

Study Report: Community Engagement Practices and Policies of Philadelphia Institutional Review Boards

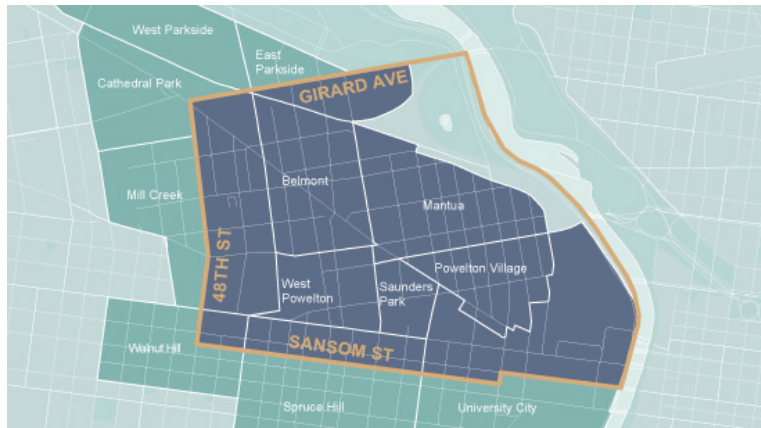
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Promise Zone
PZRC 
Research Connection

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West Philadelphia Promise Zone: A US Department of Housing and Urban Development designation from 2014-2024. Visit: bit.ly/WestPhillyPN.

West Philadelphia
**PROMISE
ZONE**

The West Philadelphia Promise Zone is an urban area of roughly two square miles, including parts of 10 neighborhoods comprised of historically vibrant, predominantly African American communities. These neighborhoods include, or are adjacent to, large educational and health institutions such as Drexel University and the University of Pennsylvania and its hospital system. Residents have largely not benefited from the economic growth of these “eds and meds,” experiencing a dramatically higher poverty (31.5%) and unemployment (11.7%) rate, and lower median household income (\$24,948), relative to other Philadelphia neighborhoods.

West Philadelphia received its Promise Zone designation in 2014 from the U.S. Department of Housing and Urban Development. Promise Zones were created in high-poverty communities where the federal government partners with local leaders to “increase economic activity, improve educational opportunities, leverage private investment, reduce violent crime, enhance public health and address other priorities identified by the community” (US Department of Housing and Urban Development).

Although the designation does not include grant funding, designees are assigned a federal liaison to help navigate federal programs, and preference points for certain competitive federal grant programs. This designation thus created an increase in the pursuit of funds for research and programs led by area research institutions, health care delivery systems, and government agencies. As a result, community residents, who had long been overburdened by research, raised concerns about growing research burden, the need for their communities to derive tangible benefits from research, and the desire to explore opportunities for more inclusive research practices.

To build community capacity around this issue, the Promise Zone Research Connection (PZRC) was created by community residents in 2016, with the goal and a plan to liaise to the many research and medical institutions in Philadelphia, and create a Community Research Review Board (CRRB) as a community-led system for research approval and oversight. The PZRC feels this is a critical step to inform research ethics and ensure community-based participatory research is standard in all place-based research. The current study was a partnership between the PZRC and the Drexel University Dornsife School of Public Health.

Promise Zone Research Connection (PZRC): A community board made up of Promise Zone residents and a few institutional partners focused on bridging the gap between researchers and residents so that research brings more benefits to the community. Visit: www.pzrc.org.

Community Research Review Board: A group of community residents who review researchers' proposed research intended to recruit from or occur in their community, in order to ensure it is ethical and beneficial to the community. Visit: bit.ly/irbs_crrb.

The goal of the IRB Feasibility Study was to explore the practices and policies of Institutional Review Boards (IRBs) in Philadelphia to understand their consideration of and systems for addressing community-level ethical research issues. This study had the additional goal of informing how community-led, place-based systems of research oversight like the PZRC’s CRRB can best collaborate with research institutions.

