

Social and Behavioral Sciences IRB Newsletter

University of Chicago

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A New Era of IRB Communications

The IRB is excited to launch the Social and Behavioral IRB Newsletter. We hope that this new form of communication will help faculty, students, and staff better understand the IRB submission and review process. While our

website is a great resource, this newsletter offers an opportunity to discuss issues in more depth. Please consider the IRB a partner in helping support the high-quality work that you do.



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In this first issue, we discuss collaborating with Non-University of Chicago researchers and how this impacts the IRB review process. Please consider the IRB a partner in supporting the high-quality work that you do.

Collaborating with Non-University of Chicago Researchers

We are in a new era of research. As communication has become easier, so has the ability for researchers to collaborate on projects. Common collaborations include:

- Sharing data with a professor with overlapping research interests from another university
- Hiring a non-U of C grad student to help with a small part of your research for a short time
- Conducting a grant-funded study with co-investigators at other institutions
- Offering to assist or consult on a project at another institution

If any of the above circumstances sounds familiar, you might have wondered how to handle IRB approval. Which researchers' activities warrant IRB approval? Whose IRB should grant approval? How should you fill out your IRB applications? Let's look at each question one at a time.



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Which researchers' activities warrant IRB review?

When collaborating with people from multiple institutions, the first question you should ask is "Which individuals' activities warrant IRB review?" Each institution with involved personnel must determine if that institution's personnel are "engaged" in human subjects research. If the answer is "yes the personnel are engaged in human subjects research," then IRB review is necessary for those researchers' activities.

To determine which researchers are "engaged" in research, we use the Department of Health and Human Service's Guidance on Engagement of Institutions in Human Subjects



Whose IRB should grant approval?

After it is determined which individuals require IRB review on a collaborative research project, the next question is "Whose IRB will review those activities?"

The University of Chicago IRB has purview to review the research activities of UChicago employees and students. As a general rule we do not provide IRB review on behalf of other institutions' personnel.

The most common arrangement is that each institution's IRB reviews their own personnel's activities on a multi-institutional project. If you report that your research is multi-institutional, we will ask for the IRB approval notices from the collaborating institutions. The coordinating PI is responsible for ensuring that all sites have met their respective compliance obligations and reconciling disparate requirements of each IRB.

Research (available online at <http://www.hhs.gov/ohrp/policy/engage08.html>). In general, an institution is considered "engaged in human subjects research" if its employees or agents:

1. **obtain data about living individuals for research purposes through intervention or interaction with them, or**
2. **obtain individually identifiable private information for research purposes, or**
3. **obtain the informed consent of human subjects**

The HHS guidance walks through various examples of when institutions are considered "engaged" and "not engaged" in human subjects research—it does not cover every situation but serves as a guide for analyzing when research activities rise to the level of "engagement."

The engagement determination depends on the specific facts of each study, and can be complex. The IRBs of the participating institutions will make the final determination regarding who is engaged in the research and therefore must undergo IRB review.

Tip: To ensure that you can share data with other researchers, include appropriate consent form language that allows for possible future data sharing. See sample consent forms on our website.

In some circumstances, a formal agreement can be entered into between IRBs, in which the IRB for one institution agrees to serve as the IRB of record for the other institution. This is relatively rare. An example where this might occur is if the University enters into a subaward with an organization, the subawardee's employees are engaged in the research, and the subawardee organization does not have its own IRB.

How to fill out IRB application for multi-institutional research projects?

Use the guide below to fill out a new protocol application or to change an existing protocol to reflect an outside collaboration:

In Section 1.5, Question 3, select whether this is a multi-site study. Here “site” means “institution”. If multiple institutions are involved in research, select “yes”. Fill out the follow-up sections 1.5.2 and 1.5.2. Consult the IRB if you are not sure whether your research is considered “multi-site”.

In Section 2.2, Question 1 and Section 2.2.3, please select the research activities performed by U of C researchers. Select **ONLY** the activities that U of C researchers are involved in. For example, if a partnering institution is collecting data but U of C will be analyzing it, then do not select “interviews” or “survey collection”.

In Section 2.2 Question 4 of the protocol, explain which research activities will be performed by University of Chicago personnel and which activities will be performed by collaborators at other institutions – be detailed on which institution

will do which research activities, and which institutions will have access to the research data.

In Section 10.2 #4 and 10.2.1 #1, explain if you will be releasing data to individuals outside of the U of C study team. Include what kinds of identifiers or codes will be included in the data you plan to share.

In Section 16.8, we will need a copy of the consent form/script even if consent is only being obtained by individuals who are affiliated with the other participating institutions.

In Section 17.1 of the protocol, upload copies of the IRB approval notices from the IRBs at the other participating institutions.

If your activities on a research study qualify for an **exemption**, we will need a copy of the IRB approval from the primary institution/lead site – we cannot issue an exemption for our institution’s portion of a research study unless the primary institution/lead site issued an exemption for the overall study.

Happy Holidays! Stay Tuned.

We hope you found this first issue helpful, and we encourage you to keep this newsletter as a reference as you consider multi-institutional collaborations. Enjoy your holidays!

Do you have any topics that you would like to see explained in a newsletter? Email us at sbs-irb@uchicago.edu!



We're moving December 9!

New Address:
Social and Behavioral Sciences
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1155 E. 60th Street, Room 414
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Phone numbers and email remain the same:

Phone: (773) 702-0472

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