesses, agencies, or community groups) to address issues affecting the well-being of those groups. It is a powerful tool for bringing about change more effectively because it engages individuals that are affected by the research in the development of the research questions, methods, interpretation, and dissemination.

Our Practice-Based Research Network

> **North Carolina Network Consortium (NCNC**) – a consortium of primary care research networks
> Co-Directors: Katrina Donahue, MD, MPH and Jacquie Halladay, MD, MPH; Pediatric and Adolescent Director Michelle Hernandez, MD
> Website: www.ncnc.unc.edu

Affiliated Practice-Based Research Networks:

- E-CARE: Eastern Carolina Association for Research and Education (East Carolina University)
- MAHEC: Mountain Area AHEC
- MAPPR: Mecklenburg Partnership for Primary Care Research (Atrium Health)

- NCnet: Practices and Practice Networks associated with UNC-Chapel Hill
  - NCCHRN: North Carolina Child Health Research Network
- PCRC: Primary Care Research Consortium (Duke University)

Pre-award: Preparing to submit your proposal

Get to know your PBRN

Please understand that UNC, NCNC Directors, and affiliated investigators and staff have spent over 15 years developing and nurturing our relationships with practices and community members. Always remember to treat clinic staff with respect to maintain relationships during your study and for future opportunities.

Meet face to face with PBRN staff and investigators at least THREE months prior to submitting your grant. The earlier the better.

Details you'll want to be thinking about prior to the first meeting:

1. Project timeline and milestones
2. Level of practice burden and division of labor between clinic staff and research team
3. Types of practices that are appropriate for your project and how they can be accessed
4. Role of PBRN staff in your study
5. Your budget

Developing your Budget – Practice-based research is likely to have specific types of costs that must be considered when creating a budget. These may include:

1. Training needed to participate as a site in the study, including general research training (like CITI) or other study-specific training
2. Time spent by practice-level providers and staff answering questions about the study from patients, other staff, and others
3. Identification of potential study participants
4. Data collection or IT support with the Electronic Health Record (EHR)
5. Coordinating with the research team, including regular study update meetings
6. Other administrative tasks

Types of compensation

1. Practice payments (typically ~ $1,000 for a "low touch" project)
2. Individual payments (to patients, specific staff members, etc.)
3. Healthcare system/practice network payments
4. Providing CME/CEU
5. Equipment/software/materials that the practice can use or keep

Budget for PBRN assistance:

1. Decide if PBRN leadership and/or staff will be included in the proposal budget
2. Discuss the specifics and review the budget and budget justification with the PBRN leadership
3. If you do not include the PBRN leadership and staff on your budget, determine how any PBRN effort be compensated or acknowledged

Designing the Research

1. When, how, and how much to involve practices in research conceptualization and design should depend on the project. In general, consultation with primary care or other relevant physicians is highly recommended as part of research development. The degree of involvement of specific practitioners and practices will, depend on the interest of providers, and how research activities balance with the expectations of clinicians to reach productivity and other targets (teaching, service, etc.)
2. NCNC has 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.

Preparing a One Pager

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 and how clinic work flow may be impacted during study implementation. Share the "how" and spend less time on the "why" as clinicians and administrators know that there are hosts of health conditions that need more research.

Approaching Practices or Practice Networks pre-award and Obtaining Letters of Support (LOS)

There are times that partnership with a PBRN by itself is sufficient. However, practice networks often require pre-award consultation to ensure the project meets their institutional goals and that they have the capacity to participate. For this meeting they will want to see your 1-pager rather than a draft of your grant. Asking individual practices for LOS's for grant proposals may be an unnecessary burden on practices. Research that is being proposed in partnership with a PBRN or practice network a letter of support should be obtained from the PBRN and/or practice network. On the other hand, if one or more individual practices has been involved in the development of the proposal, then a letter of support may be appropriate from those individual practices.

Post Award: Next Steps

Recruitment

1. Before recruiting patients or practices you must get approval from your institutional review board (IRB).
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.

Working with Practices and Patients

Practices

1. It is generally expected that a project's PI attend on-site visits to each practice during recruitment. Recommended procedures for practice recruitment include the following:
    - Review and update your one pager

- If the practice is part of a larger organization, approaching the organization's leadership is the first step and clarify practice payments and administrative details
- Practice recruitment visits should include a lead provider and a practice manager
- If possible, provide food appropriate for the time of day of the meeting
- Explain the compensation for the practice. Include a timeline for payment

2. Involve the practice staff in all decisions regarding the process of data collection in their practice.
3. Identify one or two key contacts for your project (practice champions) with whom the research study has primary communication
4. Acknowledge practices after site visits and at study end with a thank you note or letter
5. Certificates of participation should be awarded to all participating practices during the study

Patients

1. Reimburse all participants based on the amount of time and effort required. We can provide guidance regarding amounts and timing for compensation
2. All studies should follow Federal guidelines for the protection of the rights of human subjects and be reviewed and approved by the appropriate IRB prior to initiation of data collection
3. Consider providing informational signs/brochures for the waiting rooms and include a thank you for participants

As Your Study Wraps Up

Acknowledgement of Funding Source

In addition to following your funder's requirements, projects that we assist should cite the CTSA grant (UL1TR002489) that provides infrastructure support for our PBRN work.
See: https://tracs.unc.edu/index.php/who-we-are/cite-ctsa

Manuscript Development

1. Set authorship expectations at the beginning of your project.
2. It is the responsibility of each project principal investigator(s) to ensure that appropriate authorship credit is given to those contributing to various aspects of the work. This may include PBRN researchers and staff, stakeholders, community partners and providers or staff from your practices.
3. Follow guidelines on authors' professional and ethical responsibilities.
   See: http://annals.org/aim/fullarticle/710244/uniform-requirements-manuscripts-submitted-biomedical-journals

Dissemination

Share the results of the study with the practice. Ideally, present results in person. At a minimum, develop a brief report of the findings and provide copies of any published manuscripts to practice leaders and staff. Practices may want to know when results are presented at a conference or meeting and many are interested in partnering with the research teams on scholarly products (posters, manuscripts, presentations) or leading their own scholarly products.

Practice-based Research Toolkit

A website with tools for practice-based research: http://www.dartnet.info/clinicaltrialsPBRNtoolkit.htm