



Harvard University
Area

HUA IRB Newsletter - July 2020



Resumption of Research – What's Next?

As you are all aware, nearly all in-person human subjects research has been paused since March 2020.

To get things up and running, the Harvard University Provost's Office has been leading efforts for a phased reopening of research facilities. One of these efforts, the Lab Reopening Planning Committee, has developed a comprehensive [Research Laboratory Re-Entry Plan](#) that provides a road map toward re-establishing research access to buildings and laboratories. The steps that are needed for lab re-entry may be found [here](#).

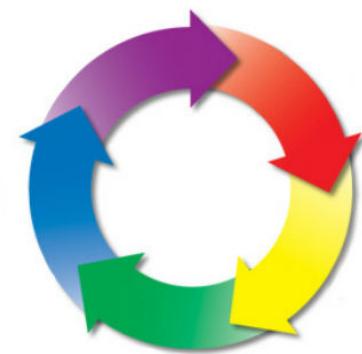
So, what's next?

The University has decided that each School will be responsible for drafting a process and criteria for the resumption of in-person research for their researchers. The principal investigator (PI) of a research program/study will be required to craft a plan outlining the COVID-19 precautions that will be undertaken for their research. The researcher's plans will be subject to School review and approval. No research can begin until a researcher's plan receives School approval.

In an effort to assist the research community and their Schools in the resumption of in-person human subjects research, the *Harvard University Resumption of Research of Human*

Subjects Research Committee (HURSRC) has been formed through a collaboration between the Harvard University Area IRB as well as faculty across FAS, SEAS and HMS. The HURSRC has developed process, guidance, templates, as well as standard operating procedures to assist researchers and their Schools to get in-person human subjects research up and running. You can find these great resources [here](#).

Have questions about COVID-19 and your research? We've got you covered. Check out the IRB webpage [here](#) as well as our handy new resumption of research study decision aid found [here](#).



IRB Lifecycle Guide

We don't need to tell you how challenging, mysterious, confusing, or (insert adjective here), that submitting your first IRB submission can be. In our continued effort to de-mystify the IRB process for our research community, we have collapsed the many tips, tricks, and resources about the IRB submission process in our new website feature, the IRB Lifecycle Guide found [here](#).

The IRB Lifecycle Guide presents information in a sequential fashion – from creating your IRB submission to closing your IRB submission and everything in-between.

Consider yourself an IRB expert? We encourage you to take a look – you might learn something that you didn't know!



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. Most universities and institutions that regularly conduct research have an 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 IRB, also known as CUHS.

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, 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 is the institution’s agents. 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 when the overall study would receive either expedited or convened IRB review. Of note, this concept 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 these “institutions” is consenting study subjects, intervening or interacting with subjects, or 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 for those activities would not be needed.

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 (cool regulatory term alert - “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 an FWA. 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 an 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 an 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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