

# Community-Engaged Research with Community-Based Clinicians

## A RESOURCE MANUAL FOR RESEARCHERS

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 UCSF CTSI Community Engagement Program



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## PREFACE

Great scientific discoveries can, but do not always, lead to great improvements in the health of our communities. Academic, industry, and government scientists have made great advances in the understanding of causes, treatment, and prevention of disease. Historically, these sectors and institutions have not usually involved communities in the process of scientific discovery, and funders have been slow to develop initiatives to bring the results of scientific research to the people who could most benefit from them. In 2006 the National Institutes of Health (NIH) instituted the *Clinical and Translational Science Awards* (CTSAs), a new funding program to facilitate the “translation” of important scientific discoveries into practice. The University of California San Francisco (UCSF) was one of the first recipients of a CTSAs and has since established the UCSF Clinical and Translational Science Institute (CTSI) to promote research and education in clinical and translational science at UCSF, at affiliated institutions, and in community settings.

NIH states that an enhanced translation enterprise should include “outreach to underserved populations, local community and advocacy organizations, and health care providers.”<sup>1</sup> Going beyond “outreach,” UCSF recognizes that strong mutually beneficial partnerships between the communities UCSF serves and the university are essential. The UCSF *CTSI Community Engagement Program (CE)* provides consultation, training, and other resources to build the capacity of UCSF investigators, community clinicians and community organizations to participate in research partnerships, translational research activities and quality improvement initiatives. The goals of this work are to support and facilitate the collaborative development

of new knowledge to address critical clinical and public health issues and to ensure that communities have access to current research findings. The UCSF CTSI Community Engagement Program invites translational researchers and community clinicians to make use of its resources to build mutually beneficial research partnerships with each other.

The Community Engagement Program’s Community Clinicians Committee (CCC) prepared this guide to describe the conceptual framework for, and processes and steps involved in, developing community-engaged research collaborations or partnerships. We have included resources to facilitate this work and address some of the barriers to collaboration. A companion guide is available on the UCSF CE website for community clinicians interested in exploring such partnerships with UCSF researchers. Organized in a question-and-answer format, these guides tap important resources for a state-of-the-art overview of community-engaged research.

While not all collaborations between researchers and community clinicians are conducted in community settings, the focus of this guide is community or practice-based research. We use the term “practice-based research” to refer to collaborative research that incorporates the expertise of community clinicians and takes place within community clinical practice settings. Practice-based research settings can include private or public clinics, pharmacies, schools, or other non-academic settings where clinicians and other health care professionals care for patients.

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<sup>1</sup> U.S. Department of Health and Human Services, National Center for Research Resources (NCRR) Press Release, September 18, 2007. *NIH News: NIH Expands National Consortium to Transform Clinical and Translational Research 2007* (see [www.nih.gov/news/pr/sep2007/ncrr-18.htm](http://www.nih.gov/news/pr/sep2007/ncrr-18.htm))



## TOPIC 1

### What is community-engaged research?

Community-engaged research is research in which community input is integrated in the development of the research question, implementation of the research project, analysis of the results and/or dissemination of the findings to community stakeholders. Community engagement is an important element of the successful translation of research from bench to bedside to community settings.

#### A Note About Terminology

In this guide we use the term *community clinicians* to refer to:

- Nurses
- Physicians
- Dentists
- Pharmacists
- CAM (complementary and alternative medicine) practitioners
- Social workers and...

Other health care professionals who work in non-academic primary care and specialty settings such as:

- Private practice
- Public health clinics
- School health programs
- Retail pharmacies

We also use this term to refer to networks or consortia of community clinicians or community providers.

It is helpful to break down the broad arena of community-engaged research with community-based clinicians into three basic types of questions. These questions are listed below, with examples focused on healthcare access and quality, patient care, and reaching vulnerable groups.

- **Epidemiological or descriptive studies:** What's true for this clinic and patient population? What are the health characteristics/needs/disparities at a clinic and/or for a patient population?
- **Creating evidence-based practice:** Does this evaluated program or treatment work in a clinical setting? What changes are needed so that this program or treatment can work in the clinical setting it is intended for? How can this intervention be brought to scale in new and different communities?
- **Creating practice-based evidence:** Does this practice-created program work? Does this practice-based program or treatment improve health outcomes, and for whom does it work and not work? Does this clinic intervention meet public health or community objectives?

For more on this, see Topic 7, What Kinds of Studies Take Place in Community Clinic Settings?

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## TOPIC 2

### Why build research partnerships with community clinicians?

*“If we want more evidence-based practice, we need more practice-based evidence.”*

— Lawrence W. Green<sup>2</sup>

Community-based clinics, where the vast majority of Americans receive their healthcare, can become partners in the creation of practice-based evidence. This vision cannot be achieved without greater partnership between researchers and community clinicians.

By necessity, health-focused research developed with input from those in community settings addresses key implementation and feasibility issues that might not otherwise be accounted for. While sometimes challenging to conduct, community-engaged research increases the likelihood that research will lead to successful implementation of interventions and changes in health policy resulting in better health outcomes for more people. Given the current emphasis on evidence-based medicine as the basis for practice, it is critical that the evidence needed for the practice of medicine be gathered in the settings where it is most likely to be applied.

Traditionally, the goal of clinical research has been to minimize variation in study populations and set-

2 This statement is the theme of LW Green's website [here](#). For more on his perspective about this statement, see Green LW and Ottoson J, *From Efficacy to Effectiveness to Community and Back: Evidence-Based Practice vs Practice-Based Evidence*. Proceedings from conference: From Clinical Trials to Community: the Science of Translating Diabetes and Obesity Research, 2004, National Institutes of Health, Bethesda, MD. Also, see Laffin M, and Black DR. An interview with Lawrence W Gree. *American Journal of Health Behavior*, 2003. 27(4):466-78.

#### Community-engaged clinical research can change clinical practice for the better.

*“Community-based participatory research brings researchers and communities into partnerships for systematic investigation, with the collaboration of those affected by the issues being studied, for purposes of education and taking action or effecting social change.”*

— Macaulay AC, Nutting PA. Moving the Frontiers Forward: Incorporating Community-Based Participatory Research Into Practice-Based Research Networks. *Annals of Family Medicine*, 2006. 4(1): p. 4-7.

*“We seek a more evidence-based public health practice, but too much of our evidence comes from artificially controlled research that does not fit the realities of practice.”*

— Green LW. Public health asks of system science: to advance our evidence-based practice, can you help us get more practice-based evidence? *Am J Pub Health*, 2006 Mar; 96(3):406-9.

#### Community-engaged clinical research can best answer clinical questions.

*“The current clinical research enterprise in the United States is not consistently producing an adequate supply of information to meet the needs of clinical and health policy decision makers. The inability to address many common, important clinical questions, despite a significant increase in public and private funding for clinical research, suggests a systemic problem in the production of clinical research.”*

— Tunis SR, Stryer DB, Clancy CM. Practical Clinical trials: increasing the value of clinical research for decision making in clinical and health policy. *JAMA*, 2003 Sep 24; 290(12):1624-32.

#### Community-engaged clinical research is consistent with ethical principals for research involving human participants, particularly marginalized populations.

*The traditional research approach has considered individuals and communities to be “subjects” or “objects” of health research. Current developments in ethics, and research methods, and an expanding recognition of what constitutes expert knowledge, justify the heightened participation of individuals and communities.”*

— Tindana P, et al. Grand challenges in global health: community engagement in research in developing countries. *PLoS Medicine*, 2007. 4(9): p. 1451-1455.

