



HUA IRB Newsletter - December 2021



Things to Know

HUA IRB Office Closed for Winter Recess

It's that time of the year again – looking forward to a blissful hiatus from the daily grind as we get closer to winter recess. This year, we can expect an extra blissful amount of time away as winter recess will begin on Monday, December 20th, 2021, and end with our return to the office on Monday, January 3rd, 2022. Although we will be busy working to ensure that submissions received by the HUA IRB Office are attended to before the holiday closure, we need your help.

- If there is an urgent submission that needs attention prior to the holiday closure, let your IRB Administrator know as soon as possible. You can find your IRB Administrator [here](#).
- The last Convened IRB meeting of the year will take place on Thursday, December 9th. As the deadline for this meeting has already passed on November 25th, any studies that qualify for Convened IRB review (i.e., those studies with an uncertain risk or greater than minimal risk) have already been assigned to the meeting. Please know that IRB Staff will be working hard to ensure that correspondence from each study's review will be sent out before Friday, December 17th.

- If there is an emergency such as an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) or other unexpected events, please submit a Report of New Information (RNI) to the IRB within five business days. An overview of this process may be found [here](#) – just click on the tab “RNI – review of new information”.

Tips for a Successful IRB Review

Here are our top tips for making sure your IRB application is off to a running start. The more complete your initial application is, with all the pieces in place, the more it may help to avoid unnecessary delay and frustration.

1. **Submit your application as soon as possible**

Give yourself enough time for requested clarifications from the IRB Reviewer. Also, remember that quality counts! Answer all questions in the ESTR SmartForm and IRB Template Protocol that pertain to your research. By doing so there will be less back and forth between you and the IRB Reviewer.

2. **If applicable, list your Faculty Sponsor on the Study Team Members page, with the role “Faculty Sponsor”**

If you require a Faculty Sponsor because you are not PI eligible and your Faculty Sponsor is not listed in your IRB application in ESTR, this will slow down the turnaround time. When your Faculty Sponsor is listed, they will get an email with a link to the application and step-by-step instructions for how to complete their ancillary review of your submission. Learn more about PI eligibility and Faculty Sponsors [here](#).

3. **Upload ALL the required forms and documents to the correct sections in ESTR**

The reason that we might seem so “picky” about the location of the documents in your IRB application is that ESTR decides which document receives an “IRB Approved” stamp based on where it is uploaded. This is especially important with study informed consent forms. If a document is uploaded to the wrong section of the SmartForm, the IRB reviewer will request that the document be placed in the correct section.

4. **Ethics training and checking Faculty Sponsor listing**

Once you have finished filling out the online form and uploaded the documents, look under the Project Contacts tab to make sure that everyone's ethics training is listed and up to date, and that your Faculty Sponsor is listed here.

If there are missing or expired certificates, ask your team members to complete the CITI course and remind them to check to make sure that their HUID is listed in their profile in CITI so that their training will be imported to ESTR (this happens every Friday, so it will not show up in ESTR until the following Friday). For instructions on which course to take and how to get to it, please see the Required Ethics Training page found [here](#).

5. **Click "Submit"**

Clicking the "Submit" arrow in the menu on the left side of the screen (visible to the PI only) sends the application to us. If the status of the application says "Pre-Submission", you have not yet submitted it. If it says "Pre-Review" it has been submitted and is in line to be assigned for review (note that the application stays in this state until it has been reviewed, aside from when it is in "Clarifications Requested").

6. **Additional or helpful notes specific to your application**

Time constraints? A plane ticket already booked to conduct the study in another location? Let us know by adding a comment on the ESTR main page of your submitted study – that way, we will see it right away. Instructions on how to add a comment may be found in the Study Submission Guide found [here](#). Just go to page 41 of the document under the heading, "Communicating with Staff during Review".

Do You Speak IRB?



HRPP & HRPP Plan

As we are nearing the 1-year anniversary of our full accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), we wanted to remind you of some key features of our Human Research Protection Program.

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 to the protection of human subjects, 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 of the pieces of our program

You can find out more about how our program works [here](#).

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

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