



## Harvard University Area IRB Monthly Newsletter

July 2022

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*For this month's newsletter, we will focus on items that deal with leaving or visiting Harvard as a researcher.*

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**Leaving  
Harvard?**

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As the end of the academic year is here, we thought this might be a good time to remind the Harvard research community about what to do with their studies if they will be leaving Harvard.

There are a few options available to you:

- **Transfer your studies to another institution:** The Harvard IRB will work with your new institution to ensure that there is continued coverage for your research study. As soon as possible, please let your [IRB Reviewer](#) know that you are leaving Harvard and that you wish to have your study transferred to your new institution.
- **Transfer to another Principal Investigator:** If taking your study with you is not an option, the study may remain open if another Harvard University Area Principal Investigator is identified. The first step is to determine if the identified individual is "[PI eligible](#)." If not, you will need to also identify a Faculty Sponsor. Once the new Principal Investigator is ready, you will submit a modification to change the Principal Investigator on your study. Information on how to submit a modification to change the Principal Investigator may be found [here](#). Of note, to change the Principal Investigator on an approved study, select the "Other parts of the study" Modification scope.
- **Close the study:** If you are not interested in continuing with your study or are just not able to carry on for various reasons, you will need to close your study. If your study is funded, it is always a good idea to check in with your funder about whether closing your study is possible. You will also want to think about what you will do with the data that has been collected. And a friendly reminder – if the data are identifiable, it is not permissible to analyze these data without current and active IRB approval. Information on how to close an IRB study may be found [here](#).



## Who Owns Research Data?

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There is often a question about whether a researcher may take their research data with them if they are leaving. According to the Office of Research Integrity (ORI), as...” support for research is typically awarded to research institutions, not to individual researchers, institutions have responsibilities for budgets, regulatory compliance, contractual obligations, and data management. To assure that they are able to meet these responsibilities, research institutions claim ownership rights over data collected with funds given to the institution. This means that researchers cannot automatically assume that they can take their data with them if they move to another institution.”

Harvard University aligns with this thinking. In the [Harvard University Data Ownership Policy](#), “...the University is responsible for complying with laws, regulations, and requirements of its research sponsors, many of which pertain to research data. To ensure its ability to satisfy those requirements, the University asserts ownership over research data generated at Harvard for

projects conducted at the University, under the auspices of the University, or with University resources.”

As noted in the policy if you will be leaving Harvard University for another institution:

*“If a PI leaves Harvard and a project is to be moved to another institution, ownership of the original data may be transferred from Harvard to the PI’s new institution upon request from the PI subject to: (a) the prior written approval of the Vice Provost for Research; (b) written agreement from the PI’s new institution that guarantees (1) its acceptance of ongoing custodial responsibilities for the data and (2) Harvard having access to the original data, should such access become necessary for any reason; and (c) relevant confidentiality restrictions, where appropriate.”*

See the [Harvard University Data Ownership Policy](#) for more information.

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**Do You Speak  
IRB?**



## **Agency and Engagement of Visiting Scholars (Fellows and Faculty)**

You may have heard the term “FWA” but really weren’t sure what it was or why it’s important. The Federal Wide Assurance (FWA) is an agreement that an institution has in place with the federal government to assure that all research taking place at the institution will abide by the federal regulations for human subject protections and will be reviewed by an IRB. Universities and institutions that regularly conduct research and receive federal money to fund research have an FWA.

The FWA defines what the “institution” is. For the Harvard University Area (HUA), the FWA lists the following as our “institution”: Faculty of Arts and Sciences, Harvard Graduate School of Design, Harvard Graduate School of Education, Harvard Business School, Harvard Kennedy School, Harvard Law School, Radcliffe Institute for Advanced Study, and the Harvard School of Engineering and Applied Sciences.

The FWA also lists the IRB that will provide review for the institution for regulated research that involves human subjects. The IRB for the HUA FWA is the HUA IRB, also known as the CUHS, the Committee on the Use of Human Subjects.

Just as an FWA defines the institution, the IRB listed under the FWA has purview over the “agents” of the institution. An agent may be an employee, a student, or a volunteer. An agent is a person who has been specifically authorized to conduct human research on behalf of the institution. So, who are the agents of the HUA? Our agents are typically faculty and students but at times those that have a limited appointment or are visiting from another institution may be considered an agent of the HUA.

If you are a Visiting Scholar, there may be uncertainty as to what institution provides IRB review for your research. It really boils down to which affiliation you are using to conduct the research. It also depends on whether there is funding supporting your activities, for example, if funding that is supporting your work at Harvard is being processed by the HUA. What we often find is that a Visiting Scholar is conducting research under both institutions, Harvard, and their home institution. In this case, oversight should be provided by both institutions or enter into a [reliance agreement](#), if applicable.

If there is any question about your agency as a Visiting Scholar, [contact the HUA IRB office](#) and we'll help you figure it out.

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