**TOPIC 2** (continued) **Why build research partnerships with community clinicians?**

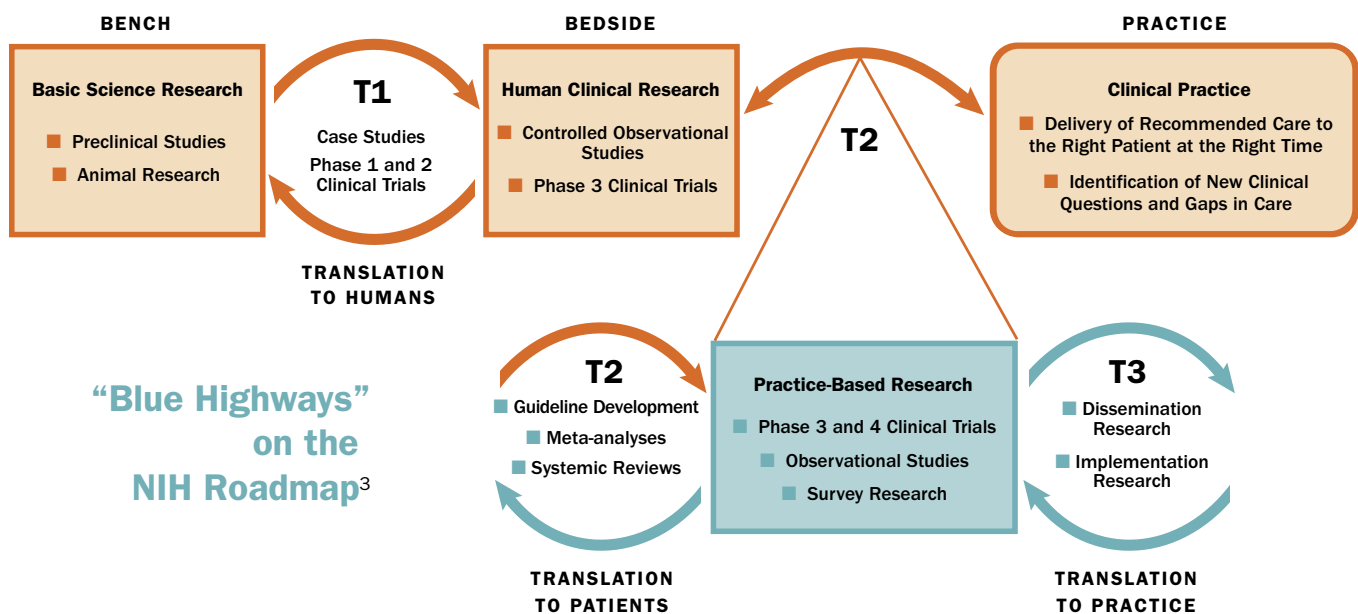
tings to increase internal validity and demonstrate efficacy, so that the results are valid and unbiased within the population studied. Translational research instead aims to determine whether research findings from homogenous populations and settings are generalizable to more diverse ones such as those encountered in “real world” practices. This generalizability is also referred to as effectiveness or external validity. Information about effectiveness enables clinicians, communities and policymakers to make decisions regarding the design of services and estimate the public health impact of the interventions being tested. Community-based settings are particularly well suited for translational research because collaborative projects developed using practice-based research or community-based research methods minimize implementation barriers from the outset.

A recent article in *JAMA* uses the figure below to illustrate the importance of practice-based research for translating research into practice and into materials for patients. This research can be accomplished in the context of community-based clinician partnerships.

Community-engaged clinical research theory and methods reflect and emphasize:

- The importance of creating and implementing effective clinical and public health services for greater population health and;
- The importance of ethical requirements for research involving human participants, particularly marginalized populations.

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<sup>3</sup> Westfall, J. and J. Stevenson, A Guided Tour of Community-Based Participatory Research: An Annotated Bibliography. *Annals of Family Medicine*, 2007. 5(2): p. 185-186.



## TOPIC 3

### Why might clinicians be interested in collaborative research?

There are many reasons why community clinicians participate in research in collaboration with academic researchers, and there are also many reasons why they would not. In the context of practice-based research networks that have had considerable experience with academic-community collaborative projects, some of the following questions are most critical for practitioners when thinking about potential research partnerships:

- Does this study address an important problem I see in practice?
- Might the research process or findings change how I practice for the better?
- Could this study change how others practice for the better?
- Will this impact the community my clinic serves?
- Is this feasible (e.g., in terms of logistics, time, cost, etc.)?
- Will changes in health policy be more likely if this research is done?
- How soon does this need to happen and how much will it impact clinic staff?

Several practice-based research networks describe in their mission statements the types of collaborative activities that appeal to clinicians. These often extend beyond the research project itself to increased contact with information and technology that can increase their knowledge and active participation in the creation of new knowledge that is directly tangible in their clinical practices or community. Often participating clinicians enjoy having contact with the research and academic community so they stay abreast of developments in their clinical areas, and have opportunities for continued learning, faculty appointments, and CME credit.

It is important to keep in mind that clinicians and researchers may have different motivations for wanting to work together, but with clear ongoing communication, those divergent needs and interests do not have to preclude working together. Researchers must address and value the concerns of community clinicians if they expect to build successful practice-based research partnerships with them.

Lawrence Green<sup>4</sup> has developed *review criteria and a rating scale* to help researchers and their partners assess the extent to which their project design is participatory and action-oriented.

<sup>4</sup> Agency for Healthcare Research and Quality. Community-Based Participatory Research - Assessing the Evidence- Evidence Report/Technology Assessment Number 99, 2004.

#### How do I find a community clinician interested in collaboration?

The **Community Engagement Program** can help you:

- Find community clinicians with similar interests,
- Establish a relationship with with a practice-based research network,
- Manage the steps of setting up a research project in community clinic settings,
- Develop rigorous, practical study designs that are responsive to community clinician interests,
- Explore the degree of involvement with community clinicians that would work best for your research.

We ask that you fill out a **Consultation Request Form** to help us learn more about you and your interests. After you submit a form, you'll hear back from us within a few days with next steps.

To have a form faxed or mailed to you,  
please call (415) 206-4048  
or email us at [CEP@fcm.ucsf.edu](mailto:CEP@fcm.ucsf.edu).





## TOPIC 4

### What questions might community clinicians have about a study?

Clinicians want to know first and foremost if there is something in the research that will specifically benefit their patients. They will want to know how the study might have an impact on the clinic and patients, whether or not there will be lasting benefits to the clinic, and if they will have to allocate additional staff time to complete the study protocols. In many cases, it may seem initially and primarily that clinicians are interested in developing an intervention, but often clinicians want a better understanding of the underlying clinical problems they face, and therefore may be very interested in descriptive studies that can include their questions.

#### ***For patients, clinicians want to know:***

- Why should research be a high priority? Why is it more important than other work I might do?
- Is there a QI component to the research that will positively impact my practice?
- How does this research get past the disease-oriented perspective and demonstrate a patient-centered approach?
- What is expected of patients?
- Which patients are eligible and which are not? Why? Why not?
- What are the potential risks and benefits for my patients, both short and long term?
- Will I get the results of any tests that are done on my patients during the study?
- What would happen if my patient gets randomized to a control group?
- What if my patient gets a complication from participating in the study?
- What happens to my patient when the study is over?

For some clinicians, randomization of their patients to control groups is not acceptable, and there have been many ideas for modifying randomized designs, such as staggering intervention exposure and crossover designs, that can address this major concern. It is also important to realize that clinicians may object to their patients being randomized to the intervention if there are not staff resources to cover the time to conduct the intervention itself.

#### ***On behalf of the clinic, clinicians want to know:***

- What is expected of staff?
- Do we have adequate staff to perform research functions?
- Will the research team bring in outside staff to perform part of the protocol?
- What kind of training is required?
- Will the practice be compensated for additional time the protocol requires of clinic staff?
- How much time and space will study procedures take?
- Will the research interfere with the flow of patients through our clinic?
- Are the medical and clinic directors and other staff on board?
- Who will own the data and findings?
- How will the clinic be recognized in any publications?
- Are the materials and the researcher culturally competent?

It is important to build and establish as much clinic-wide support for the project as possible. It may cause problems at the clinic if only one clinician wants to participate, so it is critical to meet with and learn

## TOPIC 4 (continued) What questions might community clinicians have about a study?

about the needs and concerns of other clinic members early in the process. Researchers should build a relationship with the clinic director and ensure project goals and processes are explicitly negotiated. The clinic director can provide a formal letter of support to staff and announce and discuss the project at staff meetings. Other key staff, such as support staff, are critical to conducting the projects if they take place in the clinic. It is important to compensate them and build in incentives for their involvement. These ideas can be discussed with staff supervisors.

If the clinic staff will help recruit patients, interview them, or conduct intervention-related education or services, they are required to have human subjects training. Finding time and resources for this can be challenging. Clinicians will want to know about whether they can have access to the data on their patients or for their clinic. This level of information sharing should be determined at the outset and the timing for release of study findings to the clinic and community.

