

# Community-Engaged Research with UCSF Researchers

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## A RESOURCE MANUAL FOR COMMUNITY-BASED CLINICIANS

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This is one of a series of guides developed by the UCSF Clinical and Translational Science Institute (CTSI) Community Engagement Program on conducting community-engaged and translational research.

This guide was prepared by the Community Clinician Committee of the Community Engagement Program.

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 UCSF CTSI Community Engagement Program



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## PREFACE

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

Lawrence W. Green<sup>1</sup>

Great scientific discoveries can, but do not always, lead to great improvements in the health of our communities. Historically, academic institutions have not involved communities in the process of scientific discovery, and they have been slow to develop initiatives to bring the results of scientific research to the people who could most benefit from it. In 2006 the National Institutes of Health (NIH) responded by instituting the *Clinical and Translational Science Awards* (CTSAs), a new funding program to address these discrepancies and facilitate the *translation* of important scientific discoveries into practice. The University of California San Francisco (UCSF) was one of the first recipients of a CTSA, 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 communities where patients live.

NIH states that an enhanced translation enterprise should include “*outreach to underserved populations, local community and advocacy organizations, and health care providers.*”<sup>2</sup> Going beyond “*outreach*”, UCSF recognizes that strong and mutually beneficial partnerships between the communities UCSF serves and the university are essential to a translation process that addresses the needs of all patients and works to address health and health care disparities. In order to accomplish its mission, the UCSF CTSI established a *Community Engagement Program (CE)* to provide consultation, training, and other resources to build the capacity of UCSF and local community organizations and clinical settings to conduct community-engaged research. Community-based clinicians and networks of clinicians are strongly encouraged to work with the CTSI Community Engagement Program to explore possible collaborative research opportunities to address the health and healthcare concerns of the patients they care for.

The Community Engagement Program’s Community Clinicians Committee (CCC) prepared this guide to inform community clinicians about the processes and steps involved in developing such research collaborations. We have included resources to facilitate this work and address some of the barriers to

### A Note About Terminology

In this guide we use the terms *community clinicians* and *community providers* 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, and
- Retail pharmacies

<sup>1</sup> 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.

<sup>2</sup> See NIH News, September 18, 2007 [[www.nih.gov/news/pr/sep2007/ncrr-18.htm](http://www.nih.gov/news/pr/sep2007/ncrr-18.htm)]

### What is “Health”?

Health is a broad concept, which we define here as the state of well-being and balance that individuals and communities experience when they are able to function at their full potential. This definition derives from the widely accepted definition of health used by the World Health Organization (WHO), which states that *“health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”* (WHO. Constitution of the World Health Organization Geneva, 1946). In more recent years, this statement has been modified to include the ability to lead a *“socially and economically productive life.”* Some argue that health must be seen as a process of continuous adjustment to the changing demands of living and of the changing meanings we give to life.

collaboration. The overall aim of this document is to orient community-based health providers seeking to build research partnerships with UCSF. A companion guide is available on the UCSF CE [website](#) for investigators who would like to explore such partnerships with community clinicians.

When researchers and community clinicians engage in the process of discovery together, advances in scientific knowledge can be more finely tuned and immediately applicable to clinical practice. Therefore the path from scientific discovery to practice is likely to lead to more rapid advances in the health of patients and our communities. UCSF researchers and community clinicians have much to gain from partnerships dedicated to having a positive impact on the health of communities. This guide is designed to inform, facilitate and support such partnerships.

There are many types of collaboration that can take place between community clinicians and researchers. For example, community clinicians and researchers can work together to:

- Learn about the health priorities and everyday experiences of clinicians and their patients;

- Identify research questions that are relevant to clinicians and patients;
- Recruit clinicians and patients to participate in clinical studies;
- Design and implement research projects in community-based clinical settings;
- Identify effective methods to facilitate dissemination and adoption of important research findings.

The breadth of research expertise at UCSF and the diversity of clinical expertise in our communities create the potential for exciting and productive research partnerships. At the same time, research collaboration across disciplines and professional settings can be slow to develop, because researchers and clinicians need time to get to know each other and understand each others’ priorities, belief systems, and organizational needs. Ideally, the time, expense and logistical challenges involved in developing such partnerships will be offset by research results that are more immediately relevant to clinical practice, and that could not have been achieved with any other approach.

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### Know Your Research Partner

Many institutions in the Bay Area conduct clinical and health sciences research, including *Children’s Hospital Oakland Research Institute (CHORI)*, *Kaiser Permanente*, *Stanford University Medical School*, *University of California Berkeley School of Public Health* and *California Pacific Medical Center (CPMC)*. Many of the elements discussed in this document apply to collaborations with researchers from these and other institutions, while other elements will be specific to research conducted at UCSF. If you have questions about researchers who contact you regarding a partnership, it’s important that you know about the places they work and understand the requirements of that institution before getting involved in a study.



## TOPIC 1

# Why might I be interested in clinical research, and what can it offer my practice?

Researchers may help community clinicians:

- Identify and provide access to new and better treatments for patients;
- Identify and provide support to develop better systems of clinical practice;
- Identify public health priorities that can be addressed by clinicians;
- Develop educational programs for clinicians and patients;
- Translate clinical questions into research projects that address important patient needs.