This study consisted of semi-structured qualitative interviews with IRB directors and staff. The study team included investigators from Drexel and community resident researchers from the PZRC. The team invited senior leadership from all 17 institutional review boards in Philadelphia, Pennsylvania between April and September of 2021, and successfully recruited and interviewed 15. All interviews were conducted and recorded using a web-based audio/video conference platform and lasted an average of 25 minutes. Interview questions focused on IRB practices and policies regarding community engagement in study design and study ethical review, geographic tracking of proposed research, community IRB member engagement, and the feasibility of establishing a working partnership with a CRRB like the PZRC’s. All team members contributed to thematic coding and analysis. Results were shared with the PZRC board members to co-create recommendations.

Study results, including best practices and recommendations, are contained within this report. These will be shared with all Philadelphia IRBs, their researchers, and community leaders and advocacy organizations, to create a pathway to more effective collaboration between these stakeholders around ethical conduct of research in low-resourced, research-burdened communities of color in Philadelphia.



Table 1: Sample of Philadelphia IRBs

Type of organization	Number (%)
Academic institution	7 (41.2%)
Research hospital	4 (23.5%)
Nonprofit	2 (11.8%)
Department of Public Health	1 (5.9%)
School District of Philadelphia	1 (5.9%)
Did not respond or refused to participate	2 (11.8%)
Total Sample	17



IRB Protocol Submission Processes

Most participants shared that researchers submit their protocols to the IRB for review via online application portals. These web-based platforms contain open and closed-ended questions that guide researchers through the submission process where they describe their proposed project. It was noted that these online templates not only streamline data management for the IRB, but also allow researchers to complete them collaboratively. Several participants shared that their institutions’ forms ask researchers to indicate if their study will be community-engaged research and if so, to provide relevant socio-cultural background information about that community.

However, a participant noted that a researcher’s affirmative response to that question does not necessitate their including information about how that community will be protected from harms due to research.

Upholding IRB Regulations and Researcher Requirements

Many participants considered their IRBs’ commitment to upholding governmental regulations and standards of conducting human subjects research to be a strength. As required by all federally-certified IRBs, several participants mentioned that their processes ensure that proposals include standard elements of informed consent and require additional information about how the researcher will protect vulnerable populations (e.g., children, pregnant women). However, there was no mention of internal mechanisms IRBs use to alert their reviewers to protocols which lack adequate community protections.

Some participants reported that the strict requirements of researchers prevent superfluous studies.

Participants noted that researchers' expertise was an asset to their institutions, as these individuals liaise between the IRB and surrounding community. IRBs rely on the protocol information supplied by researchers to ensure the effective implementation of protections for participants and the IRB’s adherence to regulatory standards.

“The researcher is the expert. And in that regard, the IRB relies on the expertise of the researcher to provide us with all the information we need so that we can apply the regulatory requirements and ultimately protect the participants and the communities they are a part of from undue risk.”
- IRB Director, Academic Institution

Researcher Training Requirements

Most participants reported that researchers are required to complete Collaborative Institutional Training Initiative (CITI) modules such as Human Subjects Research and the Responsible Conduct of Research with supplemental requirements per funder and study guidelines. Others reported the use of similar trainings from the National Institutes of Health or institutions of higher education. Importantly, none of the participants reported that their institutions require investigators to complete the community-engaged research or community-based participatory research modules on CITI, or any similar trainings, when proposing research that will recruit residents from, or to be conducted in, a low-resourced, research-burdened community most impacted by the topic or results.

“I think if a good case for studying a specific community isn’t made, [our IRB] will not approve the research.” - IRB Director, Nonprofit

Community-placed research: any research that proposes to occur in a community location and/or recruit from community residents.

Community-engaged research: research that engages those most affected by the research and the topic being studied in the design and/or conduct of the research.