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### Examples of Community-Based Research Collaborations at UCSF:

- **The IDEALL Project** (Improving Diabetes Efforts Across Language and Literacy) is a community practice-based comparative effectiveness trial of two diabetes self-management support interventions. The study determined that using simple communication technology, as opposed to traditional approaches, was more effective in managing diabetes in underserved populations that have limited literacy and limited English proficiency.
  - Elevated blood lead levels of pediatric patients at a small community clinic in Monterey, CA sparked a **binational collaborative study** in which clinician members of a practice-based research network and UCSF researchers investigated sources of the outbreak.
  - A UCSF researcher and a founder of the **Charlotte Maxwell Complementary Clinic** are partnering to conduct a three-year, mixed-method, longitudinal study entitled *Underserved Women with Breast Cancer at End of Life* to evaluate the effectiveness of a narrative intervention. Four research interviews form the basis for the construction of an ethical will (expressing individual values, beliefs, life lessons, hopes, love and forgiveness in a written document to loved ones) in collaboration with each patient participant, women with metastatic breast cancer.
- The goal of the intervention is to reinforce dying women's sense of meaning of their lives and ease concerns regarding death. The secondary aim is to construct a conceptual model that reflects the experiences of breast cancer patients at the end of life.
- **Practice Inquiry** is a set of small-group, practice-based learning and improvement (PBLI) methods designed to help clinicians better manage clinical uncertainty. A UCSF researcher and community clinicians conducted a collaborative evaluation that suggests Practice Inquiry is feasible, acceptable, and useful.
  - Atraumatic restorative treatment (ART) was created to treat the dental caries of refugees and poor communities that could not afford dental care. *The Benefits of ART Technique in Vulnerable Populations in US* prospectively examines the caries recurrence and clinical long-term success of ART vs. amalgam restorations in 5-11 year old children. **The CAN DO Center** and the **Marshall Lab** at the UCSF School of Dentistry are partnering with **Asian Health Services Dental Clinic** in Oakland to find in which situations and applications ART is effective.



## TOPIC 5

# In what kinds of settings is practice-based research conducted?

### Individual clinics

Studies involving individual clinics may reflect a convenience sample for finding eligible patients or may be the focus of interest for a particular reason. For example, a clinic that has recently introduced a new nurse-driven patient tracking system may be a good partner for a study wanting to examine the impact of continuity of care on risk reduction for cardiovascular disease. Some clinics are located in communities where there is considerable interest in a specific problem, and the clinic can provide important information to the community. For example, in a rural California county, community members wanted to know if access to contraceptives for teens was impacted by the closure of the student health center. The clinic where teen patients would instead go for contraception was able to track the increased frequency of Plan B and pregnancy test requests in the time after the policy change. The community was then able to advocate for increased contraceptive access for teens.

A benefit of working with individual clinics may be the relatively straightforward approach that is possible when introducing a study, as opposed to going through multiple administrative settings required for some large clinic networks. Success with one clinic for a pilot project can provide entrée for work in the broader community.

### Clinic systems

Many practice-based studies take place within clinics linked by a health system or insurance group. Working with clinic systems does not assure that each clinic does business the same way or that the

patients are homogeneous, but this diversity among clinics with the same organizing structure can be a strength of working with a larger number of clinics. To set up a project requires gathering information about the clinic systems, determining which clinics are interested and have the capacity to partner, and meeting with all the relevant stakeholders at individual clinic and clinic-wide levels. Working with clinic systems may make some aspects of research easier to address; for example, clinic networks might share electronic information systems or similar approaches to clinical problems. Individual clinics within a clinic system may or may not serve similar patients or be managed in the same way, so researchers will still need to engage individual clinicians and clinic sites in the research process when partnering with clinic systems.

### Networks of clinics (PBRNs)

Primary care, pediatrics, nursing and many other clinician specialties have a long tradition of individual practitioners conducting investigations in their offices and clinics in collaboration with academic researchers who are involved in the practice-based research leadership. Many of these efforts have been conducted in the formalized networks of practice-based research networks (PBRNs).

Formalized networks of practitioners devoted to research first arose in the United States over 20 years ago among family physicians and have been described as *“groups of practices ... affiliated with each other ... for the purpose of investigating the phenomena of clinical practice occurring in commu-*

## TOPIC 5 (continued) In what kind of settings is practice-based research conducted?

### What is a Practice-Based Research Network?

Practice-based research networks, or PBRNs, are groups of clinics or practices interested in and involved with research. PBRNs draw on the experience and insight of practicing clinicians to help frame and identify research questions, whose answers can improve the practice of primary care. By linking these questions with rigorous research methods, PBRNs can help produce research findings that are more immediately applicable for the practicing physician, and in theory more easily assimilated into everyday practice. Find out more about PBRNs, including comprehensive information on funding and other resource-leveraging opportunities for practice-based research, at [www.pbrn.ahrq.gov](http://www.pbrn.ahrq.gov).

ities.”<sup>5</sup> The special methodological strengths of PBRN-conducted research include:

- Collaborative generation of research ideas that enhance the relevance and quality of research;
- Access to non-referral study samples and hence increased generalizability;
- Interventions are more likely to be sustained;
- Better follow-up of participants in longitudinal studies due to continuity of care;
- Opportunities for large sample sizes and stratified sampling based on geography, rural/urban, type of clinic etc.;
- Inclusion of diverse practitioners and practice settings.

UCSF researchers may develop practice-based research partnerships with individual clinicians on their

own, or they may partner with one of UCSF's several existing primary care-based research networks (PBRNs), which are groups of community clinicians who conduct practice-based research together, and which may be organized around a particular discipline or specialty, or share a common research agenda. One of the most established practice-based research networks at UCSF is the UCSF Collaborative Research Network, which is family medicine-based. This PBRN is being expanded to be transdisciplinary and includes nursing, dentistry and others.

The growing interest in research networks for conducting research is evidenced by the NIH *Roadmap for Medical Research initiative*. The *Inventory and Evaluation of Clinical Research Networks (IECRN) Project* seeks to improve health and to speed translation of discoveries into practice. In particular, the IECRN is related to *Reengineering the Clinical Research Enterprise*, a Roadmap component which seeks to enhance the efficiency and productivity of clinical research by promoting clinical research networks that can rapidly conduct high quality studies capable of addressing multiple research questions. Other organizations of research networks include the *Federation of Practice-Based Research Networks* with over 75 members.

While many clinical studies that involve participatory engagement do not take place in practice-based research networks, these networks, whether they involve primary care, pediatric, dentistry, nursing or pharmacy practice settings, have been generating a renewed interest in methodologies that combine clinical research methods with those of community-based participatory research and quality improvement. The *North American Primary Care Research Group (NAPCRG)* has issued a position statement on CBPR that reflects the multiple ways community engagement in research partnerships is important.

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<sup>5</sup> Green, L.A., Lutz LL. Notions about networks: primary care practices in pursuit of improved primary care. In: Mayfield J, Grady ML, eds. *Primary Care Research: An Agenda for the 90s*. Rockville, MD: US Department of Health and Human Services; 1990:125-132. DHHS Publication No. (PHS) 90-3460 in Wasserman, R., et al., Pediatric Research in Office Setting (PROS): A National Practiced-Based Research Network to Improve Children's Health Care. *Pediatrics*, 1998. 102(6): p. 1350-1357.



## TOPIC 6

# What might I need to know about community clinicians/providers and the community setting?

Clinics often have several types of directors, both formal such as medical or clinic directors, and informal, such as staff supervisors, who will need to be involved in developing ideas for research before they are ready to be implemented. It is important to set up times to meet and discuss to what extent there are shared views on research goals, any initial investigator initiated ideas, anticipated forms of collaboration, elements of the study that can be modified for collaboration, funding circumstances and other possible resources that can be shared with the clinic, human subjects protections, training

requirements and time requirements of at all levels of the project. Some settings have formal structures to do this and others do not. Letters of support as the project is getting underway can go a long way towards developing trust and clarity. Most clinics will need to determine if they need an independent ethics review, or local IRB, review of the project before the research gets underway. When they do not have their own local review board, clinic partners can use a university IRB and be covered by its decisions.

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### Know Your Partners!

When you're getting to know your clinical partners, it's helpful to be oriented about the patient population(s) served, current practice priorities, and research questions the clinicians and administrators want to ask. Factors that may have bearing on these areas include:

- prevalence of illnesses and diseases in the patient population;
- how services are reimbursed;
- the structure and function of clinic staffing;
- language(s) spoken by patients and staff;
- characteristics of other locations or systems in which patients receive services;
- issues concerning access of patients to care; and
- characteristics of the clinic neighborhood and location.





