

Guidelines for Research Studies Involving Clinical Practices or Community Partners

Clinical research increasingly involves partnerships between researchers, clinical practices, and community organizations. Although faculty members whose primary roles are in research are typically the ones to initiate and obtain funding for these projects, faculty in the clinic and leaders in community organizations should be regarded as potential research collaborators. Research projects that involve clinics or community organizations must involve the stakeholders throughout the entire research project from planning through dissemination of results. Stakeholders are broadly defined as clinic directors, clinicians, clinic staff, business managers, and comparable positions in community organizations. Patients and their family members are also stakeholders in these settings.

The following are guidelines that researchers should incorporate into research projects that involve clinical practices or community organizations. The guidelines are written primarily in the context of a clinical partner, with the understanding that parallel practices should be done with a community partner.

Planning

The researcher should engage the clinical or community partner from the very beginning when planning a research project. Discussion with the clinical/community partner should begin well in advance of a grant submission and before the budget is finalized. The following are key considerations when planning a research study involving a clinical practice or community organization:

- Discuss whether the project is of interest to and considered a priority by the clinical practice or community organization. Involvement of patients and their families as stakeholders in these discussions is strongly encouraged.
- Discuss how the project is likely to benefit patients or clients of the organization. This may be immediate direct benefits to the patients or indirect benefits that occur over time.
- Seek input from key stakeholders in the clinic or organization (providers, staff and patients), particularly faculty that are potential research collaborators.
- Discuss the research strategy with key stakeholders to ensure that study procedures are feasible, sustainable, and desired by the patient community.
- In collaboration with the clinic director or community partner, determine what resources (e.g., personnel, space) will be needed to conduct the research.
- Develop a research budget that adequately covers the costs incurred by the clinic. The budget should include both direct and indirect costs and staff time.

- Obtain approval to conduct research in the clinic or the community organization from the division chief, clinic director, community organization leader, or his/her designee. Approval is needed for:
 - Access to the clinic and its patient population
 - Commitment of faculty and staff time and effort. Be aware of and plan for the fact that budgeted monies to secure the time and effort are likely to be required.
- Be aware of and follow any formal approval processes within Duke (e.g., Primary Care Research Advisory Board), the clinical practice and/or the community organization.

Implementation

- Have ongoing conversations with the clinic director, community organization leader, or designee about the study progress.
- Maintain communication/troubleshooting to enhance research agenda and to minimize disruptions to clinic or organization flow.
- Keep clinic/community partners aware of any changes in the scope of research and the research protocol.
- Keep the clinic/community partners informed of any adverse events related to research.
- Recommend that clinic or community partners maintain a binder (hard copy or electronic) with a description of the protocol and approval documents.
- Consider development of a patient advisory committee for the project to secure and maintain patient engagement in the project.

Analysis and Dissemination

- Consider in the analysis feasibility and sustainability questions that are important to clinic and community partners (e.g. not only is intervention effective but also how much does it cost and how much time does it take?)
- Disseminate results back to partner – do not rely only on scientific articles for communicating results to clinic or community partners.
- Conduct a de-briefing after the project to discuss lessons learned about the research.
- Include clinical collaborators as co-authors on publications as appropriate and commensurate with their effort on the project. If contributions do not meet standards for authorship, clinical or community partners should be acknowledged in manuscripts.

Resources

Principles of Community Engagement, Second Edition. 2012. NIH Publication No 11-7782.

PCORI (Patient-Centered Outcomes Research Institute) Methodology Committee. 2013. "The PCORI Methodology Report." www.pcori.org/research-we-support/research-methodology-standards

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