Clinical research often takes place in specialized settings or on patient populations that do not reflect the diversity of health and healthcare needs and resources in our communities. The findings of research conducted in these settings may not be relevant or applicable to clinical practice needs, especially in practices that serve populations of patients that are not often represented in clinical trials. When community clinicians participate in research design or in the execution of a research study, they may have an opportunity to ask and answer the questions that are most relevant to their practice and patients. More generally, participation in clinical research may bring knowledge, skills, and resources to a practice that would not otherwise be available.

Research conducted by UCSF investigators includes a wide range of study designs, such as survey research, observational studies, and placebo-controlled clinical trials of novel treatments or medications in patients. In addition, research may involve the health

care system itself in the form of studies of health systems or workforce training interventions. Often researchers are interested in finding effective treatments; learning how patients are evaluated, treated, and cared for in clinical settings (patient-centered research); and how communities experience systematic barriers to achieving optimal health (community-based research). More recently, the concept of community-based participatory research (CBPR), in which communities play major roles in defining the research questions and interventions, has expanded the definition of research to include many different types of activities, including clinical capacity building, network development, and policy action. Practice-based research is a type of community-based research that involves collaboration between academic researchers and community clinicians.

### How do I find a research partner at UCSF?

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

- Find a potential collaborator with similar interests;
- Establish a relationship with a UCSF clinical researcher;
- Manage the steps of setting up a research project with a collaborative partner;
- Explore the degree of involvement that would work best for you and your practice setting.

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 1 *(continued)*

### Why might I be interested in clinical research, and what can it offer my practice?

Clinical research takes place along a continuum of possible types of partnerships. At one end of the continuum, clinician participation may be limited to responding to surveys or recruiting patients into clinical trials, with most or all other research procedures taking place off-site. At the next level of collaboration, clinicians may engage researchers in discussions of research ideas or participate in study design and implementation at the level of their own clinical

practice. In the most highly engaged practice-based partnerships, community clinicians may serve as co-investigators or even principal investigators for a study and participate fully in the development, implementation, analysis and dissemination of a research project. More information on the various types of involvement can be found in this resource manual. On the next page, we offer some examples of collaborative clinical research projects. The Community Engagement Program is available to help clinicians assess at what point(s) along this continuum they would like to collaborate with a UCSF investigator.

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

Practice-based research networks, or PBRNs, are groups of clinics or practices primarily engaged in primary care, but also 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).

In summary, community clinicians may be interested in clinical research for many reasons. Most simply, it can be a way to offer patients access to clinical trials in the context of their ongoing healthcare. Often patients are able to access additional new diagnostic tests or treatments that would not be available outside of clinical trials. Patients can benefit from closer or more frequent follow-up visits than are usually associated with their routine care. But on a deeper level, clinical research offers community clinicians an opportunity to participate in processes of discovery that may benefit their practice, their patients, and their communities. [\[Back to Topics\]](#)





## TOPIC 2

### Why are UCSF researchers interested in working in community-based practice settings?

When research is conducted in community-based practice settings, findings are likely to be useful and lead to the implementation of feasible change. Practice settings provide a reality-based context for the implementation of new health care or health service interventions. While practice-based research poses logistical and conceptual challenges, its rewards are increasingly recognized by academic researchers. Academic research institutions and funders are beginning to align their resource allocations with those priority shifts. For example, Clinical Research Centers (CRCs) traditionally have provided the highly controlled hospital/clinical settings, equipment, and other resources for much of the clinical research that has been conducted to date. The [CRC at UCSF](#) is fully committed to working collaboratively with community settings to investigate therapies and interventions. The UCSF CRC currently is partnering with Kaiser Permanente, the Veterans Administration, Children's Hospital Oakland Research Institute, and community clinics to investigate therapies and other interventions.

When research enters the community-based practice setting, the needs and real circumstances of patients' lives can be incorporated into the questions research asks and solutions that are proposed. When commu-

nity clinicians and the settings in which they practice are not adequately part of the design, implementation, and dissemination of clinical research, scientific advances are not as likely to lead to commensurate improvements in the health of our communities. Partnerships between community clinicians and academic researchers can help research studies:

- Identify appropriate research priorities;
- Develop research questions that are relevant to clinical practice and the community context;
- Increase the participation of diverse and representative clinical practices and patient populations;
- Develop research and patient education protocols and materials informed by insights about clinical care, the busy clinical context, and patient experiences;
- Improve the implementation and dissemination of findings in the clinical context;
- Improve the dissemination and implementation of promising new discoveries; and
- Increase the generalizability of research findings.

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## TOPIC 3

# What questions should I ask about partnering with a UCSF researcher? How do I know which researchers will be good collaborators?

As is true with other relationships, successful research collaborations often depend on personal qualities that result in commitment and trust. You will need to make those assessments for yourself, and doing so will help you decide which partnerships are worth pursuing and help ensure your active participation in the collaboration. We can also help. Here are some questions to get you started:

- Is the researcher interested in a question that is important to my patients?
- Do I have the time to work with the researchers on bringing this project into our practice?
- Are my office staff and work colleagues interested in participating?
- Does the researcher understand the needs of our practice and our patient population?

