Harvard University Area

Harvard University Area IRB Monthly Newsletter

October 2023

Keep That Thinking Cap On!

Last month we welcomed new students and researchers to campus with a boatload of resources introducing the IRB. This month we follow-up with information on how to obtain and document research ethics training before submitting a study for review. (Sadly,no, reading last month's newsletter won't cover it—there's a lot for us to share, and a lot for researchers to learn!)

Human Subjects Protection Training

Anyone that will have direct interaction with research participants and/or access to identifiable information/specimens must complete human research training. In addition, Principal Investigators, Co-Investigators, and those meeting the definition of NIH "Key Personnel" must complete human research training regardless of whether or not they have direct interaction with participants and/or access to identifiable information/specimens. Faculty sponsors of non-Exempt research must also complete training.

Harvard University's training curriculum is offered through the Collaborative Institutional Training Initiative (CITI) Program. To get course information, follow the instructions here.

In addition to Harvard University's CITI training, the IRB will also accept another institution's (human research) CITI training or equivalent training. Human research training certification is valid for a three-year period from date of completion, regardless of which institution it was completed through.

URTP Training Dates

Are you a Harvard College student? Do you advise College students on their research projects? The Undergraduate Research Training Program (URTP) is our comprehensive platform to create better prepared undergraduate researchers. As part of the program,training sessions are held at various dates throughout the academic year. The sesessions are an alternative to the standard online CITI training. The sessions have been developed with students in mind: they are 60-90 minutes in length, encourage interaction, and include topics important for Harvard College researchers specifically.

Training dates for Fall 2023 may be found here.

Training Documentation in ESTR

Did you know that completion of CITI training is captured as part of your profile in the ESTR submission system? If you are a Harvard University Area (HUA) researcher and have taken the Harvard CITI training, there is NO NEED to upload these training certificates to Item 2 of the ESTR Study Team Members SmartForm page.

If you took anon-Harvard CITI training or a training other than one offered by CITI, attach that certificate to a Comment on the ESTR homepage for your submission and IRB staff will link it to your ESTR profile so it appears across all your studies!

Here is when you DO NEED to upload training certificates to Item 2 of the ESTR Study Team Members SmartForm page:

- If you are collaborating with a non-Harvard University Area researcher (meaning from the Harvard Longwood Campus or a non-Harvard

institution all together) AND the HUA IRB will provide IRB review for that researcher.

University Administrator Resources by Role

It's not just researchers who may need training! The HUA IRB has created several resources specific to the role and responsibilities of University administrators who work with the IRB during our review (e.g., fCOI and Data Safety reviewers). The home base for these materials may be found here.This page includes information such as:

- An overview of our HRPP and Toolkit of SOPs and other documents,
- A handout that describes which Toolkit documents apply to your role, and
- A presentation that covers broad topics like the HRPP and human subjects research basics.

Any Toolkit documents referenced in these materials are stored in ESTR under the Library tab.

Do You Speak IRB?

Human Subjects Research

A researcher's need for ethics training is tied to whether they are working with research participants and/or have access to identifiable information. That is, whether they are conducting research with human subjects. Let's take this chance to review what a human subject is:

The federal regulations define a human subject as a "A living individual about whom an investigator conducting research obtains (1) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens" (45 CFR 46.102(f)(1)(2)).

Phew! It might be easier to break this down into common terms:

Living individual refers to data (information or specimens) collected from living subjects. For example, research using data from the 1880 Census would not be human subjects research.

About whom refers to the fact that the information collected must be personal information about an individual and their feelings, behaviors, opinions, and experiences.For example, a survey that collects data about the activities of an organization, rather than its members, is not human subjects research. An expert in a field providing their professional opinion may still be considered a human subject if the opinion is their own (i.e., not speaking on behalf of an organization and their positions).

Intervention includes physical procedures and manipulations of the subject or the subject's environment for research purposes. For example, taking a saliva or blood sample from a subject or having a subject view a video would be considered a research intervention.

Interaction refers to communication between the researcher and the subject. For example, research that includes face-to face, mail, internet, and phone interactions (e.g.,surveys), as well as other modes of communication would be considered an interaction.

Identifiable private information or biospecimen means the identity of the subject is or may be readily ascertained by the researcher or others or associated with the information. For example, research with a de-identified data set is not research with human subjects because the data are not individually identifiable.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable to be considered information to constitute research involving human subjects. Examples of private information include medical or academic records or persona ljournals.

Still have questions? Check out our IRB Lifecycle Guide we highlighted last month. It coversall of the nuts and bolts of human subjects research. You can access the IRBLifecycle Guide on the front page of our website here.

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