Harvard University Area

HUA IRB Newsletter
November 2020

Important Reminders

Things that are important to know yet easy to forget -

Meet Your School/Department IRB Reviewer

Did you know that your School and/or Department has a dedicated IRB Administrator? What this means is that all submissions coming from your School/Department has a person that will not only provide review, but is available to answer questions, provide advice to you when you are creating an IRB submission, and is an all-around go-to person for all of your IRB needs; a true IRB concierge service! See who your IRB contact is here - https://cuhs.harvard.edu/find-your-departments-irb-contact-person

Choose URTP as Your Department if You are an Undergraduate Researcher

If you are a Harvard Undergraduate that is planning to conduct research that involves people, you probably already know about the Undergraduate Research Training Program (URTP) - a comprehensive program to create better prepared undergraduate researchers. As part of the URTP program, students complete an entry in an online decision form that assists in determining whether a project requires IRB review. When this form is completed, you will receive an outcome: IRB review needed, IRB review might be needed, or IRB review not needed. For those that receive an

IRB review needed or IRB review might be needed, you will be directed to complete an abbreviated submission in the IRB online submission system, ESTR. One important aspect when submitting the abbreviated submission in ESTR is **choosing "URTP" as your Department**.

Why is this important? When URTP is chosen as your Department in ESTR, IRB Staff immediately know that your submission is part of the URTP. URTP submissions are assigned in a different way in the IRB office. Having these submissions assigned properly facilitates review and makes the process more straight-forward. When not assigned properly, there might be delays as we must do some extra work on the IRB side to determine if the submission is from the URTP.

Don't forget – if you are submitting an URTP submission in ESTR, choose "URTP" as your Department.

Don't Forget to Manage Relationships!

We all know the importance of a healthy relationship. The same holds true for the relationship between the ESTR system and the Data Safety system. As you know, the Data Safety system was introduced almost a year ago and the Harvard Research Data Security Policy that support its use was implemented this past July.

So, what is this "Manage Relationships" thing? The overall system that includes ESTR, Agreements, and now Data Safety was developed to talk to each other. What this means is that when a certain submission has other associated records in Data Safety, ESTR, and/or Agreements, completing the Manage Related Projects activity will connect the records across the systems. By connecting the different records in the overall system, a reviewer will not only have access to information in the other systems but will also know when a review is complete. Without this notification, submissions may just sit there, 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.

Do you Speak IRB?

Human Subjects Research

All research projects meeting the regulatory definition of “research with human subjects” require submittal to, and approval by, an IRB. This includes the IRB determination that the research is exempt. However, not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research and may not require review by an IRB.

The question that must be considered when determining whether IRB review and approval is required is whether a project fits the regulatory definition of research (“regulated research”), and if so, whether it also involves human subjects.

Step #1: Let’s start with the definition of research.

While an activity may be considered research, it is important to highlight that not all research meets the threshold of “regulated research” requiring IRB review. The federal regulations have a very specific definition of what is considered regulated research that requires IRB review. The following provides a summary of the definitions used by federal regulations:

The federal regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”

What does a "**systematic investigation**" mean? 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.

What does "**generalizable**" mean? Generalizable knowledge is information that is expected to expand the knowledge base of a scientific discipline or other scholarly field 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, IRB review is required.

What isn't 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.
- An oral history or journalistic piece. These are 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.

A note about class/educational “research” activities –

Class projects and research methods classes may involve data collection activities for training purp oses that do not require IRB review and oversight because the intent is to teach methods, not to co ntribute 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.

A note about 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 cont ribute to generalizable knowledge and, thus, involve research that requires IRB review. It should be noted that even though a research activity may not qualify as "regulated research" now, this does not mean that you may not use these data for future "regulated research" activities. The use of data that was initially collected for non-research purposes is known as “secondary use of data not initially collected for research”. If you find yourself in this situation, contact the IRB office as IRB review might be needed for the secondary use of the data.

Step #2: If your activity meets the federal regulatory definition of regulated research, the next step is to determine whether your research involves human subjects.

Let’s investigate what a “human subject” is according to the federal regulations.

The federal regulations define a human subject as “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”.

“**Living individual**” refers to data (information or biospecimens) collected from living subjects. For e xample, 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 a n individual. For example, a survey that collects data about the activities of an organization, rather than its members, is not human subjects research.

“**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 or interpersonal contact 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 identifiable biospecimen**” means the identity of the subject is or may be readily ascertained by the researcher 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 personal journals.

Next Steps

- **What if I am not conducting “regulated research”?** There is no requirement for IRB review.
- **What if I am conducting research but it does not involve human subjects?** There is no requirement for IRB review.

- **What if I am conducting research that involves human subjects?** IRB review is required.
- **What if I am not sure?** The IRB office would be more than willing to help you determine whether your activity requires IRB review or not. The Harvard University Area IRB office may be reached at (617) 496-2847 or by email at cuhs@harvard.edu.

Information like this as well as other good stuff to know may be found in the **IRB Lifecyle Guide** on our website here.

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

Harvard University Area IRB

44-R Brattle Street, Suite 200 (2nd floor)

Cambridge, MA 02138

Email: cuhs@harvard.edu

Phone: (617) 496-2847

Web: https://cuhs.harvard.edu/