## TOPIC 7

# What kinds of studies take place in community clinic settings?

### Descriptive and Observational Studies

Descriptive studies involving clinicians and clinic settings can focus on clinicians' views and behaviors, patient-level health data, such as that obtained from chart review, clinical databases or patient surveys. All of these methods are critical to capturing trends in clinical medicine, patient care, and health indicators for epidemiological studies, intervention studies, quality improvement efforts, and the development of 'best practices' and guideline development.

Observational epidemiologic studies that take place in community clinic settings with local collaboration can provide first looks at the changing epidemiology of various conditions and provide for local surveillance of conditions of particular interest. The importance of generating clinic or clinic system-specific information on conditions that might be the subject of a research intervention can be critical for selecting study groups, and for health planning and resource allocation. For example, observational studies may indicate that the prevalence of childhood dental caries vary significantly between community clinic patients or analysis of a health system's diabetes registries can identify patients who might benefit from language-concordant self-management support.

With a longer time frame, the target population for a large scale intervention study could be identified from prevalence and risk factor data generated from a baseline observational study in clinical and community settings. Involving clinicians and staff from these clinics may result in a better understanding of risk factors and the impact of proposed

interventions. Qualitative interviews designed to explain descriptive findings and provide information on barriers or facilitators for planned or proposed interventions can be conducted in tandem with observational and descriptive survey studies.

Clinician surveys can capture trends in clinical medicine, patient care, and the prevalence of a range of clinical problems in a community. Clinician surveys can be conducted in a short time frame and provide information that is both clinically important and useful for the formative stages of interventional studies. For example, surveying clinicians about their experience and resources for managing emerging diseases, such as Hepatitis C or methicillin-resistant staphylococcus aureus (MRSA) infections can aid in planning for interventions that may lead to improvements in the current standard of care. Other examples of surveys that might inform future interventions could involve queries about clinician resources to implement new guidelines or priority areas for quality improvement and target areas for health disparities they see in their clinic.

It can be challenging to get a good response rate with surveys of randomly selected clinicians. Higher response rates can be achieved by working collaboratively with clinicians to develop surveys and administer them with local clinician help, keeping surveys as short as possible, providing incentives such as free CME or gift cards in exchange for participation in the surveys, or conducting surveys within a practice-based research network that has a diverse membership of clinicians who can be introduced to the survey with a cover letter from someone they personally know. Surveys can provide a forum for

## TOPIC 7 (continued) What kinds of studies take place in community clinic settings?

clinicians to learn and think about issues that are important to and useful in their clinical practice. For example, when a participating clinician reported an interest in determining patient views on prenatal vitamins in a study examining nutritional and other risk factors related to prenatal outcomes, this question was added to the survey instrument.

### Intervention Studies

Intervention trials can and have been implemented with a community engagement framework, and there are several designs/methods that are responsive to community clinicians and patients within the clinic setting. Two common decision points are: (1) whether a randomized clinical trial versus a quasi-experimental design (sometimes called a “waitlist” design, which may or may not also include some level of randomization) is possible, ethical and/or feasible, and (2) whether the research will adopt a within-clinics intervention design or a cluster-allocation design.

The within-clinics design allows patients within a given setting to be randomly assigned to the intervention or control condition. This design is advantageous because it allows analysis at the level of the patient and often requires smaller sample sizes. On the other hand, clinicians may not want their patients to be randomized to a placebo or control group. They may be concerned that it is too complicated to have more than one intervention approach taking place in the clinic at the same time, or that there will be “spillover” of the intervention to patients not receiving it. When clinic staff or patient participants talk about and share aspects of the intervention with others, the study can be compromised.

Randomizing patients to an intervention group also can be logistically difficult for a clinic when there is insufficient lead time, since an intervention may burden staff and may provide challenges for clinic scheduling and reimbursement. Sometimes clinics

want to participate in a study, but don’t feel ready to participate in an intervention.

There are several avenues for research partners to negotiate about the research design in order to address the options available and the best way to overcome concerns. Practice-based researchers may design studies in which everyone receives the intervention by staggering the timing. This can create a temporary “control group” that still receives a “comparison intervention” that is considered better than the usual standard of care.

In another type of crossover trial, patients serve as their own controls. Research partners may decide to implement a wait list intervention design in which not all clinics or patients are enrolled in a study intervention group at once. In this design, clinics or patients may be randomly assigned to receive the intervention in an initial or a later study phase, and the clinics that do not receive the intervention in the first phase can serve as a control group while waiting for their phase to begin.

A cluster-randomized design, which randomizes and analyzes at the level of the clinic or a community group of some kind rather than at the patient level, is another design strategy that addresses randomization concerns. If an intervention is designed to provide a service or care outside the clinic itself, there may be less concern about a clinical site being randomized to a control group, but this is something that should be discussed openly among research partners.

While many great ideas may be amenable to community clinic settings, when the study design is done in close collaboration with clinician and community partners, it is much more likely to be feasible for everyone. Often with practice-based studies with any level of randomization, there are considerable trade-offs between optimal design, buy-in and support from the clinical sites, fidelity to interventions or

## TOPIC 7 (continued) What kinds of studies take place in community clinic settings?

instruments, and implementation and evaluation of outcomes.<sup>6</sup> Two recent papers explore these trade-offs in conducting a randomized clinical trial with diverse community clinic settings within the UCSF Collaborative Research Network.<sup>7,8</sup>

### Qualitative and Mixed Methods Studies

Qualitative studies are useful for understanding the context in which research and interventions will occur and are especially useful to gather beliefs about research topics that may be new in a community. For example, focus groups or in-depth interviews with key informants can elicit beliefs, knowledge and attitudes about services (i.e., new cancer screening) and barriers to care (i.e., problems with patient adherence to medications). These kinds of insights can help to frame research questions so they address pertinent community strengths and challenges. Combining qualitative components with quantitative ones is called ‘mixed-methods’ design and has been well-described in relation to community clinic projects.<sup>9</sup>

Several organizations<sup>10</sup> assert that community engagement is an ethical requirement for involving human participants because community-engaged research:

- Is focused on the relevance of research;
- Assesses whether relevant research is culturally and practically acceptable in the context it is intended;
- Works to minimize community disruption, i.e., avoids the displacement of local medical staff from pressing local needs;
- Avoids exploitation by ensuring a fair distribution of the benefits of research; and
- Takes into account the ethical hazards that may be part of the social, economic, and political landscape of the community.<sup>11</sup>

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6 For more on this, see Mercer SL, DeVinney BJ, Fine LJ, Green LW, Dougherty D. Study designs for effectiveness and translation research: identifying trade-offs. *Am J Prev Med.* 2007 Aug; 33(2):139-154.

7 Schillinger D, et al., Seeing in 3-D: Examining the Reach of Diabetes Self-Management Support Strategies in a Public Health Care System. *Health Education & Behavior*, 2007. In press.

8 Handley M, Hammer H, Schillinger D, Navigating the Terrain Between Research and Practice: A Collaborative Research Network Case Study in Diabetes Research. *Journal of the American Board of Family Practice*, 2006. 19: p. 85-92.

9 Creswell JW, Fetters M, and Ivankova N, Designing A Mixed Methods Study in Primary Care. *Annals of Family Medicine*, 2004. 2(1): p. 7-12.

10 These include the Council for the International Organization of Medical Sciences, the US National Bioethics Advisory Committee and the UK Nuffield Council on Bioethics.

11 Tindana P et al, Grand Challenges in Global Health: Community Engagement in Research in Developing Countries. *PLoS Medicine*, 2007. 4(9): p. 1451-1455.

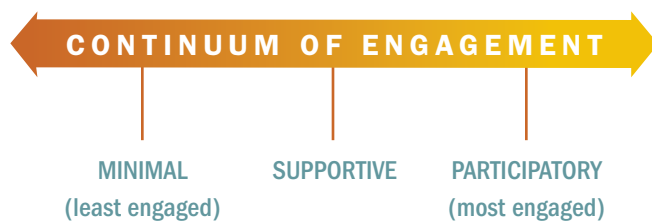




## TOPIC 8

# What options for research partnerships with community-based clinicians should I know about?

It is helpful to understand that relationships between researchers and community-based clinicians exist and function along a continuum of engagement, depending on available resources, capacity, interest, skills, and time. The model for each partnership, negotiated by all the stakeholders, should be chosen because it meets the needs of researchers, clinicians, and patients. Also, partnership styles may change over time, with a limited partnership becoming more involved as the partners become more comfortable with community-based research. This section will help to clarify various styles of collaboration and help you to understand the options available.



