



Harvard University Area IRB Monthly Newsletter

October 2022



**Reminder! Ensure
that your study
team is up to date
in ESTR.**

All individuals that have contact with human subjects, have access to data that is identifiable, are responsible for the design, conduct, or reporting of the research, or are acting as a Faculty Sponsor must be listed in your IRB submission to the HUA IRB. Over the life of the study, these individuals may remain the same or they may change. As the IRB is responsible for ensuring

that those listed as study staff have up-to-date [ethics training](#) and are qualified to conduct research on behalf of Harvard University, it is important to ensure that all study staff that is listed in your ESTR submission are current.

Note that updates to study staff are not required for studies that have been determined to be not research, not human subjects research, or exempt – *except for added study staff who might have a financial conflict of interest*. Updates to study staff are always required for those studies that have received expedited or convened IRB approval.

If you are removing a study team member from your study it is essential to check the ESTR SmartForm, your protocol, and all ancillary study documents to see if their name is listed in any of these documents. The reason for this is that the type of modification you choose can limit what documents you can edit. If the study team member that you wish to remove is only found in the ESTR SmartForm, choose the modification type “Study team member information”.

If the study team member that you wish to remove is found in the ESTR SmartForm *and* other study documents, choose both modification types: “Study team member information” *and* “Other Parts of the Study”. By doing so, you can edit the ESTR SmartForm and all other study documents included in your submission. This will save you an additional submission and some time!

Not sure how to add or remove study staff after an initial determination or approval? Check out the [ESTR IRB Study Submission Guide](#). See the section on “Creating a Follow-On Submission after Study Approval” found on page 50 of the Guide.

If in doubt, feel free to contact the [HUA IRB office](#)!



This is a Busy Time of Year for You and for Us

With the new academic year upon us, the Harvard research community is actively planning new research projects. This means that the HUA IRB is an incredibly busy office during the fall months. We strive to efficiently serve the research community however please know that we are receiving a high volume of submissions currently. We encourage all members of the Harvard research community to plan ahead to ensure a timely review. We have the following resources available to help you do so:

- [HUA IRB Metrics](#): We post IRB review metrics on our website each quarter. The Report on Operations contains information to demonstrate our effectiveness, efficiency, compliance, and outreach activities. In the section “Measures of Efficiency”, we list the IRB staff review times as well as the overall review time for the most frequent review types.

- [*Training and Resources*](#): We've compiled answers to common questions in our [FAQ section](#), [topics for guidance](#) on many common research study scenarios, [definitions](#), and an overview of [common exempt categories](#).
 - [*Tips for Speeding Up the Review of Your Application*](#): We've put together some tips on common issues that we see that might slow down the review process.
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Do You Speak IRB?



Research that Might Require IRB Oversight

Research takes many different forms and takes place in many different locations. You have probably received an email to take part in market research or to answer some questions about the quality of service that you received, however, not all research that takes place requires oversight by an IRB.

How Do the Federal Regulations Define Research?

For this newsletter segment, we will focus on the Department of Health and Human Services (DHHS) definition of “research” found in [45 CFR 46](#). The Food and Drug Administration (FDA) definition of research is slightly different. To find out more about this difference in definition, check out our information on FDA-regulated research [here](#).

According to DHHS, research is “A systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”.

A *systematic investigation* involves a methodical procedure and plan, is theoretically grounded, and specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods.

Generalizable knowledge is information that is expected to expand the knowledge base of a scientific discipline or other scholarly fields of study and yield one or both of the following:

- Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

Note that publication or other dissemination of findings does not in and of itself make the activity “research”. It has been a long-standing myth that if you publish, an IRB review is required.

The definition of what is and what is not generalizable is often the reason an activity is or is not research according to 45 CFR 46.

What is Not Generalizable?

A quality assurance/quality improvement/organizational effectiveness study where the intent is to assess, improve, or develop programs or services for an organization. Outcomes will remain specific to the organization, programs, or services, although other organizations may use the results for their own programs.

Oral history or journalistic piece that consists of published materials that are limited to only documenting or reporting on events, situations, policies, institutions, or systems without the intent to form hypotheses, draw conclusions, or generalize findings. It will not involve stories that will or may draw broad conclusions about the population, cultures, norms, and practices.

Some Other Things to Note.

Class/educational “research” activities. Class projects and research methods classes may involve data collection activities for training purposes that do not require IRB review and oversight because the intent is to teach methods, not to contribute to generalizable knowledge. The intent of other class projects may be to provide the student with real-world experiences, information-gathering techniques, and report writing. However, when the primary focus and initial intent of the class activities are to collect data to be used by students or other researchers beyond the classroom thereby contributing to “generalizable knowledge,” IRB review may be needed.

Student internships. Students within many departments or schools of the University are involved in internships or practica. Some student practica/internships may include research activities that are designed to

contribute to generalizable knowledge and, thus, involve research that requires IRB review.

Remember that determining whether an activity is research that might require IRB oversight is the first step. The next step is to determine if human subjects are involved. Check out our IRB Lifecycle Guide found [here](#) for more information.

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