



HUA IRB Newsletter - August 2021



Important News

Keep Your IRB Submission Up to Date!

Our electronic IRB submission system, ESTR, does a lot of things but did you know that it also keeps track of all changes over the lifetime of your IRB submission? It does! Whenever you submit changes to your study, ESTR creates a “snapshot”. By viewing the snapshots, you can see versions of your study at distinct time points. You can check out how this works by clicking on the tab “Snapshots” on your initial study, modification, or any other action that is connected to your study.

So, why is this important? When reviewing a study, it is important for the IRB Administrator to know what is going on in your study at that point in time. Because of this, the IRB Reviewer will have a better understanding of the current regulations that are applied to your study. This is especially important with funding (as additional regulatory requirements may be needed), when there is a Certificate of Confidentiality in place (and what security provisions and consent form language need to be adhered to) and knowing who the current study personnel is (to ensure that training is up to date and to keep track

of what other institutions may be involved).

Really, there is no need to append a redlined version of any changes that you make, multiple versions of the study protocol, or to retain old versions of informed consent forms. You may also find the following resources helpful:

- Information on how to edit an ESTR submission - <https://estrsupport.fss.harvard.edu/editing-submission>
- “How to manage documents on a submission” video - https://estrsupport.fss.harvard.edu/files/estr/files/attaching_a_document-with_audio3.mp4
- Study Submission Guide for Principal Investigators and Study Team - <https://estrsupport.fss.harvard.edu/study-submission-guide>

Harvard Catalyst Community Engagement Program

To increase evidence-based programs and policies to promote health, prevent disease, and eliminate disparities, the Harvard Catalyst Community Engagement Program is available to assist you in creating a more engaged approach with your research community. The program offers consultations and training for community impact, strategic science seminars, community engagement studios, and a community coalition for equity in research. You can learn more here - <https://catalyst.harvard.edu/community-engagement>

Do You Speak IRB?



External IRB Submissions

When Harvard researchers collaborate with those at other institutions on a research study, it may be possible to establish an IRB Authorization Agreement (IAA) allowing one institution to rely on IRB review conducted by the other institution. This helps avoid duplicative review and streamlines the review process across research sites.

When Harvard University Area is the IRB providing review, you submit a standard ESTR submission. Your trusty IRB Administrator will then get all the information that is needed to see if a reliance agreement is possible.

But what if Harvard University Area IRB is not the IRB that is providing the IRB Review? In this instance, there is a different type of submission, the External IRB submission, that is required. The process is like a standard ESTR submission however there is different study information that is needed. We will not require you to complete the standard HUA Protocol Template, instead you will provide us with information about the other IRB's review including the IRB approval and IRB study documents. From this information, the HUA IRB will work with the other IRB to ensure that all regulatory requirements are in place and proper documentation is in order.

A complete overview of the Reliance Agreement process may be found here - <https://cuhs.harvard.edu/ins-and-outs-forging-reliance-agreement>

You can find instructions on how to submit an External IRB submission in ESTR here - <https://estrsupport.fss.harvard.edu/ExternallRB>

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

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