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Harvard University Area

Harvard University Area IRB Monthly Newsletter

April 2024

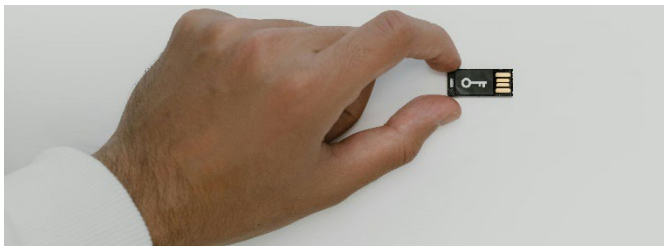
As Summer Research Approaches…

With summer in sight, the Harvard research community is actively submitting new research projects. IRB reviewers will be busy, especially as we welcome and train three new IRB Administrators. We strive to efficiently serve the research community; however, please know that we expect a high volume of submissions in the coming couple months. We encourage researchers to plan ahead to ensure a timely review. We have the following resources available to help you do so:

HUA IRB Metrics: We post IRB review metrics on our website each quarter. The Report on Operations contains information demonstrating our effectiveness, efficiency, compliance, and outreach activities. In the section “Measures of Efficiency,” we list IRB staff review times as well as the overall review time for the most frequent review types.

Training and Resources: We've compiled answers to common questions in our FAQ section, topics for guidance on common study scenarios, definitions, and an overview on common exempt categories.

6Tips for Speeding Up the Review of Your Application: We've put together some tips on common issues that we see that might slow down the review process.



OHRP Key Information Draft Guidance

In March, our federal regulators at the Office for Human Research Protections (OHRP) introduced new draft guidance on Key Information, a requirement of the current human subjects regulations (called the Common Rule). This requirement indicates that informed consent must begin with a summary of the most important study details.

From the Common Rule:

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

For those who have applied using our HUA Adult Consent Form template, you may recall section headings for Key Information and Detailed Information, the latter of which is used to expand on that introductory summary. This approach has been helpful in studies with lengthy consent forms (like drug trials with 25-page consent forms), but perhaps less so in lower risk studies with brief consent forms.

The HUA IRB is hopeful to take advantage of some of the flexibility proposed by the guidance. For now, the guidance remains a draft and open to comment. Please find the complete draft guidance here.

Do You Speak IRB?

External IRB Submissions

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

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

But what if our IRB is not the IRB providing review? In this case, submit an External IRB submission in ESTR. In an External IRB submission, 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 their approval and study documents. Our IRB will work with the other IRB to ensure all regulatory requirements are met, and proper documentation is in place.

A complete overview of the IRB Authorization Agreement process may be found here. You may also reach out to our Reliance Administrator, Katie Schaffenberger, with any questions or to arrange a meeting.

For those with existing External IRB submissions, some reminders:

- **Continuing Review.** You will be required to provide the continuing review of the Reviewing IRB, if applicable.
- **Close the Study.** If the study has been closed by the Reviewing IRB, or if your part of the research is complete, let us know by closing the External IRB submission in ESTR.
- **Report RNIs.** If something unexpected happens, let us know by submitting a Report of New Information (RNI). RNIs should be submitted when you find out about them. Please don't wait until the annual reminder sent by ESTR.
- **Changes to the Study?** If significant changes have been made to the study by the Reviewing IRB, your External IRB submission should be updated to reflect them.

Please refer to the IRB Study Submission Guide in the ESTR Library for more information on requesting and updating External IRB submissions.

IRB Staff Change

With equal parts sadness and excitement, the HUA IRB will say goodbye to Assistant Director and longtime IRB team member, Saraf Salim, on April 19th. Saraf will be joining the policy development team of our federal regulators at the Office for Human Research Protections. We are proud to see her pursue her dreams in this role and know that OHRP will be better for her contributions. Please join us in wishing all the best for Saraf!

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