Harvard University Area

Harvard University Area IRB Monthly Newsletter

January 2023

Welcome Back from Winter Recess!

We hope that everyone had a relaxing Winter Recess. As we transition back to the office, you might notice a slight delay in our typical processes as we are busy attending to those submissions that were received during the holiday break. Should you have any questions or need to reach out to your respective IRB Administrator, you can find the list of IRB Administrators on our website. If you are uncertain who your IRB Administrator is, check out our webpage Find Your IRB Contact Person.

New Year Resolution

Looking for a new year resolution for 2023? We've put together some suggestions to not only turn over a new leaf but to speed up the IRB review process.

1. **Read through each question in the IRB Protocol Template.**

We get it. There is a lot of information in the IRB Protocol Template document. Moreover, there are many questions that might not pertain to your research. However, one of the most common clarifications sent to researchers by IRB Administrators is the questions that are not answered. The IRB Protocol Template document was developed to be comprehensive so that the IRB has a good understanding of your research as well as information that is required by regulatory requirements. If this information is not provided in the IRB Protocol Template, we will certainly ask about it!

2. **Respond to your IRB Administrator's clarifications in a timely and comprehensive manner.**

IRB review involves a back-and-forth of questions and clarifications. There might be information that is included in your submission that was not clear or there might be information that was not included. By reading through the IRB Administrator's questions and clarifications thoroughly and responding in a timely manner, you might prevent further back and forth – thereby speeding up the review process overall.

3. **Don't forget to click the "Submit Response" button and other ESTR fun.**

- Another common problem that we see is when the "Submit Response" button is not clicked in ESTR. When the "Submit Response" is not clicked, your submission sits in a sort-of ESTR purgatory as no one will be notified when your submission is in this state. You can prevent this from happening by watching our video on how to submit in ESTR.
- You just submitted your IRB submission. Your IRB Administrator has finished their review and they have requested revisions. Not sure what to do? Watch our video on what you need to know to move forward with the response and review of your submission.
- ESTR requires a researcher to complete an online ESTR SmartForm as well as upload various study documents. At times, the management of the various versions of study documents can be overwhelming. Don't worry, we've got a video on what you need to know to add, update, delete, and view documents on a submission.

Do You Speak IRB?

Engagement

We've been talking a lot of about when you need to seek IRB oversight from the HUA IRB in our monthly newsletters. We have chatted about different scenarios: if you are a Harvard Graduate Student (December 2022 newsletter), a member of a Harvard Research Study Team (November 2022 newsletter), or a Visiting Fellow or Faculty Scholar (July 2022 newsletter). But what if you are involved in a multi-site or collaborative research study?

IRBs use a decision-making framework when deciding when IRB oversight is needed:

- Is the activity research according to the regulations?
- Does the research involve human subjects?

As well as the level of review once it is determined that the activity is research involving human subjects:

- Does the human subjects research meet the criteria for an exempt determination?
- Does the human subjects research meet the criteria for expedited-level approval?
- Does the human subjects research require review by the convened IRB?

If you are conducting an independent research study, the review begins when it is determined that you are conducting human subjects research. However, if you are working on a multi-site or collaborative study where multiple institutions are involved and each institution may have a different role, an IRB will look at what their people are doing in the overall research study and from this, determine if IRB review and approval is required. The criteria used for multi-site and collaborative research are based on the concept of "engagement". Specifically, whether the activities of an individual involved in the overall human subjects research "engage" the institution.

Let's go over some key concepts to bring this all together.

Federalwide Assurance

The scope of any IRB's review is based on an institution's federalwide assurance, known as the "FWA". The FWA defines the boundaries of the institution and provides the feds with the institution's assurance that the federal regulations will be followed for federally funded research. And, no, you are not off the IRB hook if you don't receive federal funding as Harvard has made the decision to apply the federal regulations to all research, whether federally funded, funded by some other source, or not funded at all.

Non-Exempt

The federalwide assurance applies to research that is non-exempt. Non-exempt

research is research with human subjects that is reviewed at the level of expedited or convened IRB review. The reason for this is that the entirety of the federal regulations only applies to research that is non-exempt. Therefore, research that is not reviewed at the expedited level or by a convened IRB is a "determination" and not an IRB approval. It is up to each FWA-holding institution to determine how these determinations are reviewed. At the Harvard University Area, determinations are made by the HUA IRB office.

Agency

The FWA not only defines the institution but also defines its "agents". An agent refers to individuals who: (a) act on behalf of the University; (b) exercise institutional authority or responsibility; or (c) perform institutionally designated activities. Agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation from the institution.

Actions of an Agent

The actions of the institution's agents determine whether IRB review and approval is needed for their activities. When an agent is part of a **non-exempt** multi-site or collaborative research study, an IRB will determine if any of the following activities apply:

- If the institution receives a direct award through a grant, contract, or cooperative agreement.
- If there is intervention or interaction with a study participant.
- If you obtain the informed consent of a study participant.
- If you obtain identifiable private information or identifiable biological specimens from any source for the research. This includes observing or recording private behavior; using, studying, or analyzing for research purposes identifiable private information or identifiable specimens

provided by another institution; and using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the researchers.

If any one (or more) of the above activities apply, approval by an IRB is required. There are some options for this review and approval:

- Institutions may review only the activities of their agents in the overall research study.
- Institutions may review the entirety of the study.
- Or institutions may rely upon the review of another qualified IRB. Yep – this is where reliance agreements come into play.

We understand that federal regulations for the protection of human subjects are complicated. The key takeaway here is that if you are part of a multi-site or collaborative study, there are different criteria at play and more options available. Of course, if there are any questions, do not hesitate to reach out – it's our job to help you navigate the regulations to ensure compliance and the protection of human subjects!

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