Harvard University Area

Harvard University Area IRB Monthly Newsletter

June 2023

AAHRPP Re-Accreditation Site Visit Coming Soon!

The end of our three-year accreditation cycle will occur in December 2023. Can you believe that it has already been three years since we were initially accredited?

With the approval of our re-accreditation application by the Association of Accreditation of Human Research Protection Programs (AAHRPP), our re-

accreditation site visit has been scheduled for Tuesday, August 29th through Wednesday, August 30th, 2023.

Before the AAHRPP site visit, we will be holding various training sessions. Training sessions will be focused on key areas of our research community - IRB staff, IRB members, and other "Key Personnel" such as representatives from the Office of Sponsored Programs, Office of the Vice Provost for Research, Office of General Counsel, other offices that fulfill a research compliance function, and researchers and their staff.

We are conducting these training sessions to re-familiarize and harmonize each of our roles in the oversight, the roles, and the responsibilities that comprise our Harvard Human Research Protection Program (HRPP). We will be utilizing the role-based training materials that were used for our initial accreditation and can be found on our website here.

Got some extra time this summer? We would greatly appreciate your attendance at one of our upcoming AAHRPP Training Sessions – dates coming soon!

To learn more about AAHRPP's re-accreditation procedures, you can visit the AAHRPP website here.

Leaving Harvard? Plan and Take Action Prior to Your Departure

If you will no longer have a formal affiliation at Harvard, there are some important steps that you need to take before your departure. Why? Well, when you are no longer affiliated with Harvard, your Harvard IRB approval will no longer be active, the Harvard University Area IRB will not be able to provide an IRB review for you, and you will no longer be able to access ESTR to make any changes to your existing study. Here is what to do:

If you are closing your study at Harvard

ESTR requires creating a Continuing Review to close your study. You will be answering "no" to four questions about your study at Harvard, even if you will be transferring your research to another institution. These are the questions:

1. Study is permanently closed to enrollment OR was never open for enrollment

2. All subjects have completed all study-related interventions OR not applicable (e.g., the study did not include interventions, no subjects were enrolled)

3. Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)

4. Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)

Important Fact! If your study received an Exempt or Not Human Subjects determination it does not need to be closed in ESTR.

Next, close your study at Harvard using these study closure instructions from the ESTR Support website - https://estrsupport.fss.harvard.edu/study-closure

If you are moving to a new institution and will continue your research

Contact your new institution's IRB office for instructions on how to open your study there. It is important to ensure that there is no gap in approval for your study during this transition. We recommend that your study has approval in place (if possible) at your new institution before closing your study at Harvard.

Next, close your study at Harvard using these study closure instructions from the ESTR Support website - https://estrsupport.fss.harvard.edu/study-closure

If you plan to transfer your research to another Harvard Principal Investigator

Determine if the identified individual who will be the new PI is "PI eligible." Check here to see - https://cuhs.harvard.edu/am-I-PI-eligible

If not, you will need to also identify a Faculty Sponsor for the new PI. To change the PI of your study, submit a Modification using these modification instructions from the ESTR support site - https://estrsupport.fss.harvard.edu/mod-smartform

Helpful Reminders

Here are some helpful tips for a successful IRB submission, review, and approval process that have come up recently:

- **Data Use Agreements** - Don't forget that the transfer of data to and from Harvard University Area may require a data use agreement. Learn more about data use agreements here.
- **Current Version of the HUA IRB Protocol Template** - Regulations that govern human subjects research change all the time. As such, our IRB Protocol Template also changes to stay up to date on the information that the IRB needs to review your research efficiently and compliantly. You can always find the most recent version of the IRB Protocol Template (HRP-503) in the ESTR Library.
- **Paying Participants** – Harvard University has a comprehensive policy on human subject payments including which form of payment is acceptable, and reporting requirements, among others. You can learn more about this policy here.
- **Use of the Harvard Name and Insignias** – Harvard is a world-renowned institution and because of this, the Harvard name and insignias must be used appropriately. Harvard University has established

the Policy on the Use of Harvard Names and Insignias to guide the Harvard community on what is acceptable and what is not.

Do You Speak IRB?

Individual Investigator Agreements

Every institution that regularly conducts human subjects research and receives money from the U.S. federal government must have a federalwide assurance or FWA. The FWA is a commitment to the government that all research conducted by the institution will be done according to federal regulations for protecting human subjects.

However, some institutions do not regularly conduct human subjects research and do not receive money from the federal government. There may also be individuals not affiliated with an institution that may be hired to help with a research study. These institutions and individuals may be from the community or located internationally.

When an FWA-holding institution, like Harvard University Area (HUA), works with other institutions that have an FWA, it is possible to use a reliance agreement, also known as an IRB Authorization Agreement (IAA). An IAA is only possible when all institutions involved in a research study have an FWA. An IAA permits one institution to rely on another institution for IRB review thereby preventing duplication of IRB effort.

As mentioned, not all institutions or individuals have an FWA. In these situations, an FWA-holding institution may provide an IRB review for the institution or individual by using an Individual Investigator Agreement (IIA). What the IIA does is permit the FWA-holding institution to extend its FWA to cover this institution or individual; basically, making this institution or individual their agent.

If the HUA IRB is willing to extend the HUA FWA to an institution or individual via an IIA, the following documents must be reviewed by that institution or individual:

- *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (see http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) or other internationally recognized equivalent (see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions on the OHRP website at http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html)
- the HHS regulations for the protection of human subjects at 45 CFR part 46 (see http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-

46/index.html) or other procedural standards designated by a non-U.S. institution under its FWA (see section B.3. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions on the OHRP website at http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html)

- The FWA and applicable Terms of the FWA for the assured institution
- The relevant institutional policies and procedures for the protection of human subjects of the assured institution.

Following this, the HUA IRB will require the institution or individual to sign an IIA. You can find the HUA IIA in the ESTR Library (be sure to be logged in with your Harvard Key!). Click on the tab “Templates and Forms” and look for the document “HRP-225-FORM-Individual Investigator Agreement”.

You can learn more about the IIA on the OHRP website here.

You can reach us at:
cuhs@harvard.edu or (617) 496-2847

Check out our website at:
https://cuhs.harvard.edu