Click on the link in the box below for more questions that will help you assess potential research collaborators. If you'd like more information about this

### More Questions for Potential Collaborators

For more questions to ask collaborators, see [Working Together: A Guide to Collaborative Research in HIV Prevention](#). Page 17 lists useful questions for all research topics. Here are a few:

- Has this person collaborated with others before?
- How did the experience go?
- Does the researcher have the skills such as formal training and language skills needed for this project?
- Is the researcher aware of the needs and assets of the population I work with?

facet of collaboration, please contact the [Community Engagement Program](#) at [CEP@fcm.ucsf.edu](mailto:CEP@fcm.ucsf.edu) or call us at (415) 206-4048.

### Sustaining the Partnership

One common challenge to academic-community partnerships is making the relationship last. Community providers often report that a researcher appears out of nowhere, requests community support for a particular project, and then disappears again at the conclusion of the project. This approach can lead to distrust the next time a different researcher (or the same one) appears. In choosing a research partner, you should engage with a researcher who understands and subscribes to the [principles outlined here](#).

We recommend that when a partnership between a community clinician and a researcher is being considered, there should be a process to assess the needs and capacity of each. At regular intervals, research partners should reassess how the partnership is progressing relative to the milestones set forth in the project proposal. This needs to be done in a consistent and explicit manner to avoid misunderstandings and distrust. A researcher should be clear about his/her current availability and career plans and set out realistic expectations for continued engagement in current and/or future project. Clinic staff should do the same. A trainee should not commit to a lengthy involvement (although a successful project may increase the likelihood of staying longer). Junior professors (those with "Assistant" in their titles) are likely to be involved in a single project for 3-5 years. It's a good idea to ask about a researcher's expected timeline for involvement in the project.

### TOPIC 3 (continued)

#### What questions should I ask? How do I know who will be a good collaborator?

Collaborators should be prepared for the fact that most projects are not funded the first time a proposal is submitted, so it can be a year or two and often more before the project actually gets off the ground. For every project that's funded, several are not. Researchers cannot guarantee that a proposal will be funded, so the time spent in study development asks all collaborators to work toward an uncertain goal. In written agreements, statements such as “if this grant

is funded, then...” or “if this project is successful, then...” are often made. But these statements should also be followed by “if this grant is not funded, then...” or “if this project does not attain its objectives, then...” It is the responsibility of both academic researchers and their community partners to make sure that both types of statements are spelled out in sufficient detail to sustain research partnerships through successes and disappointments. [\[Back to Topics\]](#)

#### Examples of Community-Engaged Clinical Research at UCSF

- Community-based clinicians and academic researchers investigated small-group [practice-based learning and improvement \(PBLI\) methods](#) designed to help clinicians better manage case-based clinical uncertainty.
- What is the best method to [increase access to emergency contraception](#) for women?
- [Understanding Repeat Cesarean Births](#) among Mexican Migrant Women in California and Mexico, a Binational Approach.
- 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.
- 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. In which situations and applications is it effective? 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 out.
- UCSF's Schools of [Dentistry](#), [Medicine](#), [Nursing](#), and [Pharmacy](#) host websites dedicated to research. Check these sites for other examples of community-engaged research.



## TOPIC 4

# What should I know about academic research when considering a research project or collaboration?

Research is about discovery which, along with patient care and teaching, is a primary mission of academic medical institutions like UCSF. Health sciences researchers usually have a specific area of interest that is important to them. These interests may be derived from care of patients with special problems or because of a larger interest in improving public health. Health sciences researchers can be physicians, nurses, dentists, pharmacists, laboratory scientists or social scientists. They typically have special training in research methods.

Built into academic research programs and institutions are structures and processes that maintain high ethical standards, support rigor, and encourage high quality work. These include governmental and institutional regulatory systems, peer review, and the standards that guide internal and external competitive funding processes.

To have successful careers, researchers must establish themselves as an expert in a particular area of inquiry, whether it be basic science, clinical, epidemiologic, or health services-related. This is typically done by building a program of related research projects and presenting the findings of this research to peers at meetings and in professional journals. Academic promotion is based on demonstration of expertise as evidenced by securing funding for research projects, authoring significant publications, serving on committees of professional organizations (e.g. the American College of Obstetricians and Gynecologists) or government agencies (e.g. the National Institutes of Health), and providing education and mentoring for young researchers and providers. The infrastructure of academic institutions

is designed to support inquiry and the standards of excellence that are a critical element of it.

At UCSF almost all research projects are funded by grants from the government (federal, state, or local), private foundations, or by the pharmaceutical industry. The vast majority of UCSF researchers are supported by grants. They raise the money for their salary and the salaries of the research team by writing grant proposals. While the requirements differ from one source to another, some issues apply generally. UCSF grants are managed by a central [Contracts and Grants Office](#).

### What kinds of rules and regulations do academic researchers have to follow?

Each research partnership will differ depending on the nature of the project and the researcher(s) and organization(s) involved. However, *all* UCSF researchers are required to follow rules and regulations that are specified by UCSF, their funders, and by state and federal regulators. Some of the most important regulations have to do with assuring that research

### Principles of Good Community-Campus Partnerships

[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 the link below to see the full text of the [CCPH Principles of Good Community-Campus Partnerships](#).

## TOPIC 4 (continued) What should I know about academic research when considering a research project or collaboration?

does not harm study participants, and that patient confidentiality is protected.

Clinical research activities that involve people must be approved by an Institutional Review Board (IRB). The purpose of the IRB is to make sure that the study has undergone appropriate scientific review, has an acceptable balance of risks and benefits for research subjects, follows appropriate methods of informed consent for research participants, and has appropriate systems in place to monitor patient safety and confidentiality as the research proceeds. Sometimes multiple IRBs need to be involved.