### Minimal Engagement

This end of the continuum still includes clinician engagement in conducting research. Researchers may contact community clinicians for help recruiting individuals for a fully designed and funded study, as has typically been done for clinical trials to investigate new drugs. Researchers might contact medical directors, health systems administrators, or individual clinician colleagues in order to identify potential study patients or clinicians. The study protocols may be modified in small ways, but usually, there is no active involvement by clinicians in developing the research questions, designing research methods, or implementing research protocols.

Minimal engagement studies can involve clinicians even if the study does not formally involve them prior to implementation. Clinician advisory groups and clinician advisors may help researchers understand how the research protocol best fits in a community clinical setting, conduct process evaluation of protocol delivery, provide feedback from participants, generate important information for subsequent studies, and be involved in the dissemination of findings. Clinicians can participate in the interpretation of results after they have been analyzed, which can create opportunities to generate new questions for future work as well.

### Supportive Engagement

In this type of collaboration, the researcher is likely to initiate the study and may include the clinician early on in the process of developing the project to address questions both parties want to answer. Community clinicians may contribute specific questions or ideas that address clinician priorities and provide incentives for clinician recruitment and participation.

For example, a researcher may want to ask: *Among the elderly diabetic population seen for primary care in the area, does a separate visit with a pharmacist increase medication adherence above that accomplished in the primary care visit?* And a clinician may want to add to that research question: *What are the most important barriers and facilitators to medication adherence for the elderly and how much are they related to the health care setting (e.g., community clinics vs. private practice clinics) compared with other considerations, such as cognitive functioning or conditions of poverty which limit access to inexpensive medications?*

## TOPIC 8 (continued)

### What options for research partnerships with community-based clinicians should I know about?

This study might involve sampling private and public clinics, clinics in a primary care-based practice-based research network, clinician members from a pharmacist-based research network, and/or pharmacy-based network sites as well. In such a study, clinics and clinicians may be recruited to conduct an intervention within their clinic that converges with quality improvement efforts that the clinics may want to undertake, but have not had time or resources to do so. Study findings can provide clinicians with useful information for direct patient care. For instance, if cognitive screening is important for their patients over age 70 years who have co-morbidities, clinicians can develop an appropriate medication action plan with patients and/or relatives and caregivers.

In this type of collaboration, researchers may need to better understand the perspective of community clinicians before developing their translational research ideas into feasible and fundable research protocols.

#### What is Community-Based Participatory Research?

**CBPR** is a collaborative research approach that is designed to ensure and establish structures for participation by communities affected by the issue being studied, representatives of organizations, and researchers in all aspects of the research process to improve health and well-being through taking action, including social change. CBPR involves:

- Co-learning and reciprocal transfer of expertise by all research partners with particular emphasis on the issues being studied with CBPR methods;
- Shared decision-making power; and
- Mutual ownership of the processes and products of the research enterprise.

—U.S. Agency for Healthcare Research and Quality<sup>12</sup>

12 Viswanathan M, Ammerman A, Eng E et al. Community-Based Participatory Research: Assessing the Evidence. Evidence Report/Technology Assessment No. 99 (Prepared by RTI-University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016). AHRQ Publication 04-E022-2. Rockville, MD: Agency for Healthcare Research and Quality. July 2004.

In such a situation, researchers may work with a practice-based research network to conduct focus groups to get ideas from community clinicians about study designs and implementation protocols that could be successful. Alternatively, researchers may visit community-based practices in person to interview potential participants and learn about the characteristics of the practice settings they hope to work with before the study is finalized and funded. Clinicians who are engaged at this level are often willing to write letters of support to funders or to help recruit other clinicians within their organization or in other community-based settings to participate in the study. Practice-based research that involves clinicians at earlier phases of the research project is less likely to encounter logistical barriers when it is implemented.

#### Participatory Engagement

Research that takes place at this end of the continuum is the type of close affiliation with clinician community members that involves discussion with or solicitation from a community-based clinician or representative of a practice-based research network to begin investigating a research idea that may be developed and implemented as a *collaborative* research study. The clinician may function in an advisory, co-investigator, or investigative leadership role depending on a variety of factors, including his/her time, research experience, interest and overlap with university researchers' interests, and research funding availability. In some cases, the clinician may be part of a clinic-wide or health system quality improvement effort for which the research can provide a dual function.

It is often the case that clinicians are not interested in research per se, but are more open to collaboration to participate in a quality improvement effort. For example, for patients targeted for a clinic-wide quality improvement initiative aimed at colorectal cancer screening, a clinic might administer a cancer screening protocol during a flu shot vaccine visit. Clinicians may

## TOPIC 8 (continued)

### What options for research partnerships with community-based clinicians should I know about?

have a particular concern about a patient population, such as patients who bear a particular burden of disease, vulnerability, or constellation of vulnerabilities such as recent migration, lack of health insurance, limited access to care, limited English proficiency and/or limited health literacy.

Studies that result from participatory collaborations are more ‘grassroots’ in their development, but are capable of accomplishing levels of research rigor associated with all types of study designs, including randomized clinical trials, and have led to some new methodologies for conducting clinical trials. Within this category are the studies that demonstrate the greatest level of engagement, where the clinician(s) and the university researcher enter into a partnership to jointly explore a problem that is of interest to all, and cooperatively develop the specific research question, methods, a plan for decision-making, and an equitable sharing of resources and findings.

Participatory research collaborations are often slower to develop than less engaged practice-based research projects. However, research that emerges from participatory engagement may be easier to implement once funded, with results that are often more immediately relevant to clinical practice settings, and easier to disseminate for the benefit of patients in other clinical settings.

Research at this end of the continuum is more likely to take place in community settings. This type of research, referred to as community-based *participatory* research, or **CBPR**, is a model developed by researchers and their collaborative partners who realize the mutual benefits of participating in the most engaged collaborative research. CBPR is well suited to and instructional for academic researchers interested in collaborating with community clinics. CBPR provides a methodological and theoretical framework that is especially useful if the project’s goals are taking action or effecting social change, including improving disparities in outcomes or access and translating research into practice.<sup>13</sup> One of the

tenets of CBPR that is most relevant to CTSI is to ground clinical research in real-life patient experience.<sup>14</sup>

#### Efficacy, Effectiveness, Internal and External Validity

Many minimal engagement studies are designed to facilitate efficacy research, in which the study determines which patients improve with specific medicine regimens, holding other factors constant. The results of efficacy research have a high degree of internal validity, which is important to demonstrate the potential benefits of the treatment being studied. However, it has only been more recently understood that efficacy research followed by “effectiveness research” demonstrates the external validity of the research—the practical benefits that can be expected when the intervention makes its way into clinical practice. Effectiveness research takes place in community-based clinical practice settings with more heterogeneous patient populations. More and more often, the best clinical trials incorporate the concepts of efficacy and internal validity that are familiar to academic researchers with the concepts of effectiveness and external validity that are intuitively most familiar to community clinicians. The need to merge these principles to create practice-based evidence that can improve the health of patients is a compelling reason to build research partnerships with community clinicians. In addition, soliciting input from participating clinicians about their views of the study’s successes and shortcomings can help capture the risks and benefits of the medication or intervention under study for the broader spectrum of patients the participating clinician might see, even if those patients are not participants in the study. Researchers should be aware of these types of opportunities to expand and increase the range and productivity of their research agendas.

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13 Macaulay AC, Nutting PA. Moving the Frontiers Forward: Incorporating Community-Based Participatory Research Into Practice-Based Research Networks. *Annals of Family Medicine*, 2006. 4(1): p. 4-7.

14 Westfall JM, et al. Community-Based Participatory Research in Practice-Based Research Networks. *Annals of Family Medicine*, 2006. 4(1): p. 8-14.



## TOPIC 9

# What are the challenges I should think about as I consider collaborating with a community-based clinical partner?

Some of the obvious obstacles to progress in this area are the time and funding required to establish and maintain mutually beneficial relationships. Collaborative relationships often require a shift from investigator-driven study designs to designs that incorporate meaningful and relevant outcomes and outcomes that overlap with quality improvement efforts clinicians and clinic settings will value.

### Funding and pace to create the shared sense of community and goals

There are few infrastructure funds to get clinicians, community members and academic researchers together to discuss and develop formal projects to answer questions of value to all in the group. It is difficult to coordinate meetings with broad-based representation from the research team, providers, and community stakeholders. Such meetings need to take place at times that are convenient to those with the least flexibility, i.e., clinicians who have busy clinic schedules. At the same time researchers may have time tables that are based on funding cycles or IRB related administrative issues. Researchers and providers need to have realistic expectations and understand that the process takes time and can be slow. Building in longer timelines for planning can alleviate the pressure to get projects underway.

