



Harvard University Area IRB Monthly Newsletter

December 2022



More Resources to Prepare You for the NIH DSMP

As you are aware, the [NIH Data Safety and Management Policy \(DSMP\)](#) goes into effect on January 25, 2023. With this policy, researchers must submit a plan on what they will share, how it will be shared, and how long it will be shared. This policy pertains to new NIH funding as well as competing funding.

Harvard University has developed many resources for our research community (see the [August 2022 Newsletter](#) and the [November 2022 Newsletter](#)) and in this

season of giving, NIH has added more resources. See the **12 Days of DSMP Resources** on the NIH website [here](#).

Winter Recess Reminder



It's that time of the year again, a blissful hiatus from work or school at the end of the year. This year, the Harvard Winter Recess will occur from mid-day on Thursday, December 22, 2022, through Monday, January 2, 2023.

Just to let you know, the IRB staff will be busy, working to ensure that submissions received by the HUA IRB office are attended to before the winter recess closure. For those submissions submitted during the month of December, we will do our best to ensure that they are wrapped up, but some circumstances are beyond our control.

The last Convened IRB meeting of the year will take place on Thursday, December 15. As the deadline for this meeting has already passed on November 23, any studies that qualify for Convened IRB review (i.e., those studies with an uncertain risk or greater than minimal risk) have already been assigned to the December meeting. Please know that IRB Staff will do their

best to ensure that correspondence from each study's review will be sent out in a timely fashion after the meeting thereby providing study teams with ample time to work on their response before the next IRB meeting deadline.

Don't Forget! If there is an emergency such as an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) or other unexpected events, contact the HUA IRB via email at cuhs@harvard.edu. The HUA IRB email inbox will be monitored for emergency situations.



Are You a GSAS Student Working on Your Dissertation? Let's Chat About Agency

Many students work in another researcher's lab to gain experience and gather data in support of their dissertation work. This lab may be at Harvard, another institution, or at a local hospital. When working in this lab, the activity that you are conducting is most likely covered by that institution's IRB. That IRB may be a Harvard IRB or another institution's IRB.

Things get a little complicated when working in another institution's lab, gathering data in support of dissertation work, and receiving that institution's IRB oversight. Why? Well, when you are working at another institution, you are most likely working in that lab as an affiliate (or in regulatory speak "agent") of that institution. This is most likely true when the other institution is a hospital or other HIPAA-covered entity. Specifically, although there is IRB oversight for your role and activities in that lab, this IRB oversight typically does not extend to your role (and dissertation work) as a GSAS student.

The reason for this is based in what is known as the federal wide assurance, or "FWA". As we described in a newsletter earlier this year, 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 an FWA.

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

Just as an 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, who are the agents of the HUA? Our agents are typically faculty and students (including GSAS students) that have been authorized to conduct research on behalf of the HUA, including dissertation work.

So, if you are conducting work in a non-Harvard lab or institution (which also includes labs on the Harvard Longwood Campus) to gain experience and gather data in support of dissertation work, please check in with the [HUA IRB office](#) to ensure that your dissertation work has IRB oversight.



A Gentle Reminder – Use the Most Current Version of the IRB Protocol Template

The HUA IRB office regularly updates the IRB Protocol Template (also lovingly known as “HRP-503 - TEMPLATE - HUA Protocol in the [ESTR Library](#)) because of changes in regulation or policy as well as to better capture necessary information for the IRB’s review. As such, if you are not using the most recent version of this document, you are missing out on the benefit of these updates. You might also unnecessarily lengthen the time of the review as staff will need to ask you additional questions. Not sure if you are using the most current version? If you download the form from the [ESTR Library](#), you are.

Do You Speak IRB?



Scientific and Scholarly Review

Scientific and Scholarly Review is part of the criteria for approval found in the federal regulations that govern human research protections and is required before an IRB can approve a human research study.

The regulations at 45 CFR 46.111(a) and 21 CFR 56.111(a) include the following approval criteria that specifically pertain to Scientific and Scholarly

Review:

- Risks to participants are minimized (i) By using procedures consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Scientific and Scholarly Reviews can happen in a few ways. For sponsored research, Scientific and Scholarly Review occurs during the peer review process. For Harvard student research with an identified Faculty Sponsor, this review occurs when the Faculty Sponsor ensures and provides attestation that the scientific and scholarly validity of the proposed research has taken place. Scientific and Scholarly Review also takes place during the IRB's review of the study. For those studies reviewed by the Convened IRB (i.e., research involving uncertain or greater than minimal risk), Scientific and Scholarly Review is undertaken by an IRB member. For all other studies, IRB staff conduct the Scientific and Scholarly Review.

The Scientific and Scholarly Review ensures the soundness of the research design, and the ability of the research to answer the proposed questions and provides the IRB with the information it needs to determine whether regulatory criteria for approval are met.

The HUA IRB uses the worksheet HRP-320: Scientific and Scholarly Review for

all studies that receive a review. We've also created a new Standard Operating Procedure for this review, HRP-046: Scientific and Scholarly Review. You can check out both in the [ESTR Library](#).

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