The IRB at UCSF is called the [Committee on Human Research \(CHR\)](#). The CHR reviews research proposals and grants permission for implementation, once the safety and privacy of study participants is established. The review process is intended to protect those who participate in research by providing oversight of issues such as study quality (*Is it good science?*), disclosure of risks and benefits (*If there's the possibility of any benefit or discomfort or risk to the participants, how will you let participants know about it?*), and the design and administration of consent forms (*Are the consent forms clear and explained in a consistent manner?*). This process must take place, even if your practice site holds the main grant and the researcher is only working for you as an evaluator. The UCSF researcher is responsible for submitting the application to the CHR and following the regulations, but this process very likely will require your organization's input.

The type of CHR review that is required depends on the type of research—for example, expedited review is appropriate for research studies that involve no patient contact, whereas full committee review is required for studies that involve clinical interventions such as the use of an experimental therapy. CHR approval must be renewed annually, and changes in the research protocol must be submitted, reviewed, and approved as they occur. The [CHR website offers](#)

[forms](#) that UCSF researchers are required to use for different types of human research.

Obtaining informed consent from research subjects is one of the most important responsibilities of clinical research teams. The UCSF CHR provides templates and examples of consent forms to assist researchers with the appropriate language for informed consent. When study procedures are complex, when a language other than English is spoken or read by research participants, or when the literacy level of participants is low, clinicians and researchers can work together to develop an appropriate consent form for participants from the clinician's practice. Read about [consent forms](#) on the CHR website. NIH offers information on [what makes a good consent form](#).

Though IRB review usually takes no more than two or three months to complete, it can take longer, depending on the complexity of the study and number of groups that must provide final approval before a study can be implemented. Therefore, even after a research project has been funded, additional delays in implementation that pertain to IRB approval and other bureaucratic requirements should be anticipated both at the beginning of a project, and sometimes even after implementation of the

### On Conducting Human Research

The UCSF CHR requires that members of the research team, which may sometimes include you or your clinic staff, 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 patient confidentiality and privacy. See [more information on HIPAA](#), and more information on [HIPAA training at UCSF](#).

## TOPIC 4 (continued) What should I know about academic research when considering a research project or collaboration?

study has begun. IRB delays can be frustrating, but the proper human subjects review is an essential part of the research process.

On a final note, the results of research sometimes have implications for public policy. Researchers are expected to advocate for dissemination and implementation of their research results in the community. However, recipients of federal or state funds are prohibited from lobbying as part of these efforts (i.e., promoting specific legislation). UCSF researchers, who are employed by the State of California (and who might be funded by governmental grants), fall into this category, as are employees of governmentally funded clinics. This can seem a fine line to walk in some circumstances, but it is legal for these employees to educate policy makers, advocate for proven scientific solutions, or advocate for a position as an individual.

### Key decisions about design, implementation and dissemination in a collaborative research project

#### *To what degree will community clinician partners define the research question?*

Community clinical partners can define research questions they and their patients need to have asked. When clinicians contribute their clinical and practical expertise to the definition of a research question, they take a critical first step in designing a feasible study and give research findings the best chance to be applicable and valid. Clinical research traditionally has been very restrictive when it comes to forming the research question. In pharmaceutical trials, for example, industry sponsors usually have very clear objectives that need to be met for drug approval requirements. Community clinicians traditionally do not have much impact on the research question in this scenario. Increasingly, however, there are good opportunities for community clinical partner participation in deciding what research questions are asked. Research on best clinical practices, for example, offers a number of

options in this regard. Quality improvement (QI) or practice redesign studies are good examples of research that benefits from clinical research partner participation from the outset.

#### *To what degree will the community clinician partners participate in the development of the study design?*

In general, the study design is driven by the type of questions being asked and the answers sought. Study design will also be dictated by logistics of the clinical practice setting. For example, it may be unrealistic to expect potential study participants to complete study procedures in your practice if the procedures are time-consuming and might interfere with patients' clinical care. The community clinician partner's input will be critical in the design decisions.

#### *What role will the community practice staff play in recruiting and enrolling participants in a study?*

A mutual decision must be reached about practical expectations for clinic staff, reimbursing staff for their work on the project, and management of potential disruptions in the normal clinic flow. In some cases, the research plan may need to provide for the hiring of a research assistant to manage participant recruitment, informed consent, and other non-clinical requirements of the study.

#### *Will community clinicians be co-authors on final study research papers and presentations?*

Most peer review journals require co-authors to play an active role; that means providing intellectual content or making a specific contribution to the design or to the analyses that result from implementation of the study. Authorship of scientific publications is usually determined by rigorous criteria, and community clinicians who contribute intellectual content to the research will qualify. Researchers and community partners should decide up front what role each will have in preparing manuscripts. Often the determination of authorship is decided in the MOU or as publications are being planned. Conflict may arise when authorship decisions are de-

## TOPIC 4 (continued) What should I know about academic research when considering a research project or collaboration?

ferred 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 may be 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.

### Find out more!

For an example of a presentation by a researcher to partner clinics, educational institutions, and pharmacies, please see the [CTSI Community Engagement Program's Resources webpage](#).