### Time for planning

It is essential to allow time for community clinicians to participate in the many key formative discussions that precede project design and implementation. All participants should contribute to and gain from

the process, again requiring that flexibility be built into the timelines. This approach requires a major attitudinal shift for many academicians, because in the collaborative model researchers contribute methodological expertise but generally are not able to dictate timing for the implementation of the study and interpretation of the results, even when they are beholden to funding agencies with specific timeline expectations.

### Change in expectations from exclusively Principal Investigator-driven outcomes

Investigators need to learn to negotiate between their own research agendas and the needs identified by the combined research and community team, thereby building in 'win-win' or 'piggy back' proposals that are more inclusive. This may take more time and will often require more resources than a more traditional single purpose study. Offering training in research skills to interested collaborators can also help bring together different research ideas into more practical studies, and this requires resources and commitment.

Hopefully these potential obstacles or drawbacks will not outweigh or override the long and short-term benefits of a research collaboration. Your active collaboration in a research partnership means the discoveries you make are more likely to be translated into action and better outcomes for more people. The *CTSI Community Engagement Program* can help you as you take any number of small or large steps at any point(s) along the continuum of engagement with a community clinician collaborator.

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## TOPIC 10

### How do I initiate working relationships with clinicians in community settings?

Personal contacts are usually the best way to start, either by asking colleagues or approaching the UCSF CTSI Community Engagement Program for advice on whom to contact to get a project started. Often the first step is a visit to the clinic to solicit ideas or present them to one or two clinicians. No matter where the study lies on the continuum outlined in Topic 8, when beginning a relationship with a potential new community-based clinical partner, the researcher should be prepared to discuss how the clinic can benefit from the project. Benefits might include access to certain clinical services for patients, special clinical training for staff, or continuing medical education for clinicians. Researchers should also be prepared to respond to tough questions and to be open to developing meaningful incentives for clinician participation.

Researchers might recruit clinics in a specific geographic location, approach a particular clinic because the researcher and clinician share an interest in a clinical issue, or because the clinician is known to work in a setting that has a special interest in the problem that is being studied. Clinician partners may be recruited because they have a track record of having participated with other researchers on related projects. Sometimes community clinicians contact researchers to begin this exploration process. Community clinicians are likely to be receptive to forming partnerships with researchers who have ties to the community that they serve. When researchers become involved in advocacy work that relates to the research project and is valued by patients that the clinic serves, the connection between researcher and the community contributes to the strength of an eventual partnership.

Once there is approval to participate in a study, it is sometimes best for the researcher partner to make a clinic presentation of the study concepts. In other settings, a more informal meeting with clinic staff, such as at a lunch session (with lunch provided), can be a good way to introduce a research idea. It is best if there is someone in the clinic who has some familiarity with the project and can introduce it. In some cases, the medical director may agree to introduce the project idea, and that may be a good place to start. Setting up a flexible time to follow up with the clinic and suggesting questions they might want to think about ahead of time can be helpful. Questions should be framed from the perspective of the clinician on behalf of their patients, their staff and their time, and regarding their interest in the project and desired level of engagement. These can be discussed at a follow-up question and answer session with the clinic.

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#### Guidelines for Participatory Research

*Campus Community Partnership for Health (CCPH)* at the University of Washington has developed an excellent set of guidelines for collaborations between academic researchers and community partners. These guidelines can help you work with your collaborator to establish good communication and processes for decision-making. Click [here](#) to see the full text of the CCPH Principles of Good Community-Campus Partnerships.

Dr. Lawrence Green has also developed [guidelines for participatory research in health promotion](#). These can be used to provide focus to the early development of a collaborative research project.



## TOPIC 11

### What are steps of collaborative research I need to know about?

Step	Action Items for Collaborative Partners	Possible Benefit for Community Clinician Partner	Possible Benefit for Research Partner	Research Challenges and Caution Areas
<b>Step A:</b> <b>Groundwork for Partnership</b>	<ul style="list-style-type: none"> <li>Assemble research team. Team should include community clinicians, clinic staff and other community members who are decision-makers and can move project forward with research collaborators.</li> <li>Develop consensus on ethics and operating principles for the research, including protection of patients and clinic staff as well as clinic-level functioning.</li> <li>Set up a patient advisory board if possible, to be involved throughout the research process.</li> </ul>	<ul style="list-style-type: none"> <li>Groups that are formed can focus on several objectives in addition to the research so that resources can be used efficiently. For example, setting up a clinic database for identifying study patients can also be used for reminders for screening and preventive visits. Additional staff can help patients fill out insurance forms in between study activities.</li> </ul>	<ul style="list-style-type: none"> <li>Motivation in determining areas of focus and need will translate into activated collaborators who will see the project through.</li> </ul>	<ul style="list-style-type: none"> <li><b>Challenge:</b> Time it takes to pull together a group.</li> <li><b>Caution:</b> Ensure that the project is not perceived as conducting research 'on' the clinicians and their community, or in 'using' their clinic for research.</li> </ul>
<b>Step B:</b> <b>Identify Research Area</b>	<ul style="list-style-type: none"> <li>Full participation of community clinicians and advisors in identifying issues of greatest importance and where new knowledge could create most benefit.</li> </ul>	<ul style="list-style-type: none"> <li>Relevance to and resonance with daily work and larger views on patients and community.</li> </ul>	<ul style="list-style-type: none"> <li>Establishing a consensus regarding areas of focus will translate into activated collaborators who will see the project through.</li> </ul>	<ul style="list-style-type: none"> <li><b>Challenge:</b> Can be difficult to facilitate and focus and reduce conflict when different ideas cannot all be brought into sync.</li> <li><b>Caution:</b> Ensuring this phase is well perceived as 'fair' and 'ethical' is the most critical step and cannot be rushed.</li> </ul>
<b>Step C:</b> <b>Generate Study Questions</b>	<ul style="list-style-type: none"> <li>Community clinicians and advisors involved in writing process and details of determining what questions are feasible to address.</li> </ul>	<ul style="list-style-type: none"> <li>Relevance, as above.</li> </ul>	<ul style="list-style-type: none"> <li>Ownership of the ideas as demonstrated by research questions will motivate clinicians and staff about the research belonging to their goals for patient outcomes.</li> </ul>	<ul style="list-style-type: none"> <li><b>Challenge:</b> Fitting ideas for questions to fundable projects, especially if different than researchers' expertise and interests.</li> <li><b>Caution:</b> Validation of all questions is critical to show respect to clinicians and advisors. Create a mechanism so that ideas not used in current project are not lost.</li> </ul>

Adapted from Viswanathan M et al. Community-based Participatory Research: Assessing the Evidence. Evidence Report/Technology Assessment Number 99. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. July 2004. AHRQ Publication No. 04-E022-2 Prepared by RTI International-University of North Carolina, Research Triangle Park, North Carolina. [www.ahrq.gov](http://www.ahrq.gov).

