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CAPS Policy and Ethics Roundtable

IRB Approval in the Context of Collaborative Research

Agenda

- When collaborators need to obtain IRB approval
- When the CHR will agree to be the IRB of record for a collaborator
- What an FWA is and when it's needed
- What it means to be engaged in a human subjects research project
- Navigating the logistics of multi-IRB approvals



Questions to Ask

Is the collaborator ...

1. Conducting research? If so, does the research involve human subjects?
2. Engaged in the research?
3. Obtaining IRB approval? If not, would the UCSF CHR agree to be the site's IRB?

Additional questions:

1. How is the project funded? Any federal \$\$?
2. Are there logistical issues that may affect the IRB approval process?

Question #1: Human Subjects Research?

- First, confirm that the collaborator is conducting **human subjects research**.
- **If not**, the collaborator does not need IRB approval.

Definition: Research

- **Research = A systematic investigation, including**
 - Research development, testing and evaluation
 - Designed to develop or contribute to generalizable knowledge

- **Not Research Examples =**
 - Public health surveillance
 - Quality improvement or quality assurance activities

Definition: Human Subjects

- **Human Subject = Living individual about whom an investigator conducting research obtains**
 - Data through intervention or interaction with the individual, or
 - Identifiable private information
- **Not Human Subjects Research = An investigator obtains de-identified or coded data or biological samples under the following conditions:**
 1. The research is not regulated by the Food and Drug Administration (FDA); and
 2. The investigator never obtains identifiable information.



If the collaborator is not conducting human subjects research, IRB approval is not required.

Is the Collaborator Engaged in the Research?

- In general, a collaborator is considered *engaged* in a research project when its agents for the purposes of the research project obtain:
 1. data about the subjects of the research through intervention or interaction with them;
 2. identifiable private information about the subjects of the research; or
 3. the informed consent of human subjects for the research.

Engaged vs. Not Engaged: Recruitment

Engaged

A collaborator at a clinic in the Tenderloin tells potential participants about your study, collects basic eligibility information from them (such as age and condition), and verbally consents them on to the survey study.

Not Engaged

A collaborator at a clinic in the Tenderloin tells potential participants about your study, collects basic eligibility information from them (such as age and condition), gives them a copy of the consent form, and instructs them to contact you if they want to participate.



Engaged vs. Not Engaged: Study Activities

Engaged

- Your collaborator interviews participants.
- Your collaborator draws blood from participants, analyzes the samples, and will be acknowledged in the resulting publication.

Not Engaged

- You pay a professional firm to administer a survey to participants.*
- You hire a private laboratory to conduct blood draws for the study.*

* None of these services merit professional recognition or publication privileges, and the services are typically performed by those institutions for non-research purposes.

Engaged vs. Not Engaged: Add'l Study Activities

Engaged

- Conducts research-related monitoring tests that are not part of routine clinical monitoring
- Administers the study drug to participants each week

Not Engaged

- Provides clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring
- Administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis

Engaged vs. Not Engaged: Use of Facilities

Engaged

- A staff member at a homeless shelter interviews subjects for your research study

Not Engaged

- A homeless shelter permits UCSF researchers to use a private room in the shelter to interview subjects

Engaged vs. Not Engaged: Analysis of Specimens and Data

Engaged

- A collaborator at Johns Hopkins analyzes specimens that include identifiable private information and will be named in the publication.
- A collaborator at Johns Hopkins shares data that include identifiable private information to UCSF. The collaborator also assists in the analysis of the data for research.

Not Engaged

- A collaborator at Johns Hopkins analyzes de-identified specimens and will be named in the publication.*
- A collaborator at Johns Hopkins releases data that include identifiable private information to UCSF for research.**

* May not be human subjects research. Confirm using the [Self-Certification Form](#).

** There may be institutional or legal requirements that would need to be satisfied before identifiable data or specimens can be released.

Engaged vs. Not Engaged: Funding



Engaged (UCSF)

UCSF receives an award from the CDC and has a subcontract with a site in Kenya. The Kenyan researchers will conduct the research intervention, but UCSF will help with data analysis and technical assistance.

UCSF is engaged, but only in the data analysis portion of the study and as the prime recipient of the award.

Not Engaged (UCSF)

UCSF has received an umbrella award from the CDC and is funding several research projects in Africa with the money. The UCSF researchers will serve as mentors on these projects, but they will not interact with research participants and will only assist with data analysis of de-identified data.

Outside Collaborator IRB Approval

- **Needed if the collaborator is engaged in human subjects research**
- Does the collaborator have its own IRB or access to one? If no, see next slide.
- Consider what research activities the site is doing vs. what activities UCSF is doing
 - Example: UCSF is only conducting data analysis for a more-than-minimal risk intervention study being done in India.

Submit a full committee application to the Indian IRB and an expedited review category 5 study to the CHR.

When the CHR Will Be the IRB of Record

- **The CHR may agree to review the study on the collaborator's behalf and be the IRB of record if:**
 - The institution does not have its own IRB
 - The research procedures conducted by the other institution are minimal risk

What's an FWA and When Is It Needed?

- **FWA (Federal Wide Assurance):** An agreement that the collaborator and the IRBs upon which it relies will follow U.S. human subjects regulations
- **When is it needed?** When a collaborator is engaged in human subjects research that is conducted or supported by any U.S. federal department or agency

IRB Approval Logistical Questions

- **Does it matter which IRB approves the study first?**
 - Generally, no. However, research cannot begin at a site until its IRB approves the study. Approval from the lead/funding site also is required before research can begin. Ask collaborating sites if they have different requirements.
- **Which site's consent form template should the study utilize?**
 - The site that is conducting the research intervention/interaction.
- **Do approval letters need to be translated?**
 - No.

CHR Application Information

Sites Section

9.2 Check all the other types of sites not affiliated with UCSF with which you are cooperating or collaborating on this project:

- Other UC Campus
- Other institution
- Other community-based site
- Foreign Country

List the foreign country/ies:

 [Click here to access the text editor.](#)



9.3 * This is a multicenter study:

Yes No



CHR Application Information

Outside Site Information Section

Section view of the Form

Entire view of the Form

1.0  IRB Approval Certification

2.0  Request for UCSF to Serve As the IRB of Record

Site name:

Test University

Contact person:

Melanie Mace

Email:

melanie.mace@testuniversity.edu

Phone:

+44 890 099 8777

1.2 For Federally-funded studies only, corresponding FWA#:

FWA00011398

1.3 * The research will be or has already been approved by:

- Non-affiliated site's IRB or private IRB
- Neither: the site is requesting UCSF to be the IRB of record for this study
- Neither: the site is not engaged in the human subjects research and has provided a letter of support

If the other site's IRB approval letter is available now, attach it to the application. If the IRB approval letter is not yet available, submit it once you receive it.

More Information

- **Engagement Guidance:**
<http://www.hhs.gov/ohrp/policy/engage08.html>
- **FWA:**
<http://www.hhs.gov/ohrp/assurances/assurances/index.html>
- **CHR Website:**
<http://www.research.ucsf.edu/chr/Inst/chrInst.asp>