### Research Design and Methods

Even when the research question is of great interest to you, the way the project is designed may have an even greater influence on your willingness to participate. Therefore, it is important to understand the requirements of participation before agreeing to take part. For example, you will want to work closely enough with the researchers to anticipate the time and resources that will be required of you and your practice in order to meet the requirements of the research project.

For example, if informed consent or other procedures will have to take place in your office, you may need to be sure that you have a private space in which to complete these tasks.

A common methodological issue that research collaborators should discuss is the use of control groups, in which one group of patients serves as a comparison group to the group receiving treatment or participating in the intervention being tested. In these kinds of studies, control groups do not receive

the new program or intervention. In comparative effectiveness studies, two or more treatment or intervention options may be tested and compared at the same time.

Another common issue that might impact the participation of clinical research collaborators is randomization, the process by which participants are not allowed to choose their group (intervention or comparison), but are assigned to groups by a random method. A third common issue concerns the quantity of data that researchers want to collect. Sometimes the size of the sample of participants is not realistic given the size of the patient population that qualifies for the study.

While randomized clinical trials will continue to form the foundation of advances in medical knowledge for the foreseeable future, community clinicians can often help researchers come up with research designs that will provide appropriate incentives for participation. For example, if your practice is assigned to be in the control group for a study that will test a promising new procedure for preventing dental caries in young children, you could suggest a research design that allows all practices to share in whatever lessons are learned as a result of participating in the study. Another area in which community clinicians can participate in study design is in the definition of process and outcome measures. When research is defined too narrowly, the benefits to participants may be limited. Community clinicians may have ideas for including measures that will be immediately useful to research participants, and thereby encourage recruitment efforts. We encourage open discussion between researchers and community clinician collaborators about issues such as these early in the research collaboration. When these issues are addressed during the planning process, they are more likely to be addressed successfully.

## TOPIC 4 (continued) What should I know about academic research when considering a research project or collaboration?

### Publications and Presentations

Publishing and presenting research findings is part of the dissemination process. Researchers typically present research findings at scientific meetings and publish findings in scientific journals. When findings are important or unexpected, the popular media (TV or newspapers) may report on them. Medical organizations or insurers may use study findings to create practice guidelines for providers advocating use of treatments or interventions that are found to be effective in research studies.

Researchers' career advancement is dependent on obtaining grants and publishing the research results in scientific journals. Thus, they have a vested interest in presenting and publishing in scientific venues. Publishing research findings helps share information with a wider audience. Many researchers are also enthusiastic about participating in research presentations in community venues. If this is important to you or your clinic, you and your research partner should pursue these kinds of opportunities both to present and host presentations. Work with your research partner to create and plan presentations that are appropriate for your audience(s). Ask researchers about the opportunity for your staff to be trained to present at scientific venues. Community clinician collaborators and academic partners should work together to share findings locally with patients and other clinical partners. These [Recommendations for Research Dissemination](#) published by the UCSF Center for AIDS Prevention Studies (CAPS) Community Advisory Board offer useful ideas and guidelines for successfully communicating updates and findings to collaborators, par-

ticipants, policy makers, and other stakeholders. When dissemination is effective and well thought out, it encourages and facilitates the application of research so that research can make a positive difference in patients' lives.

#### Find out more!

For more information on writing up research, see [Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication—Authorship and Contributorship](#)

### What are some limitations to keep in mind about participating in research?

- **Limited time:** there will always be pressure to accomplish the protocol requirements mentioned here;
- **Limited space:** for outside research staff and equipment;
- **Limited financial resources:** for anticipated and unanticipated research costs.

Hopefully these potential limitations will not outweigh or override the long and short-term benefits a research collaboration could bring your patients, your practice, and the communities you and UCSF serve. 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 UCSF research collaborator.

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## TOPIC 5

### What might an academic researcher need to know about practice settings like mine?

What counts as useful information about your setting depends on what is being studied and the level of involvement your practice elects to have with the study. If you are simply referring patients to participate in a study of a new treatment for diabetes, for example, then the researchers may not require any information about you or your practice. However, if you are working with researchers to evaluate the effectiveness of a diabetes outreach program on the health of your patients, then much more detailed information about the practice environment will be required. While some researchers are clinicians and have a good idea about clinical practice, they may not be familiar with a particular practice setting. In this case, it may help the project to have baseline data such as the number of diabetes patients you care for, their demographic characteristics, how often you see them, who checks them in and out of the practice, and how you monitor each patient's success with treatment goals. Typically, the type of practice information that researchers need to know falls somewhere in between, and general descriptions that you can provide about your clinical practice can often be enough to get started.

The type of questions that researchers may ask about your practice may vary somewhat, depending on where it is located, e.g., in a hospital, clinic,

pharmacy, dentist's office, or other setting. However, some of the same questions may apply, no matter where you work or whom you serve:

- Who are our patients?
- What services do we provide?
- How do we track who our patients are and the services they use?
- How do our patients use our services?
- How are we staffed?
- What kind of time and money pressures are we up against each day as we see patients?
- Who in our office is available to work with researchers on projects that are important to me and my practice?
- What is our relationship with clinicians in other practices that serve our patients or that serve similar patients in our community?
- Do we need authorization from anyone outside of our practice to participate in clinical research projects?
- Do we belong to any practice groups or networks that could be recruited to participate along with us in some of these research projects?

