

An IRB Resource for Investigators and Research Teams:

Including the Community Voice in Clinical Research

To increase the understanding, engagement, participation, and impact of clinical research, it is important to involve the community – at least in part – in the research process. ‘Community’ refers to a group of people with diverse characteristics who are linked by social ties, share common perspectives or situations, and/or engage in joint action in geographical locations or settings.¹ There is no singular approach for inclusion of community voice or input in research and the spectrum of inclusion ranges from designing research with community input at the center, such as in Community Based Participatory Research (CBPR),² to lighter engagement activities such as patient and community surveys. The CDC defines community-engaged research as *“the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people.”*³ Community involvement during the design of a research study allows the study to be grounded in the needs and concerns of the community.

Clinical research teams and their institutions can understand and help address community perspectives through engagement with community health centers, patient advocacy organizations, faith-based institutions, neighborhood centers, gyms, libraries, schools, and other settings where people gather, work, and play. The philosophy of community engagement supports partnership and respect. The US Department of Health and Human Services (HSS) supported the development of [Principles of Community Engagement \(Second Edition\)](#), a primer that provides public health professionals, health care providers, researchers, and community-based leaders, and organizations with both a science base and practical guidance for engaging partners in projects that may affect them.

The following list suggests preliminary steps and resources that investigators and their research teams can use to gain participant and community input into their study question and design:

- Determine the community stakeholders impacted by your research
 - This [Worksheet 1](#) from Tufts CTSI provides steps and questions for identifying stakeholders

¹ MacQueen KM, McLellan E, Metzger DS, Kegeles S, Strauss RP, Scotti R, Blanchard L, Trotter RT. What is community? An evidence-based definition for participatory public health. *American journal of public health*. 2001 Dec;91(12):1929-38.

² See the National Institute of Health (NIH) Community-Based Participatory Research Program (CBPR) at <https://www.nimhd.nih.gov/programs/extramural/community-based-participatory.html>

³ *Centers for Disease Control and Prevention. Principles of Community Engagement (2nd ed.)*. Atlanta, GA: CDC/ATSDR Committee on Community Engagement; 2011.

- Examine the institutions' [Community Health Assessment \(CHA\) and Community Health Improvement Plan \(CHIP\)](#) Reports to understand the health issues facing the surrounding community

- Determine if your Institution/organization has trusted community partners, and whether those partners are the appropriate stakeholders for your research. It's important that investigators and research teams cultivate their own community partner relationships. To do this consult with your community engagement office if available. If not devise your own strategy.
 - Use the [Principles of Community Engagement \(Second Edition\)](#) guidance to frame your unique community engagement strategy.

 - See the [Community Outreach Guide](#) from the Recruitment Innovation Center (RIC) on how to do begin outreach. This guide can also be an additional resource if your organization already has established community partnerships.

 - See this [Quick-Start Community-Engaged Research Guide](#) for Investigators and their teams that's been developed by the CTSI at UCSF.
 - Get advice from others who have done this work before.

 - Listen to the community partners to understand their perspectives and expectations.
 - Hold [Focus Groups](#) and/or [Listening Sessions](#).

- Create a process to make your research participant-centric
 - This [Worksheet 2](#) from Tufts CTSI provides a stepwise process for including participant perspectives.
 - Consider asking about participants' perspectives and input on the protocol as applicable. Participants can provide ideas and feedback on study design, recruitment strategies including outreach flyers and events, informed consent form, and interview guides.

- Communicate and clarify the goals and processes of the partnership

- This [Toolkit](#) from Southern California CTSI provides a framework for developing community partnerships and provides Community- Engaged Research strategies for investigators and community members along with Case Study examples.
- This [Tool](#) from Tufts CTSI provides questions that help with defining the working partnership.
- A [Community Engagement Studio Toolkit](#) that the Meharry-Vanderbilt Community Engaged Research Core program developed provides an example of how community engaged research can be approached.

Establish engagement activities and ongoing partnership

- [Worksheet 3](#) from Tufts CTSI provides queries that will guide you through and summarize the engagement process.
- This [Toolkit](#) from Southern California CTSI gives guidance on integrating community voices in a research study particularly through Community Advisory Boards.
- These [“Community Partnered Research: How to series” documents](#) developed by the UCLA CTSI are designed to inform and guide community partners on a range of clinical research topics.