Community-based participatory research: research that engages those most affected as equitable partners in all stages of the design and conduct of the research, and has the goal of using research for community benefit and action.

IRB Member Training Requirements

Participants reported that IRB members, including community members who serve on review committees and assist in approving protocols, must complete CITI training and institution-specific modules. One best practice emerged from an IRB that requires its members to complete community-engaged research modules. This participant discussed how they require these courses to help IRB staff better understand how to review community-engaged research proposals, specifically looking for how community voices and input are prioritized in the proposed project. A couple of IRBs noted that although their institutions do not have or require these educational opportunities currently, it is a best practice they would like to explore to ensure their staff is well-versed in how to review this type of research.

“The thing I think we do well is that we have a lot of great members on our roster who do some great work in Philadelphia. And they're really good at basically assessing procedures and assessing recruitment plans and really probing and prompting researchers to think about these things differently and to do it in a really independent way that doesn't really care about how long it takes to get approved or whether they get funded.” - IRB Associate Director, Academic Institution

**“All of our IRB members are required to undergo CITI training and that includes several modules on community-based research.”
- IRB Coordinator, Nonprofit**



Specific Requirements for Community-Placed Research

Many IRBs explained that their submission forms require researchers to provide information about the target population from which participants will be recruited, and about whom the research is intended to draw conclusions. Some participants reported their IRB requires researchers to describe how the target population will be included in the dissemination phase.

Most participants recognized the value of this information with some acknowledging that their study protocol submission processes are imperfect, thus hindering the thorough evaluation of these submissions for community-level benefits or harms. Some participants explained that their institutions are actively improving their protocol applications with the hope that these enhancements will push researchers to include more community-relevant information and, in turn, improve the review process and the conduct of the research.

However, some participants explained that their institutions do not require researchers to submit additional information when proposing community-placed research. They view the investigator as the subject-matter expert.

“There aren't really additional requirements. The researchers need to submit the appropriate documentation. Anything we would need to know for a research study, we would need to know for a community-involved research study. We would rely on the researcher to tell us particular information we might need to know, such as the fact that community members are involved in the study design, that it's community-based participatory research as opposed to simply research being done in the community. So they are the experts. They are informing us.” - IRB Director, Academic Institution



Geographic Tracking of Research

Despite the frequent geographic overlap of research proposed and conducted by their researchers, nearly all IRBs explained that they do not have any systems that allow them to track the geographic locations of their research.

Reasons given for this this shortcoming were:

- Lack of clarity on which geographic variables to track
- Inadequate technological infrastructure to capture geographic identifier variables (e.g., zip code, neighborhood name). Location detail is often collected in narrative form.
- Uncertainty of how to acquire this information from researchers

Participants mostly agreed that the creation of a geographically-focused tracking process would be advantageous for their institution to track and summarize in order to understand the geographic spread and overlap of their research. However, many expressed that this organizational-level change would require adjustments to their protocol submission processes and additional staff changes. Some expressed concern that researchers would complain about additional protocol submission requirements, while others said they could justify them to researchers.

One participant discussed a process for identifying study overlap employed at their institution, despite the fact that they do not track or consider geographic location of studies in their review process (see quote below).

“... one of the things that [the research review committee] does is a feasibility review, and they want to really know if there's any competing or overlapping studies that are being conducted at the same time. And it's something that the investigator is supposed to address when they're submitting a study for a preliminary review. So that's done prior to it getting to the IRB.” - IRB Director, Research Institution

Geographic Tracking of Research (cont.)

Notably, two participants felt that geographic tracking would not be useful or applicable to their institutions because their research spans many geographies and because their focus is on protecting the rights of individuals as opposed to communities.

