Harvard University
Area

HUA IRB Newsletter - April 2021

Important Research News

WAIT Tool Update

The WAIT (Web-based Agreement Identification Tool) has now officially been launched! As stated by the WAIT developers:

"*WAIT is a web-based application designed to assist researchers, faculty, and administrators with the identification and internal routing of legal agreements. The tool presents users with a series of straight-forward questions about an unclassified agreement, the responses to which result in both the identification of the agreement type and the point of contact responsible for such agreements at Harvard.*

Simply respond to a series of "Yes" or "No" questions about your agreement to identify your agreement type and whom you should contact to facilitate agreement review. This tool is designed for usage University-wide. Appropriate routing information will be provided regardless of the submitting office with which you work. Visit the WAIT page on the OSP Website to access the application (HarvardKey required) or to read the WAIT User Guide for further information."

Cool Regulatory Items

Conducting Research as a Student

During your time as a student at Harvard University, you may come across many research opportunities. You may engage in research because of a course or degree requirement or just because you want to gain some real-world research experience. Depending on the reason that you are engaging in research and how you represent yourself has an impact on whether IRB review is required as well as where that IRB review will come from.

Engaging in Research as an "Experience"

If you have the opportunity to take part in a research study at another institution, you will most likely be considered as part of that research study's team. As such, you would be added to the study's IRB submission as a study team member. As you are working on the study to gain research experience, you would not be undertaking this activity as a representative of Harvard as the activity would not be because of a course or degree requirement. In this situation, you would not need IRB oversight from the HUA IRB.

Engaging in Research as a Course or Degree Requirement

If you are conducting research to satisfy a course or degree requirement, you will be conducting your own research and representing yourself as a Harvard student. In this situation, you will need to check to see if your research meets the threshold of "regulated research" – the kind of research that requires IRB review and oversight. The HUA IRB office has developed a program that will not only assist in the decision of whether IRB

review is required but will also guide, train, and provide you with some great resources – the Undergraduate Research Training Program. Find out more about the URTP here.

What if Your Research Activity is a little bit of both?

Being part of a research study as a study team member and collecting data for a course or degree requirement is not uncommon. There might be a challenge in navigating IRB review, however. As a rule of thumb, the portion of work that you are conducting for your course or degree requirement should be reviewed by the IRB of the university that is granting your degree. In this case, the HUA IRB. Now what about the study team member piece? Well, that aspect should be handled by the institution's IRB where the research is taking place.

Let's use an example.

You have an opportunity to work on a large research study happening at a local hospital. You are brought on to the project as a study team member at the hospital. However, as the Principal Investigator knows that your own research goals align with theirs, they agree that you can use some of the data collected from the project for your undergraduate thesis.

In this example, the Principal Investigator of the research study would need to add you as a study team member by way of a modification to their IRB submission at their hospital's IRB. This would cover you as a study team member. Now, the student part. As you are not a student of the hospital, it would not be appropriate for the hospital's IRB to provide oversight for your activities as a student. This is when you reach out to the HUA IRB for guidance on next steps.

As these situations can be complicated, you can reach out to the HUA IRB at any time by contacting us at cuhs@harvard.edu.

Do You Speak IRB?

FWA, Agency, and Engagement and Why It's Important in Collaborative/Multi-Institutional Research

You may have heard the term "FWA" but really weren't sure what it was or why it's important. The Federal Wide Assurance (FWA) is an agreement that an institution has in place with the federal government to assure that all research taking place at the institution will abide by the federal regulations for human subject protections and will be reviewed by an IRB. Universities and institutions that regularly conduct research and receive federal money to fund research have a FWA.

The FWA defines what the "institution" is. For the Harvard University Area, the FWA lists the following as our "institution": Faculty of Arts and Sciences, Harvard Graduate School of Design, Harvard Graduate School of Education, Harvard Business School, Harvard Kennedy School, Harvard Law School, Radcliffe Institute for Advanced Study, and the Harvard School of Engineering and Applied Sciences.

The FWA also lists the IRB that will provide review for the institution for regulated research that involves human subjects. The IRB for the Harvard University Area FWA is the Harvard University Area (HUA) IRB, also known as CUHS, the Committee on the Use of Human Subjects.

Just as a FWA defines the institution, the IRB listed under the FWA has purview over the "agents" of the institution. An agent may be an employee, a student, or a volunteer. An agent is a person who has been specifically authorized to conduct human research on behalf of the institution.

So, let's recap here – there is the FWA which defines the institution, identification of the IRB that is listed on the FWA, and the purview of that IRB according to who the institution's agents are. Now let's look at how the activities of those agents determine when IRB review is required.

The regulatory concept of "engagement" comes into play when there is more than one institution involved in a study AND when the overall study would receive either expedited or convened IRB review. Of note, the concept of engagement is not applied when the overall study would be considered "exempt" or "not human subjects research". The IRB uses this regulatory concept to determine which institutions require IRB review in the overall study. Engagement is determined by the actions of the agents.

When a research study involves multiple institutions, it is important to delineate who is doing what. If a person (or "agent" if we want to use the regulatory term) that is affiliated with one of the institutions involved in the research is 1) consenting study subjects, 2) intervening, or interacting with subjects, or 3) analyzing private, identifiable data, then that institution (by way of their "agent") would be considered "engaged" in the research and IRB review for their activities would be needed.

There are also instances when an institution may not be engaged. For example, telling a subject about a study or providing other researchers with identifiable information when they are not part of the overall study would not be considered "engaged" in the research and IRB review would not be needed for those activities.

As it is important for IRB's to know who needs IRB review and who doesn't, the IRB reviewer will also ask about the activities of those that are not affiliated with the institution. If it is determined that the individual's activities "engage" them in the research, then the IRB reviewer will ask if the non-affiliated person is obtaining IRB review from their own institution. Often, the IRB that is conducting the review ("Reviewing IRB") may allow the non-affiliated person to be included in the Reviewing IRB's review. This is done by way of a reliance agreement. This reliance agreement will vary in type by the type of institution.

An IRB Authorization Agreement (IAA) is used when the non-affiliated individual is associated with an institution that has a FWA. Most institutions now use the SmartIRB system to accomplish this task. An Individual Investigator Agreement (IIA) is used when the non-affiliated individual is either working on their own or is affiliated with an institution that does not have a FWA. Most independent contractors or smaller institutions that regularly do not conduct research will need to enter into an IIA with the reviewing IRB as they typically do not have a FWA.

Whew! That was a lot of information, but now you can impress any IRB with your collaborative/multi-institutional research knowledge!

Find this topic interesting? You can check out our one-stop shop about all of this on our website here.

And, if you have a hankering for the hardcore regulatory stuff, more information on engagement may be found here.

From all of us at the HUA IRB, Be Well and Stay Healthy!

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