**TOPIC 11** (continued) **What are steps of collaborative research I need to know about?**

Step	Action Items for Collaborative Partners	Possible Benefit for Community Clinician Partner	Possible Benefit for Research Partner	Research Challenges and Caution Areas
<p><b>Step D:</b></p> <p><b>Design and Implement Study</b></p>	<ul style="list-style-type: none"> <li>■ Researchers need to communicate the relevance of specific study designs, yet be open to modifying design with approaches more acceptable to partners. Community-acceptable approaches may involve gathering focus group or other qualitative narratives.</li> <li>■ Recruitment strategies should be developed with clinician and advisor ideas for effective ways to reach patients and keep them actively involved.</li> <li>■ Pilot testing with review of findings and revisions through clinicians and advisor feedback.</li> </ul>	<ul style="list-style-type: none"> <li>■ Actively building on unmet needs and therefore contributing beyond the patient-by-patient level, in parallel with community oriented primary care principles.</li> </ul>	<ul style="list-style-type: none"> <li>■ Project details less likely to fall through the cracks and lose momentum and day to day research operations will likely be more smooth because of this sustained interest by clinicians and staff (and community).</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Challenge:</b> Keeping integrity of the research design when community clinicians and staff also feel ownership, as in keeping randomization protocols in place, even with wait list designs. Balancing time and cost considerations with goals to find the 'best' answers. Hiring local staff and training them to do research is important but complex at times.</li> <li>■ <b>Caution:</b> Pilot test findings may result in new ideas or changes that may delay the project.</li> </ul>
<p><b>Step E:</b></p> <p><b>Analyze and Interpret Data</b></p>	<ul style="list-style-type: none"> <li>■ Community members should review findings and interpret in local social and cultural context to inform developing dissemination strategy. Clinicians will want to see their clinic or patient data, so strategies to disaggregate by local area, if possible, while protecting privacy will need to be ensured.</li> </ul>	<ul style="list-style-type: none"> <li>■ Clinicians and advisors will likely find results 'resonate' with previous views, or, if they contradict them, may find new knowledge generating useful to challenge preconceptions.</li> </ul>	<ul style="list-style-type: none"> <li>■ Community clinicians and advisors will find smart ways to translate findings into local knowledge sharing and ideas for dissemination.</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Challenge:</b> Interpretations of data by non-researchers may be different; may require thoughtful negotiation and mutual learning. Be mindful that local findings will be of primary interest to clinicians too.</li> <li>■ <b>Caution:</b> Presentation of findings for this discussion of interpretation should allow for alternative interpretations, rather than present data as 'final'.</li> </ul>
<p><b>Step F:</b></p> <p><b>Implement Results</b></p>	<ul style="list-style-type: none"> <li>■ Follow-up strategies to build on results should also have a community review process, with original group and additional identified stakeholders that may play a role in future work.</li> </ul>	<ul style="list-style-type: none"> <li>■ Pride in accomplishments and validation of work with new energy to follow-up if changes are occurring as a result of research.</li> </ul>	<ul style="list-style-type: none"> <li>■ Longevity of research collaborations and sustaining of projects over time.</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Challenge:</b> Writing additional grants while projects are underway to sustain continuity.</li> </ul>
<p><b>Step G:</b></p> <p><b>Implement Results</b></p>	<ul style="list-style-type: none"> <li>■ Community clinicians and advisors as authors on scientific papers and presenters in community and broader settings.</li> </ul>	<ul style="list-style-type: none"> <li>■ Recognition and authority related to community work, extension of COPC ideas.</li> </ul>	<ul style="list-style-type: none"> <li>■ Findings will reach larger audience and generate interest among new stakeholders, including policy makers and health systems players.</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Challenge:</b> Publishing papers may not be the primary interest of community clinicians; other dissemination strategies may be of more interest.</li> </ul>



## TOPIC 12

### What do I need to know to obtain funding for collaborative research?

It is not easy to build the longer timelines and dissemination of findings that may be most suitable to practice-based collaborative projects into grant proposals that are not intended for them. Practice-based research partnerships take time to develop and funding is usually scarce for the time it takes to build these relationships. Once these relationships are established, obtaining funding can still be very competitive. Because multisite practice-based interventions can be expensive and logistically difficult to implement, it is often best for researchers who are new to practice-based research to begin with smaller studies that employ fewer resources and are easier to fund, moving on to larger and more ambitious studies after successful pilot studies have been successfully carried out. Whether at one site or many, collaborative projects should start with topics of interest to all parties. One advantage of working with PBRNs is the cost savings that can take place because their infrastructure and the data systems they have in place.

The promising news is that, increasingly, major foundations and federal funders recognize the importance of practice-based research, and more funds are being allocated to practice-based research than ever before. NIH and [AHRQ](#) requests for proposals have specifically called for practice-based research within the context of PBRNs in recent years, and the [NIH CTSA initiative](#) was in part designed to promote more research that takes place in community-based practice settings. Grants for collaborative research are often successful since the outcomes are grounded in realistic settings and often focused on practical uses of funds to achieve the outcome under study.

A researcher may approach a clinician or clinic system about a practice-based research project after having received a grant. When funding has already been secured, it is essential that potential partners develop a working partnership and agree on the scope of work in relation to the available funding. This can be challenging if the researcher is obligated to deliver a specific product to the funder and the community-based clinic has other objectives in mind. Community clinician input is nonetheless still important as a “reality check” on the proposed plans for data collection and research instruments (surveys, questionnaires, etc.), and a good researcher will incorporate community input and adjust the plans as needed.

Another scenario is that a researcher and community clinician are interested in the same topic and decide to write a grant proposal together. In this case, there is usually very little funding available for the work required to develop the new project. In some cases, researchers may be able to capture the interest of clinicians by providing stipends for participation in early formative work, or in some cases larger clinic systems may have a strong enough stake in the research project donate resources to help develop the proposal. Negotiations about the type of project, the methods of gathering data, how clinicians may participate, desired endpoints, and the allocated resources should take place at this stage. It is important to clarify with each person involved about the degree of certainty of the scope of work and the budget. Since a grant administrator may have to respond to granting restrictions for how the money can be spent, it is important that clinician and clinic partners know about what options are available to share resources with them.

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## TOPIC 13

# What administrative mechanisms should I know about when setting up a research partnership with a community clinician?

### Letters of Support

Community clinicians and organizations that represent them or departments or systems in which they work (like the Community Health Network in San Francisco) are often asked to write *letters of support* and a description of their capabilities and contributions to a project. The letter of support usually names the grant and funding mechanism, describes partner organization and its relationship with the researcher, and states what part each organization will play if the grant is funded. A letter of support is not a formal commitment.

### Subcontracts

Depending on the research budget, tasks required of community-based clinical partners, and requirements of prospective funders, it may make sense to discuss drafting a *subcontract* even before the research project gets funded. A subcontract is a formal legal agreement between UCSF and non-UCSF research partners. A subcontract in which your collaborative practice partner provides services to UCSF requires at minimum:

- The overall scope of work;
- A timeline for deliverables;
- A listing of participating clinic staff, including their expected roles on the project;
- The proportion of clinic staff time spent on the project, their tasks, their salaries and benefits;
- Other costs including indirect costs; and
- Reporting requirements.

Recipients of subcontracts on federal grants also have to agree to specified salary caps, human subjects protection guidelines, and prohibition on lobbying. Multiple revisions of subcontract agreements may be required to satisfy UCSF Contracts and Grants requirements.

### Memorandum of Understanding (MOU)

A *memorandum of understanding* describes the types of deliverables and general timeline of the deliverables between the UCSF researcher and community clinic or clinic system. It is more formal than a letter of support and is signed by both the researcher and the leader of the clinic. Before the research project begins, it is important to determine if this person is the clinic director, medical director or some other clinic level administrator, or perhaps a combination of stakeholders. [Read more information about MOUs.](#)

### Accounting

The [UCSF Office of Contracts and Grants](#) must review agreements between researchers and clinics to make sure it follows regulations from the funding agency and UCSF. The Contracts and Grants office is also the office that receives the funds. Once funding is obtained by UCSF, funds flow from the University to subcontractors and partners.

### Local Institutional Review Boards (IRBs)

Before the research involving human subjects can begin, the researchers must obtain Institutional Review Board approval. Some clinics have their own internal IRB mechanism and others will defer to the

## TOPIC 13 (continued)

### What administrative mechanisms should I know about when setting up a research partnership with a community clinician?

decisions of the *UCSF's IRB*, known as the UCSF Committee on Human Research. To avoid costly delays after funds are awarded, it is advisable for the researchers to learn which types of human subjects approval will be needed and begin drafting the necessary documents early in the research process. Clinic staff who will work on research projects will be required in most cases to complete human subjects certification programs if they will be working with patient data for research purposes. The UCSF Committee on Human Research *provides training on human subjects protection in online modules*.

#### Community Advisory Boards

Broad and meaningful support from the communities involved in the research is important to the success of community-engaged research. As the research idea moves closer to being a proposal, a community-based and oriented Community Advisory Board (CAB), Scientific Review Committee (SRC), Community Clinician Advisory Board or Scientific Advisory Board (SAB) can be established to review elements of the study. These groups can meet throughout the life of the project.

#### The UCSF Committee on Human Research

The UCSF *Committee on Human Research (CHR)* requires that all members of the research team, which may include you or staff from your clinical partner(s), take part in online training to assure that everyone who is involved in the study has an appropriate level of understanding of the principles of the safe conduct of research. Since 1996, this training has included education on requirements of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA training is meant to assure that any research information that is derived from the medical record is handled appropriately with respect to participant confidentiality and privacy. See *more information on HIPAA*, and more information on *HIPAA training at UCSF*.