“We never consider geography in a medical context. In fact, the opposite, we'd actually discourage considering geography because we want equitable access....to these treatments... Anyone should be able to come to [our institution].”
- IRB Director, Academic Institution

“...we do not have a tracker for that and have not really considered it because one of the main things that we rely on is that every [participant] is an agent into it of themselves and has the autonomy to say yes or no to research opportunities as presented to them.” - IRB Director, Academic Institution

Inclusion of Community Members in IRB Review Process

All federally-certified IRBs are required to have community representation on their review committees. Many participants highlighted the value that community members bring to reviewing research protocols and noted that they work diligently to recruit and retain these individuals.

Two participants also shared a best practice where they provide their community IRB members with training to enhance their understanding of how to review research protocols. Despite the benefits that community members bring to IRBs, two participants shared that these individuals' consistent participation can be challenging due to outside commitments, ethical issues relating to compensation, and poorly defined job descriptions.

“...It's not easy to get community members on the committee... We do have them because it's a requirement, but it's not easy, and we have to really think about who they are and who they're representing, what their background is.”
- IRB Analyst, Research Hospital

Many IRBs expressed difficulty defining a community for the purposes of ensuring community representation on the IRB, given the diversity of Philadelphia and communities where their institution's researchers conduct research. This becomes especially difficult when considering the many other geographies outside of Philadelphia, the US, and globally where their researchers conduct research. Additionally, some IRBs noted that their researchers' study recruitment occurs in what they described as a non-geographic way, typically patients who are recruited from within a healthcare system.

“...it's reasonable to define community as a disease population in a lot of instances.” - IRB Director, Academic Institution

One participant shared a best practice where they include community members in their pool of consultants whom they can contact as needed to represent the wide range of content and research expertise needed to evaluate IRB protocols.

“So we have a consultant feature. So if we do not have but we need extra stakeholder input, we have a mechanism where, under a confidential basis, we can reach out and ask people who could likely answer the question through subject matter expertise or other things. Answer questions and help us be better at resolving potential regulatory questions or ethical questions. So that does get activated sometimes because we don't have a board that has one of everything or several of everything. We try to distribute our memberships accordingly, but it just always isn't possible.”
- IRB Director, Academic Institution

Institutional Challenges

Many participants explained that their institutions struggle with organizational challenges, namely inadequate staffing, outdated technology, and a culture that lacks an understanding of how to prioritize communities in research. Participants also mentioned that COVID-19 pandemic restrictions amplified these limitations via the disruption of IRB service provisions, the prevention of regularly scheduled review board meetings, and an increase in staff turnover. It was shared that insufficient staffing slows operations, reduces IRB capacity and responsiveness, and decreases institutional memory.



“...one of the pieces of feedback we got is that new students are coming in and just wanting to go in [to the community]. ... But it's not just students. There could be just turnover with faculty and project managers. ...Maybe somebody is like, "You know, we had this conversation with somebody from [research institution] two years ago. Where were you then?" ...I don't know how to stop that problem from an IRB standpoint.”
- IRB Director, Academic Institution

Several participants mentioned that their web-based submission portals and internal data management systems were outdated and cumbersome. Engaging with these antiquated platforms is not only challenging for IRB members when reviewing protocols and tracking metrics, but also for researchers when completing applications and responding to queries. Importantly, participants explained that these antiquated systems would likely preclude them from incorporating new elements such as queries regarding geographic focus or community engagement approaches. Optimistically, one participant also shared a best practice where their institution recognized the limitations of their antiquated system and plans to transition to a more sophisticated platform that will enhance their operational capabilities.

“Our current system... is bad. It's a dumpster fire in many, many ways. So that's interesting because we're actually moving...to implement a new system.”
- IRB Director, Academic Institution

A couple of participants also shared that institutional culture is a limiting factor in developing new practices that protect communities and prioritize their needs. One participant explained that their institution's culture around upholding all federal regulatory standards tied to the conduct of human subjects research is a barrier to implementing procedures that would elevate community needs. Another participant mentioned that many researchers adhere to the mainstream academic philosophy which pushes researchers to conduct a high volume of studies to ensure professional success rather than community benefit. One can also infer that if researchers continue to work at this rapid pace, there is limited time for partnership with communities around research and dissemination, but also that community residents' feelings of being overstudied and overburdened by research will only increase.