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## TOPIC 6

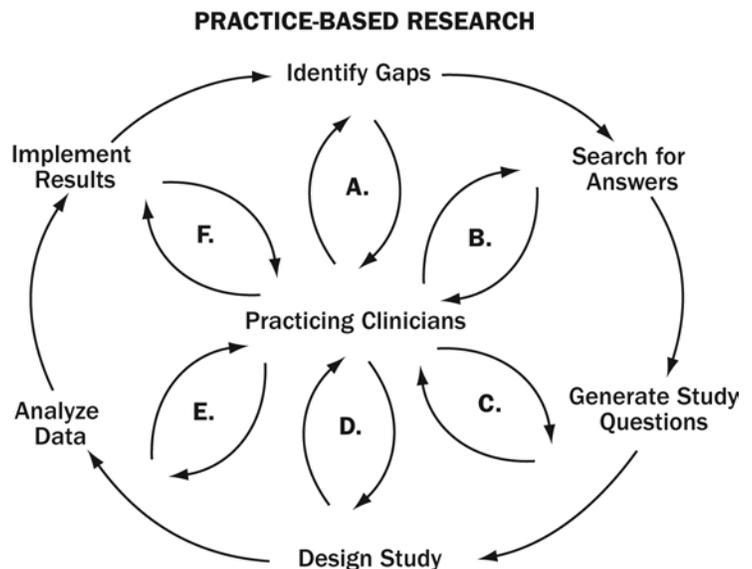
### What are the steps of collaborative research I need to know about?

Collaboration revolves around processes of joint decision-making related to the three major steps of research: design, implementation, and dissemination. Mutual decisions should be made on the design (research question, the research plan, and research methods); implementation (the intervention delivery, data collection, data analysis); and dissemination (publishing, presentations, reporting and networking). Individuals differ in how they share decision-making authority. We recommend that collaborating partners identify a decision-making process that will keep the project on target and is appropriate to the interests and skills of the partners. As mentioned above, it is often helpful and even necessary to set up an advisory board comprised of key staff at the study site(s), community members, and researchers to guide decision-making about study design and implementation. At the outset and throughout the project, partners should discuss what decisions must be made, who

will be involved in making decisions, who makes final decisions, and about what facets of the project. A good place to begin this conversation is to discuss who is and who should be at the table from the very beginning. While ultimately the Principal Investigator is responsible to the funder to complete the research and oversee the budget, there are many decisions that can be made together or by the community partner if a clear process for shared decision-making is put in place at the outset.

The diagram below, *Practice-Based Research Involving Clinicians in Research Steps*,<sup>3</sup> shows the discreet elements of research and how researchers and clinic partners should establish communication and feedback loops at each step in the process. Community clinicians, researchers and participants can engage with each other at each lettered step while progressing around the circle. [\[Back to Topics\]](#)

- A: Identify a problem, issue, concern, or asset that triggers investigation.
- B: Look for answers, hypothesize.
- C: Develop refined questions for rigorous study.
- D: Design the study based on literature review, theories and methods.
- E: Collect and analyze data. Dissemination can begin here.
- F: Build on lessons learned, implement interventions based on findings. Dissemination can continue.



<sup>3</sup> Primary Care Practice-Based Research Networks: Working at the Interface Between Research and Quality Improvement. James W. Mold, MD, MPH and Kevin A. Peterson, MD, MPH *Annals of Family Medicine* vol. 3:S12-S20 (2005). Diagram constructed by Nutting at the Primary Care Methods Conference, San Antonio, Texas, 2000. [[http://www.annfammed.org/content/vol3/suppl\\_1/images/large/moldfig1.jpeg](http://www.annfammed.org/content/vol3/suppl_1/images/large/moldfig1.jpeg)]



## TOPIC 7

# What resources or structures need to be in place to support collaborative research? How might they impact my practice?

### Funding

A researcher may approach you or your practice group after having received a grant. This may be the easiest type of collaboration because there is already funding available, so the most important part is to agree on the scope of work in relation to the available funding. However, the researcher is obligated to deliver to the funder the promised objectives and work plan, thus there is less flexibility to accommodate your input for defining or designing the research question. Your input is 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 you and a researcher 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 write a good grant. Collaborating providers are often asked to write *letters of support* and a description of their capabilities and contributions to a project. Sometimes, a *memorandum of understanding* is needed. Rarely, a *subcontract* needs to be signed prior to the submission of the grant. Usually at this point in the process, collaborating partners only need to sign a form that reflects their intent to subcontract. This is a good time to clarify the goals of the project and the distribution of resources. Negotiations about the type of project, the methods of gathering data, how your clients may participate, desired endpoints, and the allocated resources should take place at this stage. It is important to clarify the degree of certainty the researcher has with regard to

the scope of work and the budget, since the degree of flexibility in terms of these items can vary according to the requirements of the funder.

Once the grant is submitted, there is no guarantee that it will be funded. Sometimes it may take up to 6 to 12 months to find out funding status, as research grants usually go through a peer-review process by other scientists, followed by reviews from the funding agency. It is not unusual for a large grant to be revised and submitted up to three times or to multiple agencies before it is funded. The researcher should notify you when a revision or resubmission occurs, particularly if there is an impact on your practice. During this waiting time, it is advisable for grant planning and collaboration work to continue so implementation can begin on schedule if you are successfully funded. Ongoing communication, planning, and meeting during this uncertain time can help the collaboration continue to grow and develop uninterrupted.