Most CABs are comprised of leaders and other individuals representing various parts of the community, such as patients, office staff, representatives of local health-related organizations, schools, religious groups, media, other clinicians, and other interested parties.

CABs are generally made up of no more than 20 people who serve as primary liaisons between the community and the trial researchers. Often a senior scientist or physician and/or other member of the trial staff will attend CAB meetings on a regular basis, a sign indicative of the CAB's importance in the trial process.

CAB members may take on active roles in planning for and undertaking research projects. Examples of their numerous activities include:

- General community outreach and education;
- Support for volunteer recruitment by disseminating information about the study;
- Providing feedback on trial protocols, including criteria for participation, informed consent forms and processes, and volunteer recruitment and retention;
- Advising investigators regarding potential participants' perspectives about the trial;
- Providing a safeguard (in addition to institutional ethics review committee) for participants' rights;
- Representation at important national, regional and international meetings and conferences.

CABs may provide feedback on the actual trial protocol, the informed consent document and any educational materials to be used in the community. Although these consultations are not part of the formal approval process, researchers may make changes to the trial protocol and other documents to reflect this community input. This process helps to ensure that communities receive appropriate information, that their concerns are addressed and that the trial will run smoothly in the community.

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### What administrative mechanisms should I know about when setting up a research partnership with a community clinician?

CAB meetings are a useful forum for addressing ongoing concerns and project progress.

#### Staffing

Practice-based researchers must anticipate the staffing needs of clinics that participate in research. Since research needs to be integrated into the regular clinical activities of clinical sites, research staff works closely with each site to maintain dialogue between the investigators, clinic administrators and providers throughout the course of the study. Investigators meet with key clinic staff on a regular basis to get input on hiring research staff, the development of study tools, piloting instruments, involving and motivating clinic staff to participate and stay involved, and protecting patient rights and confidentiality. If patients are recruited in a doctor's office where study procedures take place on site after the doctor visit, then additional staff may be needed to provide informed consent or other research procedures. Research partners must decide whether this type of research activity will be carried out by paid research assistants, by clinic staff, or both.

Generally, whenever more than minimal effort is required to coordinate activities that will take place at the clinical practice level, it is advisable to hire a research assistant. Administrative staff at the study sites can be involved in the selection of research assistants and research assistants may need additional training on the particular practice's procedures during the preliminary stages of the project at the study sites. Research assistants that are hired to work in clinical practice settings should ideally have experience in both research methods and working in healthcare settings. Good "people skills" are important. Research assistants interact closely with clinicians and staff in the study sites to identify and recruit eligible patients and integrate the study procedures within the flow of the clinic. It is ideal when the research assistants that are hired to work on the study already have experience working within

the specific practice groups where the study will take place. Research assistants need to learn the flow of patients through the clinic, appropriate means and times for initiating contact with patients, and how to handle clinical issues that arise in the course of a study (i.e. for positive test results).

*Since most clinic staff are busy with the daily demands of running a practice, it is usually unreasonable to expect them to be responsible for principal activities of the research project unless staff are given additional time to work on the project and will be compensated for their time.*

Research assistants typically:

- Undergo training in participant recruitment and interviewing techniques, research ethics, reporting procedures and policies and procedures to maintain confidentiality;
- Complete training in the clinical site to learn standard practice protocols at the clinical sites;
- Attend frequent meetings with the project coordinator to discuss all aspects of the study, especially those that relate to participant interactions, recruitment and study procedures.

Counselors, clinicians, and ancillary staff at the study sites may assist in a study by identifying eligible study participants, informing them of the study and giving them a flyer with information on the study. Clinic staff can notify the research staff and/or refer patients who appear eligible for participation in a study. In addition, research assistants can review the clinic schedule each day with the clinic staff to identify potential participants according to study criteria. Research assistants check with staff on a regular basis throughout the day to identify potential participants.

Investigators should visit the research site frequently from the outset of the study and meet with key clinic staff on a regular basis. These meetings can serve as opportunities to ensure that the re-

## TOPIC 13 *(continued)*

### What administrative mechanisms should I know about when setting up a research partnership with a community clinician?

search process is not too burdensome for the clinic, and that the agreed-upon research procedures are being followed with good fidelity while leaving open the possibility that modifications may need to be considered if the protocol is not working for various reasons. Unexpected logistical issues such as staffing changes can cause problems and compromise the study's timeline. The closer the contact research partners are able to maintain, the easier it is to develop good solutions to problems that will usually keep the research going while being considerate of the realities of clinical practice.

#### Reporting

Researchers are obligated to report, usually on a semi-annual or annual basis, the progress of their work to the funder. You may want to ask your community clinician partners to submit reports on behalf of their clinic or network of clinical sites prior to the release of UCSF funds to the clinic. The timing of reports and expectations for what reports contain should be made clear in your Memorandum of Understanding or Subcontract.

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## TOPIC 14

### What do I need to know about publishing a practice-based collaborative study?

Authorship and presentations are key elements of disseminating research findings. *These guidelines for successful dissemination* are very helpful to collaborative research partners. Community clinicians who contribute intellectual content to the research are entitled to co-authorship on academic papers that result from the research study on which they were a collaborating partner. Researchers and community partners should decide up front what role each will have in preparing manuscripts. Often the general requirements for authorship are decided in initial discussions of roles and responsibilities, and can be spelled out in the MOU. Exact roles and responsibilities are often determined or as publications are being planned and prepared. Conflict may arise when authorship decisions are deferred until

the results are submitted for publication. If community partners cannot or choose not to be formal co-authors, a published acknowledgement of the contribution of community partners is a good alternative. Sometimes clinical practice settings are acknowledged or site directors may be one of many authors (i.e. a research study group). A similar process should take place regarding presentations of research findings at community and clinic meetings, academic conferences, and other venues. Research geared toward dissemination and implementation are addressed in more depth in this CTSI Community Engagement Program Guide: *An Introduction to Effectiveness, Dissemination, and Implementation Research*.

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#### How Do I Contact the CTSI Community Engagement Program?

You can reach us by email: [CEP@fcm.ucsf.edu](mailto:CEP@fcm.ucsf.edu)

You can reach us by phone: (415) 206-4048

Visit us on the web at:

[www.ctsi.ucsf.edu/ce](http://www.ctsi.ucsf.edu/ce)

Fill out a consultation *request form* online!



## GLOSSARY

Below are some definitions we use in this guide to describe practice-based and translational research that involves community practice settings.<sup>15</sup>

**Practice-based research:** Research that is located in, informed by, and intended to improve practice and the care of patients.

**Primary care research:** Research directed at understanding and improving the primary care function as defined by the Institute of Medicine. Primary care research includes theoretical and methodological research, health care research (investigations of the components of the primary care function itself), clinical research, and health systems research. Primary care practice-based research is located in, informed by, and intended to improve primary care practice.

**Practice-based research network:** A group of separate practices that collaborate with each other and often with outside experts to conduct multiple research projects over an extended period of time.

**Community-based research:** Research that is conducted in community settings and is intended to improve community-based interventions and community health.

**Participatory research:** Systematic inquiry, with the collaboration of those affected by the issue being studied for the purpose of taking action or effecting change.

**Community-based participatory research:** Participatory research conducted with the collaboration of a community for the purpose of taking action or effecting change. The community, in this case, could be any geographically, socio-culturally, or occupationally defined group with common interests and goals. In both participatory research and community-based participatory research, the research questions generally emerge as a result of the attempt to move forward toward a set of objectives, not as the a priori reason for the research.

**Translational research:** Translational research is the term NIH uses to refer to *this model* of research that aims to bring scientific discovery to patients. Ranging from bench science to effectiveness research, translational phases include T1 (basic science to human research or human research to basic science), T2 (human research to practice-based and community-based research or practice-based and community-based research to human research), and T3 (practice-based research to practice and community or practice and community to practice-based research). T3 translational research is often further divided into dissemination research, implementation research, and diffusion research.<sup>16</sup>

**Dissemination research:** The study of how the targeted distribution of information and intervention materials to a specific audience can be successfully executed so that increased spread of this knowledge achieves greater use and has increased impact.

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<sup>15</sup> These definitions are taken from the North American Primary Care Research Group (NAPCRG), Sub-Committee on Practice Based Research for the Future of Family Medicine Project. Chair: Jim Mold, MD

<sup>16</sup> For a clear summary and explanation of the T1, T2, and T3 phases of translational research, see Woolf, S.H. The Meaning of Translational Research and Why It Matters, *JAMA*. 2008; 299 (2) 211-213).



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