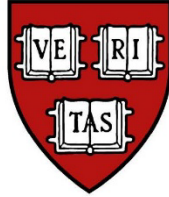


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## Harvard University Area

# Harvard University Area IRB Monthly Newsletter

September 2023

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### Welcome to Harvard!

With the start of a new academic year, there are a lot of new faces on the Harvard campus. Navigating a new campus can be daunting, as is knowing what resources are available to you. The Harvard University Area IRB is here to help!

The Harvard University Area IRB provides IRB review for the Harvard Faculty of Arts and Sciences, Harvard Graduate School of Education, Harvard Kennedy School, Harvard Divinity School, Harvard Business School, Harvard Law School, Harvard Graduate School of Design, the Harvard School of Engineering and Applied Sciences, and the Radcliffe Institute for Advanced Study. The IRB of record for the Harvard University Area is referred to as the Committee on the Use of Human Subjects (CUHS).

The HUA IRB administrative office is responsible for managing the day-to-day operations and support of the IRB. The HUA IRB office staff perform a variety of functions in addition to supporting the IRB such as providing IRB determinations, reviewing studies on behalf of the IRB, assisting researchers with IRB-related questions, and providing training and outreach.

The HUA IRB staff are assigned a portfolio according to Schools and their Departments. IRB staff are here to help. You can locate your go-to IRB staff member [here](#). Or, for a staff directory, you can go [here](#).

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## **IRB Lifecycle Guide – Your Lifeline for All Things IRB**

Navigating the IRB approval process can be challenging, especially if you are a new researcher. Since there are numerous regulations that may apply to your research, as well as different levels of IRB review, knowing what to do or what to expect can seem intimidating.

The HUA IRB office has broken this process down into manageable, bite-size pieces according to the stages of IRB review – whether you are just starting to think about a research project, wondering what comes after IRB approval, or you are not certain what your responsibilities might be as a Principal Investigator. Check out our IRB Lifecycle Guide [here](#).

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## **Managing Relationships—The Compliance Kind**

A pro-tip for researchers new to Harvard: A research project may require concurrent reviews from the IRB, Office of Sponsored Programs, and/or a School-based data security officer depending on the procedures of the study. These reviews take place in separate sections of our research compliance system—ESTR for IRB review, Agreements for contracts, and Safety for data security review. These sections were designed to talk to each other to facilitate the concurrent reviews and to foster a deeper understanding of a project for all reviewers.

When a submission in one section (Safety, ESTR, or Agreements) has associated records in another section, complete the Manage Related Projects activity to connect the records across sections. Connecting the records ensures that a reviewer will not only have access to information across the system but will also know when a review is complete! Without this notification, submissions may sit, leading to delays.

Now that you know the importance of “Manage Relationships,” how do you do it? A comprehensive document has been created to guide you through the process, which you can find [here](#) - just go to page 20 for all the details.

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Do You Speak IRB?



## PI Assurance

For each application submitted to the IRB, the Principal Investigator must acknowledge a “Principal Investigator Assurance Statement” in ESTR. The Principal Investigator Assurance includes statements that assure that the research will be conducted ethically, safely, and according to federal, local, state, institutional, and other requirements.

For example, these statements include:

- I will not start Human Research activities until I have obtained all other required institutional approvals, including local ethics committee review for international sites; and approvals of departments or divisions that require approval prior to commencing research that involves their resources.
- I will ensure that there are adequate resources to carry out the research safely, e.g., sufficient investigator time, equipment, and spacing.
- I will ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
- I will update the IRB office with any changes to the list of study personnel.

The Principal Investigator must adhere to each requirement throughout the duration of the study (from initial submission to study closure). Assurance is provided by clicking “OK” during the formal submission of any action to the IRB: initial application, modification, study closure, etc.

If you want to see the assurance before submitting, you can find the full text in the ESTR Library under the tab “Ancillary Review and Other Reference.”

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## **Hello and Goodbye**

As the Harvard University Area IRB welcomes students and researchers to the Harvard community during this new academic year, we must formally thank and bid adieu to some longtime staff members as well.

At the end of July, the HUA IRB said farewell to Shannon Sowards, who served as our Director since January 2015. In her time, Shannon oversaw our [AAHRPP](#) accreditation; launched an undergraduate research advisory council and training curriculum that has been widely embraced across the University; expanded training and outreach to the research community overall (including this newsletter!); wrote, harmonized, and made transparent our SOPs to streamline and clarify our review process; among many other initiatives.

For the IRB staff and researchers, though, there was something more. Shannon worked to bring our two sides together in a way that felt productive, educational, and collaborative. With a warm spirit, soft voice, and unwavering patience, Shannon strived to build relationships simply by listening and learning, and she encouraged the IRB staff to do the same—we will continue to do so.

We are grateful to her for putting us on a path to success and excellence as a program, and for building the genuine community of researchers, IRB staff, and other University administrators that’s so essential for meeting our collective mission to protect human subjects in research.

This month the HUA IRB also thanks Alicia McGovern and Katie Schaffenberger, IRB Administrators whom many of you have worked with through reviews of your studies. Both Alicia and Katie have served as model IRB professionals—articulate, well-studied, detailed, and available to provide rich guidance and support to their research communities. We will miss their thoughtful contributions to the HUA IRB team and wish them all the best in the future. Thank you both!

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