A researcher may ask your organization to write a letter of support for a grant application. The letter of support usually names the grant and funding mechanism, describes your organization and its relationship with the researcher, and states what part your organization will play if the grant is funded. A letter of support is not a formal commitment. Once the grant is funded, the researcher should let you know the next step of formalizing the relationship.

### Subcontracts

Grants can include salary support for community providers or staff. This arrangement may require a

## TOPIC 7 (continued)

### What resources or structures need to be in place to support collaborative research? How might they impact my practice?

formal arrangement or subcontract. While your organization and the UCSF researcher are responsible for drafting a subcontract, the formal legal agreement is between UCSF and your practice organization. As a result, there may be multiple revisions required to satisfy UCSF Contracts and Grants requirements.

A subcontract in which your practice provides services to UCSF requires at minimum:

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

In addition, other requirements may be necessary depending on the source of the funding. For example, recipients of subcontracts on federal grants have to agree to specified salary caps, human subjects protection guidelines, and prohibition on lobbying.

A *subcontract agreement* may be needed either at the time UCSF is submitting the grant proposal or after the proposal has been funded. If submitted prior, this ensures that both UCSF and your clinic are obligated to carry out the terms of the subcontract once the grant is funded. Waiting until after the grant is funded to create a subcontract agreement does entail the risk that a researcher may not go back to your organization after funding but has the advantage of not having to go through the entire process without assurance of funding. For these reasons, your clinic or network may be asked for a memorandum of understanding.

#### Memorandum of Understanding (MOU)

A memorandum of understanding describes the types of deliverables and general timeline of the deliverables between the UCSF researcher and your clinic

or consortium. It is more formal than a letter of support and is signed by both the researcher and the leader of your clinic. [Read more information about MOUs.](#)

#### Staffing

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 protecting patient rights and confidentiality.

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.

On the other hand, in order to identify, screen, and recruit an unbiased sample of study participants, research assistants will need to be able to work closely with clinicians and their staff in the study sites to identify and recruit eligible participants. Ideally, research assistants should have experience in both research methods and working in clinical practice settings; research staff who are health educators or nurses often work well as project coordinators or research assistants. Generally all research assistants are hired by the investigators and supervised by the PI and the Project Coordinator. 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 need to learn the flow of patients through

## TOPIC 7 (continued)

What resources or structures need to be in place to support collaborative research?

How might they impact my practice?

Typical Roles and Responsibilities in a Clinical Research Project		
Position	Description	Possible role for collaborating partners
<b>Principal Investigator (PI)</b>	<p>From development of the research question to proposal writing to dissemination of findings, the PI has primary responsibility for executing the research project. The PI supervises all phases and aspects of the study, including determining the significance of the question to be studied and what is already known about the particular question; deciding how a study will be conducted; who should participate in the study; what outcomes are important to monitor; and what steps should be taken in the study. The PI is accountable for patient safety, the confidentiality of patient health information, and the project budget. The PI is also responsible for making sure the information from the study is collected appropriately and interpreted using standard research methodology. Finally, the PI is responsible for disseminating findings from a study. The PI works with any Co-Investigators and is responsible for hiring and supervising the Project Coordinator, who in turn handles more day-to-day facets of the study.</p>	<p>A collaborative partner can be the PI or Co-PI on a study.</p>
<b>Project Coordinator</b>	<p>The Project Coordinator is responsible for the day-to-day operations of study activities at all research sites. The Coordinator works under the direct guidance of the Principal Investigator. Typically, the Project Coordinator hires and trains all research staff, works with the PI to ensure that the projects' activities are in line with and approved by the Committee on Human Research (CHR), develop study questionnaires and system for data entry, and supervise subject recruitment, data collection and management.</p>	<p>Clinic staff who have management skills, know the clinic setting well, and are experienced with and/or interested in research are often hired as Project Coordinators.</p>

## TOPIC 7 *(continued)*

### What resources or structures need to be in place to support collaborative research?

#### How might they impact my practice?

Typical Roles and Responsibilities in a Clinical Research Project <i>(continued)</i>		
Position	Description	Possible role for collaborating partners
<b>Research Nurse</b>	The Research Nurse usually assists with processes such as informed consent for clinical trials, hands-on involvement with blood tests or other more invasive procedures that may take place during the study, monitoring side effects of study treatments, and communicating important clinical findings that result from the study to patients and their medical providers. Research Nurses can fill a wide range of roles on a research project, and they often serve as the Project Coordinator.	Nurses at the clinic site who are experienced with and/or interested in research are often hired to fulfill this role.
<b>Research Assistant</b>	The Research Assistant works under the direct guidance of the Project Coordinator. The Research Assistant is responsible for working directly in the clinical sites and with clinic staff to recruit study participants or carry out project activities. Research Assistants may be responsible for enrolling study participants, obtaining informed consent, working with participants to complete study instruments, providing study participants incentives, and tracking study participants.	Clinic staff who are experienced with or interested in research are often hired as research assistants. If clinic staff cannot afford the time to take on this role, outside staff are hired and clinic staff may be asked to orient research assistants to the clinic setting.
<b>Evaluator or Statistician</b>	The Evaluator or Statistician works under the guidance of the Principal Investigator to develop and implement an evaluation or statistical analysis plan. The role of the Evaluator or Statistician ideally begins when the study is being designed, to set enrollment targets and develop research measures that will allow for the primary research questions to be answered. The Evaluator or Statistician can also help develop data systems that will assure uniformity in the way that data is collected, and that will protect the privacy of research subjects who are enrolled in clinical trials. They also typically are involved in data analysis and interpretation of research results after the intervention has been completed.	Data collection and analysis is enhanced by advice and suggestions by those close to the clinic setting. Meetings between clinic personnel and evaluators or statisticians are necessary for the collection, analysis, and dissemination of accurate and pertinent data.