“I think a lot of people have this attitude of like, "Oh, well, I have to publish as many papers as possible...and basically, I think the institution doesn't do a great job at basically connecting an individual's work with the work of the institution as a whole.” - IRB Director, Academic Institution

Value of Community Engagement

There was a lack of interest around community engagement among the majority of the IRBs that were interviewed. Some felt that it would have little to no effect on how they conducted their research. Others reported that competing priorities combined with a lack of internal motivation are to blame for a lack of focus on process improvements around community engagement. Some reported that this is not the role of an IRB, but instead the role of their researchers to forge their own community partnerships and inform the IRB in their protocols about any ethical considerations.

“The researcher is the bridge to the community. They obviously want to do research in that community. They either have existing relationships or they want to forge relationships with people in that community.” - IRB Director, Academic Institution

A few participants noted that researchers prioritized conducting research for their own competitive and professional purposes, inferring that it was not always for community benefit. Additionally, several participants referred to researcher submissions of IRB protocols as “checking boxes,” noting a disconnect from critically engaging in the ethical implications of the work being done. However, there were a few participants who championed the concept of IRBs facilitating community engagement in their institution’s research, noting that it could improve IRB operations and the quality of the research.

**“This is sort of a new thing in the realm of human research, involving the community. And I've learned quite a bit in the past couple of years working with the experts that we have at the institution, some of whom are IRB members. So not only are we gaining their expertise through the studies they submit, but they sit on the committees. So they're informing our reviews, and we're building our understanding.”
- IRB Director, Academic Institution**

Nevertheless, some participants cited challenges around an institutional lack of awareness regarding the importance of community engaged research.



Value of Community and Local Perspectives

Many participants reported deliberate efforts at their institutions to involve local laypersons to serve as investigators, review board members, and community board members at various stages of the research conceptualization and protocol approval process. It was noted that local expertise and perspective of community members improve the quality of submitted research, shift researcher perspective, and amend current review practices. Some participants highlighted that their institutions valued community members' involvement and expertise regarding areas where research is proposed to occur.

“And we also understand that community members may have different roles within the research. So some of them may be investigators, a formal role where they might be involved in obtaining informed consent or analyzing data. Or they might be more of an advisory role where they're providing information guidance to the study team but aren't necessarily engaged and we don't need to impose training requirements on those individuals, for example. So I think we understand that research is varied based on the different settings where it's being conducted.” - IRB Director, Research Hospital



Responsiveness to the Social and Political Contexts of Research Participants

Another best practice was shared by two participants who informed study team of their organizations' active efforts to increase their awareness and responsiveness to the social inequities and racial justice issues faced by the research participants. One respondent mentioned their work in response to the 2020 murder of George Floyd to reaffirm their institution's commitment to justice, as outlined by the Belmont Principles.

“In the wake of George Floyd, especially, I also overhauled a section of our IRB website which deals with the justice portion of the Belmont Report or the Belmont Principles. While we tend to address the autonomy and beneficence, we very often don't do a great job with the justice. So that has to do with making sure that we share or distribute in an equitable manner, the burdens, risks, and benefits of research participation.”

- IRB Director, Academic Institution

Another respondent detailed their institution's recognition of the material needs of their study participants. Subsequent efforts were thus made to properly compensate participants for their involvement in studies.

“I think we try to lessen the burden for the subjects the best we can... We provide transportation reimbursement if they need to come here... And they may not have a working phone number or a steady address. And so we do try to - if follow-up is required - we try to come up with the best ways possible to conduct the research, given their specific barriers.”

