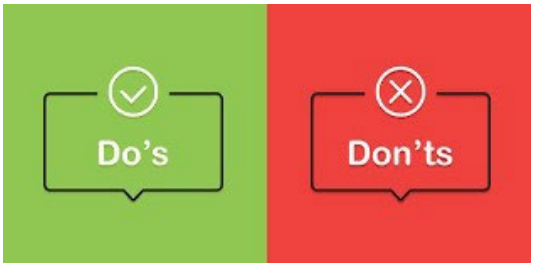
Harvard University Area

Harvard University Area IRB Monthly Newsletter

June 2022

For this month's newsletter, we will focus on items that prevent your IRB submission from reaching the pinnacle of IRB submission perfection. These are common missteps that are often seen by IRB staff and require correction, thus delaying your submission from seeking IRB approval bliss.



ESTR Etiquette

Do not email irb@harvard.edu - it's not the IRB Office

Have a question about your submission? It might seem intuitive, but the email address irb@harvard.edu does not reach the IRB office. This email address is a

general inquiry line for our online submission system, ESTR. Instead, email the IRB office directly at cuhs@harvard.edu. We may also be reached by telephone at (617) 496-2847.

Don't Upload pdf's

ESTR is picky about the format of documents that are uploaded with your submission. The reason for this is that when your submission is finalized, ESTR places a watermark on each approved document. ESTR adores Word versions of documents but finds pdf versions in bad taste. Please respect ESTR by only uploading Word versions (if possible) to your submission.

Revising Some Submission Documents? Choose "Update" Instead

When reviewing a submission that has made changes, it is important for an IRB Reviewer to see where those changes have occurred. ESTR has made the lives of an IRB Reviewer easier by implementing a system that automatically highlights all changes that have occurred on a submission from one iteration to the next. However, for this system to work effectively, it is important for documents that have been uploaded to be "updated" rather than replaced.

Here are the instructions to make the most of our system, ESTR:

1) From the Dashboard, click the name of the study to open it. Note: If the study does not appear in the Dashboard, see Accessing a Submission.

2) Click Edit Study (or site) on the left. For Modifications or Continuing Reviews, click Edit Submission.

3) Make changes as appropriate. When updating a study document previously submitted to the IRB, revise it in tracked-changes format and replace the original document with the tracked-changes version. When the IRB

approves the document, all tracked changes will be accepted and comments removed in the final version.

4) Exit the study. Choose one of these ways to exit:

- Click the Exit link. If prompted to save the study, click Save Changes & Exit.
- Click Continue on each form and then click the Save & Exit button on the Next Steps page of the form.

Don't Upload Revised Forms as a Comment - Upload Them in the ESTR SmartForm Instead

Related to replacing instead of making revisions to existing documents, we find that many researchers upload revised documents as a comment rather than making the changes in the ESTR system. By doing so, the IRB Reviewer is not able to see revisions that were made. Also, the documents are not part of the study record and therefore not documented by the system.

When updating your study in ESTR, please follow the instructions for updating the study record in ESTR instead of uploading documents as a comment.

But ESTR Told Me to Upload Training Certificates to Item 2!

Did you know that CITI training certificates are captured as part of your profile in the ESTR system? Suppose you are a Harvard University Area (HUA) researcher and have taken the Harvard CITI training. In that case, there is **NO NEED** to upload these training certificates to item 2 of the ESTR SmartForm section, "Study Team Members".

Here is when you **DO NEED** to upload training certificates to item 2 of the ESTR SmartForm section, “Study Team Members”:

- If you took a non-Harvard CITI training or training other than that offered by CITI.
- If you are a non-Harvard University Area researcher (meaning that you are either from the Harvard Longwood Campus or a non-Harvard institution altogether) AND the HUA IRB will provide an IRB review for these researchers.

Don’t Forget to Select “IRB Coordinator” when sending a Comment

ESTR does a lot of things but one thing that many people forget is that ESTR is also a place where you can communicate with your IRB Reviewer during and after the review of your study. Using this feature in ESTR is the preferred method of communication as ESTR keeps a tidy record of the correspondence all in one place.

One thing that you might forget is to select a person to send this comment to in item 3 (“Who should receive an e-mail notification?). If “IRB Coordinator” is not selected, your IRB Reviewer will have no idea that you sent a comment to them. Truly, we are not ignoring you, we just didn’t know that a comment was left for us.

Are You Using the Most Current Form?

Regulations and other requirements change. Because of this, we update our various forms and templates accordingly. If you are not using the most recent version of a form or template, this may require an extra question from your IRB Reviewer to capture this missing information. Not sure where to access the

latest and greatest version of our forms and templates? You can find them all in the ESTR library here (be sure to be logged into ESTR).

Include the Text for "Future Use of Data" in the Informed Consent Form Template – It's a Requirement!

If your research will be collecting identifiable data, you must include specific text in your study informed consent form. With the revised regulations (also known as the "2018 Requirements"), specific text regarding the future use of identifiable data is considered an element of consent and therefore required. What does this language look like? Well, here you go:

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements. Otherwise, delete.]

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all your identifiers are removed.

Do You Speak IRB?

HRPP and HRPP Plan

As a reminder of the importance of our Human Research Protection Program and Plan, we offer the following refresher on one of our most significant documents.

What is an HRPP?

The Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The HRPP is based on all individuals in this Institution, along with key individuals and committees fulfilling their roles and responsibilities as described in the HRPP plan. The HRPP demonstrates the commitment of the entire organization, not just the IRB.

What is the HRPP Plan?

The HRPP Plan provides an overview of the Human Research Protection Program at Harvard University. The document defines the scope and mission of the HRPP and includes a complete outline of the regulatory requirements that must be adhered to. It also defines and outlines the roles and responsibilities of

the Institutional Official (IO), the IRB, and other officials in the University, research education and training requirements, monitoring and audit functions, as well as how to report and manage concerns. It truly is the "30,000-foot view" document that ties all the pieces of our program together. You can find our HRPP Plan here.

Our mailing address is:

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Cambridge, MA 02138

You can reach us at:
cuhs@harvard.edu or (617) 496-2847

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