Harvard University Area

HUA IRB Newsletter - July 2021

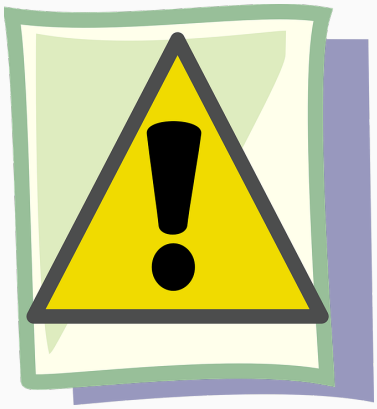
Important News

Resumption of Research – COVID-19 Update

With COVID-19 restrictions changing across the country, the Harvard restrictions and processes that were in place have now been re-visited. Please see the updated guidance here - https://cuhs.harvard.edu/questions-about-covid-19-and-your-research?

CITI Training Now Available in Spanish!

The CITI (Collaborative Institutional Training Initiative) Social & Behavioral Research ethics online training is now available in Spanish. To take this training in Spanish, just log in to the Harvard portal on the CITI website. You can find information about how to log in to the Harvard CITI portal here - https://cuhs.harvard.edu/required-ethics-training



Important Things to Know

Just Arriving at Harvard? Or Are You Departing Harvard? Check out these tips for a successful transition

Welcome to Harvard! Here are some tips to get your research up and running

Local, state, and institutional laws and policies
While all IRB's follow the same set of regulations, there are different local, state, and institutional laws and policies that may impact how an IRB reviews your research. At Harvard, there are quite a few of these and it is beneficial to know how they might impact your research.

- Harvard Principal Investigator eligibility requirements – https://cuhs.harvard.edu/am-I-PI-eligible
- Harvard required ethics training - https://cuhs.harvard.edu/required-ethics-training
- Harvard Research Data Security Policy - https://vpr.harvard.edu/pages/harvard-research-data-security-policy

Hello, I'm Harvard, Nice to Meet You!
Get a lay of the land by looking through the following:

- Read our HUA Human Research Protection Program Plan - https://cuhs.harvard.edu/files/cuhs/files/hrp-101_-_hua_human_research_protection_program_plan_1.pdf
- Read our Investigator Manual - https://cuhs.harvard.edu/files/cuhs/files/hrp-103-hua_investigator_manual_3.pdf
- Learn about ESTR, our online IRB submission system - https://estrsupport.fss.harvard.edu/
- Harvard's various data management systems and requirements - https://researchdatamanagement.harvard.edu/

Connect with Us Early

We are here to help you get your research up and running. Whether it be with a new study or if you are transferring a study from another institution. Contact us at cuhs@harvard.edu

Leaving Harvard? Plan Ahead 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 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:

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g., study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- 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 prior to 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

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Do You Speak IRB?

Prompt Reporting Requirements

You've received approval form the IRB to conduct your research but what if something goes wrong? What do you need to report to the IRB? The HUA IRB Investigator Manual provides a comprehensive overview of what needs to be reported. You can find the Investigator Manual in the ESTR Library as well as on our website here - https://cuhs.harvard.edu/files/cuhs/files/hrp-103-hua_investigator_manual_3.pdf

Report the information items that fall into one or more of the following categories to the IRB within **5 business days.** Information that does not fall under any of the categories does not require reporting to the IRB. If unsure, contact the IRB office.

1. Information that indicates a new or increased risk, or a new safety issue. For example:
    a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk or uncovers a new risk that might adversely affect the safety of the participants or the conduct of the research.
    b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk or describe a new risk.
    c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
    d. Protocol violation that harmed participants or others or that indicates participants or others might be at increased risk of harm.
    e. Complaint of a participant that indicates participants or others might be at increased risk of harm or at risk of a new harm.
    f. Any changes significantly increasing the risk to participants and affecting the conduct of the research.
2. Harm experienced by a participant or other individual, which in the opinion of the investigator are unexpected and at least possibly related to the research procedures.
    a. A harm is "unexpected" when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB (via protocol, consent forms, etc.) in terms of nature, severity, frequency, and characteristics of the study population.
    b. A harm is at least "possibly related" to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the event/harm.

3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
4. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483.)
5. Written reports of study monitors.
6. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7. Breach of confidentiality.
    a. Per Harvard Information Security policy, it is required that any researcher who experiences a security incident or breach involving research data levels 2-5 report the breach to the appropriate Harvard personnel. Detailed information about these reporting requirements can be found on their website.
8. Change to the protocol without prior IRB review to eliminate an apparent immediate hazard to a participant.
9. Incarceration of a participant in a study not approved by the IRB to involve prisoners.
10. Complaint of a participant that cannot be resolved by the research team.
11. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
12. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.)

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

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