## TOPIC 7 (continued)

### What resources or structures need to be in place to support collaborative research?

#### How might they impact my practice?

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). 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; and
- 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.

Posters and leaflets outlining eligibility criteria and study contact information in the appropriate language(s) can also be displayed at the study clinics. All screening and recruitment methods must be clearly spelled out in the CHR/IRB application and steps must be taken to insure that patients' information and confidentiality will be maintained by study staff. Sometimes practice staff may be asked to obtain consent from a potentially eligible patient for future contact, so that research staff can contact a patient at a later time to determine if a patient is a candidate for enrollment in a study.

It is helpful, but not necessary, for clinical research partners to have or learn some research skills. A basic understanding of statistics and data analysis is helpful. UCSF either has or is developing the resources to help community clinicians learn about:

- Study Design;
- Methodology;
- Grant Writing;
- Publishing;
- Regulatory Issues;
- HIPAA Administration;
- Good Clinical Practices Research Policies.

CHR's Human Research Protection Program offers [this information about online research training](#). The UCSF CHR's Human Research Protection Program (HRPP) offers training to research staff on Good Clinical Research Practice (GCRP). This [tip sheet](#) offers information on best practices.

#### Data Collection Equipment

To begin conducting on-site clinical research, the project will need some or all of the following:

- Space for additional research-related staff;
- Storage space for Manual of Operations, case report forms, other source documentation (unless housed at central site elsewhere);
- Locked cabinet(s);
- FAX machine, scanner, copier, computer.

#### Lab Equipment

If the community collaborator will be collecting specimens, the project (and its budget) will have to provide laboratory equipment, such as the following:

- Phlebotomy supplies;
- Sharps containers;
- Centrifuge;
- Freezer;
- Overnight mail supplies;

## TOPIC 7 (continued)

### What resources or structures need to be in place to support collaborative research? How might they impact my practice?

- Messenger services;
- Instruction on proper specimen handling, labeling and shipping.

#### Information Management

The project budget should include appropriate tools for managing study data. These could include:

- FAX-based image collection or optical scanning systems;
- Electronic transmission and receipt of data from external sources;
- Laptops;
- Hand held devices and PDAs;
- Shared server for file sharing;
- Website;
- Databases;
- Electronic medical records.

#### Staff and Patient Education

At the outset of the study and throughout the research process, staff, patient, and participant education/out-reach are critical to the success of the study. Because staff and patients may not be accustomed to research at a provider's office, community clinic partners should keep in mind that the project should provide:

- Staff trainings before and after the project launch;
- Patient education about the study (flyers/brochures in the office);
- Participant information, including:
  - Study information (flyers/brochures);
  - Consent forms;
  - A copy of the *Human Subjects Bill of Rights*;
  - Contact information for an Ombudsman, if one is provided or available.

#### Accounting

The research budget can be written by community partners and investigators together. If both partners are at the table for this process, realistic costs for the following can be represented in the budget:

- Personnel costs;
- Supplies;
- Communication;
- Travel to meetings;
- Patient reimbursement for participation if appropriate.

A sample budget is available on the *CTSI Community Engagement Program Resources* webpage. The *UCSF Office of Contracts and Grants* must review the budget developed by your practice site and the researcher 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. Your practice site must issue an invoice to the researcher, who then forwards it to UCSF Accounting, which then writes the check. This process can be slow, so practice organizations are advised to plan for delays in receiving funds. Timely delivery of funds can be facilitated by frequent communication between you and the researcher, but often these problems are out of the control of individual investigators.

#### Reporting

Researchers are obligated to report, usually on a semi-annual or annual basis, the progress of their work to the funder. Research partners may ask you to submit reports on behalf of your site prior to the release of funds to your agency and to help them write their reports more accurately. The timing of reports and expectations for what reports contain should be made clear in your memorandum of understanding or subcontract.

## TOPIC 7 (continued)

### What resources or structures need to be in place to support collaborative research? How might they impact my practice?

#### Scientific Advisory Boards and Community Advisory Boards

Most researchers acknowledge that for a study or trial to be successful, it is important to obtain general support from the communities that will be involved in the research. At any time during the collaboration, the circumstances of your partnership may lead to the decision to establish a formal community-based and oriented Scientific Review Committee (SRC), Community Advisory Board (CAB) or Scientific Advisory Board (SAB) to review elements of the study. Generally speaking, the earlier in the process such a group is convened, the better. These groups can meet throughout the life of the project.<sup>4</sup>

Most CABs are comprised of leaders and other individuals representing various parts of the community, such as religious groups, schools or universities, media, clinicians, patients and non-profit or community-based agencies.

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 study or 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 study or 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 study or trial will run smoothly in the community. While CABs require a commitment of human and financial resources, successful CAB meetings are a uniquely useful forum for addressing ongoing concerns and project progress.

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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!

<sup>4</sup> See: *What is a Community Advisory Board? International AIDS Vaccine Initiative*, [<http://www.iavi.org/viewfile.cfm?fid=10784>]



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