sIRB Researcher Responsibilities

When you are part of a research project that involves more than one collaborator, the IRB’s that are involved work with each other so that only one IRB is the “Reviewing IRB” and the other IRB’s involved are the “Relying IRB”. This relationship is documented via a “Reliance Agreement”. In those studies where an IRB other than the Harvard University Area IRB is the Reviewing IRB, the Harvard University Area researcher still needs to check in with the HUA IRB. Here are the first steps:

- Determine if your project is eligible for sIRB. Only non-exempt research (research reviewed at the expedited and the convened IRB level) qualifies for sIRB. Not sure? Contact your IRB contact [here](#).
- Submit an External IRB submission to the HUA IRB. This is a special submission to the HUA IRB that is specifically for those situations where another IRB will be the Reviewing IRB. Instructions on how to submit an External IRB may be found [here](#).
- Depending on whether the Reviewing IRB is part of the SmartIRB consortium, the Reviewing IRB researchers will need to create a separate submission in the SmartIRB system. Note sure? You can contact the HUA IRB Reliance Administrator [here](#).

Now that you’ve finished these first steps and the Reliance Agreement is in place, there are responsibilities for you, the Relying IRB researcher, for the duration of the research study:
• Comply with protocol as approved by the Reviewing Institution's IRB.
• If applicable, submit a continuing review application according to the Reviewing Institution’s IRB requirement.
• In the event of a suspension or termination, stop work on the study as instructed by the PI at the Reviewing Institution.
• In the event of the need for an audit, allow the PI and institutional officials from the Reviewing Institution access to your research related records.
• For any study data maintained by the Harvard researcher, comply with the applicable Harvard Research Data Security Policy requirements. If the study involves receiving data, refer to the Data Use Agreement Guidance to determine if a DUA is required.

Submit to PI at Reviewing Institution:

• Any unanticipated problems involving risk to subjects, major deviations or reports of noncompliance.
• Information regarding study conduct, as requested by the Reviewing Institution.

Submit to the IRB at Relying Institution (this would be the HUA IRB) within 30 days unless otherwise specified:

• Copy of the initial approval notification by the Reviewing Institution’s IRB.
• Continuing approval notification(s) by the Reviewing Institution's IRB, if applicable.
• Any modifications impacting Harvard involvement, e.g., changes to funding processed by Harvard or to Harvard personnel.
• Study closure by the Reviewing Institution's IRB.
• Any lapse of Reviewing Institution's IRB approval within five days.
• Any Harvard site-specific unanticipated problems involving risk to subjects or others, serious and/or continuing noncompliance within five days of Reviewing Institution's IRB making a determination.
• Any suspension or termination of Reviewing Institution’s IRB approval of protocol within five days of Reviewing Institution's IRB making the determination.

You can find more information about sIRB, reliance agreements, and collaborative research on our website page here.
Holiday Break Reminder

It’s that time of the year again, a blissful hiatus from work at the end of the year. This year, we can expect an extra blissful amount of time away as our holiday break will be from Monday, December 21st, 2020 through January 1st, 2021. 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 17th. 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 on Friday, December 18th.

- If there is an emergency such as a Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) or other unexpected event, contact the HUA IRB via email at cuhs@harvard.edu. The HUA IRB email inbox will be monitored daily for emergency situations.

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Conducting International Research?

Check this out.

In case you were not aware of this great resource, we wanted to let you know about the comprehensive compilation of international human research standards that OHRP has
developed; the same people that brought us the Common Rule, the code of federal regulations that the HUA IRB follows. This compilation is a “listing of over 1,000 laws, regulations, and guidelines on human subjects protections in 133 countries and from many international organizations.” The compilation may be found here. We’ve also placed this link on the resources page of our website here.

As a reminder, it is the researcher’s responsibility to ensure that all regulations are adhered to when conducting international research.

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Do you Speak IRB?

*Scientific and Scholarly Review*

Scientific and Scholarly Review is part of the criteria for approval found in the federal regulations that govern human research protections and is required before an IRB can approve a human research study.

The regulations at 45 CFR 46.111(a) and 21 CFR 56.111(a) include the following approval criteria that specifically pertain to Scientific and Scholarly Review:

- Risks to participants are minimized (i) By using procedures consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Scientific and Scholarly Review can happen in a few ways. For sponsored research, Scientific and Scholarly Review occurs during the peer review process. For Harvard student research with an identified Faculty Sponsor, this review occurs when the Faculty Sponsor ensures and provides attestation that the scientific and scholarly validity of the proposed research has taken place. For all other research, the Scientific and Scholarly Review takes place “in house” during the ethical review of the study. For those
studies reviewed by the Convened IRB (i.e., research involving uncertain or greater than minimal risk), Scientific and Scholarly Review is undertaken by an IRB member. For all other studies, IRB staff conduct the Scientific and Scholarly Review.

The Scientific and Scholarly Review ensures the soundness of the research design, the ability of the research to answer the proposed questions, and provides the IRB with the information it needs to determine whether regulatory criteria for approval are met.

The HUA IRB uses the worksheet HRP-320: Scientific and Scholarly Review for all studies that receive an in-house review. We've also created a new Standard Operating Procedure for this review, HRP-046: Scientific and Scholarly Review. You can check out both in the ESTR Library.

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

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