- IRB Analyst, Research Hospital

Feasibility of IRB Partnership with a Community Research Review Board

A key activity of the PZRC is the creation of a Community Research Review Board (CRRB) whose members are tasked with evaluating research that is proposed to occur in the West Philadelphia Promise Zone. Notably, several IRB study participants expressed an interest in creating a relationship with the CRRB. Some said their interest in prioritizing community engagement was a driving force in their desire for this collaboration. Some also shared that senior investigators and students from their institutions have expressed a similar interest in working with the community in a research capacity.

While there may be support for this partnership, the challenge lies in the incorporation of the necessary programmatic and structural changes in institutions' existing practices and policies. For example, some participants were cautious to support the implementation of these changes due to organizational capacity limitations. Although many participants expressed a desire to collaborate with the CRRB and develop new strategies such as identifying which of their institution's studies occur in the Promise Zone, there are barriers such as insufficient staffing, antiquated technology, and a lack of institutional will.



The following recommendations emerged from study findings and were also informed by the experiences of the community residents on the PZRC Board. When we use the term *community* in these recommendations, we are referring to the kinds of communities that experience social, economic, racial, and political inequities and injustices. The same communities that are over-burdened by research due to researchers wanting to understand either the root causes or the consequences of inequities, or to evaluate the outcomes of programs or policies meant to address these inequities.

1. Require community-placed research to articulate benefits to the community and plan for engagement and dissemination

When research is proposed to occur in a community(ies), IRBs should require researchers to clearly state the benefits their research should bring to the participants and their communities. In addition, IRB reviewers should require investigators of such studies to create community engagement plans to ensure their research questions, recruitment, and data collection efforts are approved and endorsed by community leaders. They should also be required to create dissemination plans that allot the proper timeline and budget to translate their research findings back to the community from where and whom the data was obtained.

2. Require community-engaged research training

IRBs should require training for all IRB staff and IRB review committee members on community-engaged and community-based participatory research, such as the ones readily available through the CITI Program. These educational models will increase their awareness of the importance of these approaches in addressing historical trauma and mistrust of research in communities disenfranchised by research, and by governmental, medical, and academic institutions. This will increase IRB capacity to recognize which studies these approaches are best applied, and require researchers to complete similar trainings, connect with any CRRB in the study location, and create community engagement and dissemination plans.

3. Track where an institution's research is being conducted

IRBs should add geographic focus fields to their IRB protocol submission forms and/or software. This can include country, city/town, zip code, or neighborhood, or just be limited to zip code and neighborhoods for those studies proposed to occur in Philadelphia. This will allow the IRB to a) identify where the proposed study will be conducted, b) consider overlap and density of research already occurring in a geographic area during the review process, and c) facilitate institutional reporting of the geographic distribution of their research.

There was a lack of acknowledgement that patients live in communities where structural and systemic forces have shaped vulnerability to a disease or a condition, which in turn makes them eligible for a clinical trial. Yet residents of communities of color are much less likely to enroll in clinical research, resulting in under-representation of non-white participants in clinical research. Clinical research institutions should also track the geographies in which their patients and participants live to understand geographical clustering of their study participants. This can help to understand overlap and burden and to improve outreach and engagement within these highly-researched communities, which will benefit the community as well as increase representativeness of the research.



4.

Increase community representation on IRBs

IRBs should engage with many more than the required one community member to ensure the required expertise is represented when evaluating place-based research, as they would with content or methodological expertise. IRBs should create a plan for how community board members and consultants will be recruited, engaged, and compensated for their time. A best practice identified by this study was engaging with many community representatives to serve on a consultant basis for protocol reviews relevant to their community identity and expertise. All community IRB members should be listed on the IRB website for transparency and accountability.

5.

Create an IRB community of practice in Philadelphia

While many IRB directors and staff know each other, they reported not convening at any time. A community of practice would allow IRBs across the city to share best practices about engaging with Philadelphia communities over-burdened by research in general, and about strategies for engagement in specific communities studied by all Philadelphia research institutions. A community of practice will also allow for the sharing of other challenges and best practices unique to IRBs.

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