INSTITUTIONAL REVIEW BOARD (IRB) CONSIDERATIONS FOR COMMUNITY- & PATIENT-ENGAGED RESEARCH

Community- and Patient-Engaged Research is a research approach that involves people with lived experience, such as youth, families, community members, or patients, or groups like community-based organizations, public health departments, advocates, or key-decisionmakers. In this approach, researchers work with these partners throughout the research process, including for example working on research questions that are of importance to patients and community partners, co-designing and implementing research to solve problems, and using data to influence policies and programs.

<table>
<tr><th colspan="3">Commonly Asked Questions Regarding Working with the IRB on Community- or Patient-Engaged Research Studies</th></tr>
<tr><td>Does my community-engaged and/or patient-engaged study qualify as human subjects research requiring IRB approval?</td><td colspan="2">Human Subjects Research must be submitted to the IRB and receive approval before any study activities take place. Further, any changes to the research protocol must also be approved by the IRB before implementation. The IRB website can assist you in determining whether your study meets the definition.

Often program development and program evaluation, as well as quality improvement studies, are not considered human subjects research. This occurs when the findings of the evaluation serve to inform the program and are unique or specific to a program and are therefore not classified as research. If in doubt, it is good practice to contact the IRB and you can also submit a IRB Human Subject Research (HSR) Determination Form.</td></tr>
<tr><td>Are my community and/or patient partners considered to be engaged in human subjects' research to the extent that IRB approval is required?</td><td>Not Engaged in Human Subjects Research

Below are examples of activities that partners or advisory boards may engage in, which are generally not considered human subjects research. (Consult the IRB regarding the specifics of your study.)

1. Advising the research process
2. Helping facilitate recruitment of participants (e.g., post flyers)
3. Assisting to broker partnerships with the community
4. Delivering an existing community program or intervention (i.e., was not developed/modified as a part of the research study)
5. Analyzing deidentified data (e.g., coding interview transcripts with no identifiers)
6. Helping disseminate study findings

In these cases, you may briefly describe these activities but please specify that your partners ARE NOT engaged in human subject's research. If your partner</td><td>Engaged in Human Subjects Research

If your partner or advisory board is participating in any of the research activities below, IRB approval is required.

1. Consenting study participants
2. Delivering an intervention that is developed/modified for the research study
3. Collecting data
4. Accessing or analyzing identifiable data
5. Serving as participants in a research study themselves that will produce generalizable knowledge

*If your partner organization is a site for the study and conducting any of the above activities, please add them to the General Checklist Cooperative/Collaborative Study section in the IRB protocol, upload their site's letter of support for the research, and mark that they ARE engaged in research.</td></tr>
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	organization is a site for the study, please add them to the General Checklist Cooperative/Collaborative Study section in the IRB protocol, upload their site's letter of support for the research, but DO NOT mark that they are engaged in research.	

Any partner or site that is participating in human subject's research will need IRB approval. There are several options for IRB approval:

1) IRB approval is available through the partner organization
2) Outside IRB approval is obtained (See section below for outside IRBs)
3) Stanford serves as the single IRB (sIRB) of record. (At this time, Stanford serves in this role on a limited case-by-case basis and this also has a cost.)

In some cases, a partner or collaborator is hired as a part- or full-time Stanford employee as a part of the Stanford research team. In this case, the Stanford team is supervising the partner's participation in research and their work is covered under the Stanford IRB. This can also help build research capacity for the community partner and allow them to have access to a range of Stanford databases and resources.

Does my study need a Single IRB (sIRB) and what are sIRB options?

All multi-site studies should contact Stanford IRB in advance of grant submission and budget preparation to determine if single IRB is needed.

Many multi-site studies require a single Institutional Review Board (single IRB or sIRB) to coordinate the IRB for all of the sites. A single IRB is an arrangement where one IRB of record (or Reviewing IRB) provides the regulatory and ethical review services for multiple sites participating in one study.

The use of single IRB and external IRBs are associated with a substantial cost. Please contact Stanford sIRB in advance of grant submission to obtain the cost estimate for your grant budget (see below).

Stanford has a Master service agreement with Advarra and WCG IRB.
North Star Review Board is another option.

Outside Commercial IRB	Overview
Advarra	Advarra has the largest AAHRPP accredited independent REB/IRB in Canada, based in Ontario, which supports research conducted exclusively in Canada as well as cross-border studies. They also offer review services outside of the U.S., Puerto Rico, and Canada. They have flexible review schedules: 22 full board meetings Monday through Friday, and minimal risk/expedited reviews are conducted daily.
WCG IRB	WCG has been leading ethical review for more than 50 years. They offer more than 20 full-board WCG IRB meetings each week, 1-2 business days for minimal risk studies, 1 business day for multi-site study review.
North Star Review Board	North Star Review Board is a new IRB which believes protocol review should be ethics-based and data-driven. Their reviews have emphasis on collaboration, consistency, and transparency.

When is Human Subjects Training required for my patient and community partners?	**If your patient or community partner is going to be engaged in human subjects research, they can take a training that is specific to partners.** CIRTification Online is a free, web-based human research protections training program tailored specifically to the needs and roles of patient and community research partners. This training is available to anyone in the community, and has been approved by the Stanford IRB. This training can substitute for the Stanford CITI training requirements for community partners only, not Stanford students or employees. ***This training certificate will need to be uploaded in the attachment section of eProtocol.*** *CIRTification Online is also available in Spanish and Haitian Creole. Simply access the training portal, enroll in CIRTification or login, and select the option to launch the course in Spanish (Empezar en español) or Haitian Creole (enskri an kreyòl ayisyen).*

What are the requirements and process for translating consent forms for participants who do not speak English?	**There are some Stanford resources and guidance for translation of consent forms?**
	
	• Review the practical guide from IRB: Consent Form Do's & Don'ts
	• When participants in a study (i.e., the target population) are anticipated to be non-English speaking, a full translated consent is needed. Stanford has interpretation/translation resources:
	  ○ Stanford Medicine Children's Health Interpretation Services resources
	  ○ Stanford Health Care Interpretation and Translation Services: One Point Lessons (sharepoint.com)
	• Steps for translation of consent documents:
	  ○ English versions of study documents are approved by the IRB.
	  ○ Approved English versions are translated into the participant's language by a certified service. Best practice is to then have a bilingual expert (e.g., a native speaker of the translated language) conduct a quality check on the translations.
	  ○ A modification is submitted to the IRB with translated documents attached.
	  ○ Once the modification is approved, the documents can be disseminated, as needed.
	• The short form consent process is an alternative method to obtain consent for occasional and unexpected enrollment of non-English speakers by verbally translating the IRB approved consent forms into the participant's language and documenting the consent process. Use of the short form consent process and documents requires prior IRB approval. There are short form templates in many languages.

Does my study need a Data Use Agreement (DUA)?	A data use agreement (DUA) is an agreement that is required before there is any use or disclosure of a limited data set to an outside institution or party. A limited data set is still protected health information (PHI), and for that reason, covered entities like Stanford must enter into a data use agreement with any recipient of a limited data set from Stanford. Please see Stanford's guidance on DUAs for more information.

For detailed guidance and information, please visit Stanford IRB Website

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