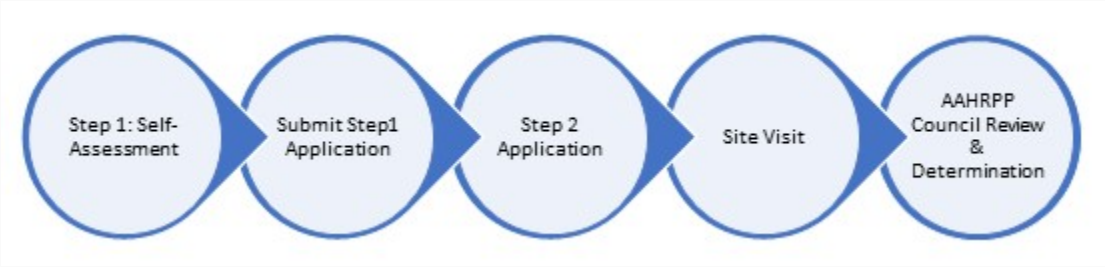
Harvard University Area

HUA IRB Newsletter

September 2020

AAHRPP Site Visit – Less than a Month Away!



We're almost there! The Harvard University IRB began the process of accreditation for our HRPP in November 2019. We have made it through two separate evaluations of our written materials (standard operating procedures, forms, processes) and the site visit is the last step prior to being accredited. Our site visit has been scheduled for Monday, September 28th and Tuesday, September 29th. Because of the COVID pandemic, the entirety of the site visit will occur remotely, via Zoom.

The Site Visit will consist of various meetings with institutional and IRB office representatives, IRB members, key stakeholders from across the university, as well as a few researchers. AAHRPP has selected those that they would like to interview, so if we have been in touch with you, you already know! A BIG thank you to all who are part of this effort!!!

Whether you are taking part in the Site Visit or not, knowing about our HRPP as well as other aspects related to human subjects research is a good thing. We have created an AAHRPP Training Webpage that goes over various aspects of accreditation, things that are important to know, as well as what one can expect from the Site Visit. You can check out our AAHRPP Training Webpage here.

Resumption of In-Person Research

Just a reminder about the resumption of in-person research resources, restrictions, and other good stuff that are available for Harvard University researchers.

Lab Re-Opening Process

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, 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.

Instructions for Seeking Approval from Your School

Each School is 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 is required to craft a plan outlining the COVID-19 precautions that will be undertaken for their in-person research. The researcher's plans are subject to School review and approval. No research can begin until a researcher's plan receives School approval - this is regardless of where the research is taking place. Instructions on how to request resumption of in-person research may be found here.

Important Things to Note!

- Should a researcher receive approval from their School/Department for in-person human subjects research and their study is taking place at a location outside of Harvard, it is important that these studies follow any guidelines or instructions from the specific facility where in-person research would occur. As some research may occur in another state, with another institution, or under the direction of another IRB (as in a reliance agreement situation), this is especially important. It is the responsibility of the Study Team to keep apprised of potential restrictions and conduct their study accordingly.
- Harvard Affiliates should note any travel and other restrictions that are in place by visiting the Harvard COVID-19 website - https://www.harvard.edu/coronavirus.
- Please know that the default for all research involving in-person contact is to be paused. To the extent possible, study activities that can be done remotely by telephone or electronically, such as screening or follow-up, should be done in this way.

- Should further restrictions pertaining to contact with study subjects be imposed at any time, it is the responsibility of the study team to follow guidance regarding when to pause a study and contact the HUA IRB.

Available Resources

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 (HURHSRC) has been formed through a collaboration between the Harvard University Area IRB as well as faculty across FAS, SEAS and HMS. The HURHSRC 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 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.

GDPR Reminder

The European Union (EU) General Data Protection Regulation (GDPR) took effect on May 25, 2018. The regulation is "designed to harmonize data privacy laws across Europe, to protect and empower all EU citizens' data privacy and to reshape the way organizations across the region approach data privacy."

The GDPR applies to all individuals, organizations, and institutions that collect personal data from individuals residing in the EU.

While the GDPR may appear to not be applicable to researchers in the United States, here are some aspects of the GDPR that may affect you and your research:

Increased Scope: The GDPR protects the personal data of those that reside in the EU. However, the location of those that are collecting the data extend beyond the EU boundaries. For example, if you are conducting an online survey that collects data from EU residents, you may be subject to GDPR.

Consent: GDPR requires that consent be "clear and distinguishable" and provided in an "intelligible and easily accessible form, using clear and plain language." The GDPR goes on to say that, "It must be as easy to withdraw consent as it is to give it."

Right to Access: The GDPR requires that individuals from whom personal data are collected have a right to know that their data was collected, where and how it was collected, and for what purpose. Individuals also have the right under the GDPR to request a free electronic copy of the data that was collected from them.

Right to be Forgotten: The "right to be forgotten" also known as "Data Erasure" has become the hallmark characteristic of the GDPR. The GDPR provides individuals the right to have data that was collected from them to be erased, to cease their data from being further distributed, including third parties that may have received their data.

Check out our news article on GDPR here which contains common questions and answers as well as more information about how GDPR may affect your research.

Do you Speak IRB? *Exempt*

Let's start with some regulatory background about where exempt review fits in…

IRB review occurs on a continuum according to risk. Once an activity meets the definition of regulated research and involvement of human subjects, the level of review is determined. Exempt review is the lowest level of review which is then followed by Expedited review and then review by the Convened IRB/Full Board. See more about level of review in our IRB Lifecycle guide here.

Below are some common questions that we encounter regarding exempt review that we thought might be helpful.

Exempt research and not human subjects research mean the same thing, right?

Well, actually no. Unfortunately, terms used in the IRB world are not as straight-forward as one might think. The IRB's use of the word exempt means that the research does involve human subjects however the activities that are part of the research fall into one (or more) of the federal regulatory designated exempt categories. Because of this, the research is *exempt* from the regulations.

What are the exempt categories?

The categories are activity focused. For example, exempt category 2 focuses on research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.
While exempt category 3 focuses on what are called "benign behavioral interventions". You can find more information about some of the more popular categories on our website here.

Can I make my own exempt determination?

The federal regulations do not specifically state *who* should make exempt determinations however our federal regulators, OHRP, state, "OHRP recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is exempt." You can read more about OHRPs current guidance on exempt research here.

What if I need to make changes to my study that has determined to be exempt?

Most exempt submissions do not require a modification if the exempt determination does not change. You also do not need to submit a modification when study team members change.

When should an Exempt study submit a modification?

- If including children, prisoners, or other protected populations.
- Study procedures that fall outside the exempt category. For example, an intervention was initially going to take place in one sitting, but the research team decides to include longitudinal effects, so they implement a follow-up treatment.
- Increase in risk.
- Ancillary policy / regulations: GDPR, collection of sensitive information requiring a Limited IRB review, change in data security assessment.
- Change in Principal Investigator.
- Change in Faculty Sponsor.
- If there is new funding.

What about other changes? If an exempt study is changing the design of the study or major revision to the procedures, a new exempt determination request should be submitted.

What template do I use for the consent process for my exempt study?

As studies that have been determined to be exempt are exempt from the regulations, the standard template for the informed consent form does not have to be used. Instead, you may

use the “HUA Exempt Human Research Consent Script Template” (HRP-502-c in the ESTR Library). You will find the Exempt Script to be much shorter than the standard consent form but still include all of elements that are needed.

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

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