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Harvard University Area

Harvard University Area IRB Monthly Newsletter

November 2023

Do You Speak IRB?



Ancillary Review

We're jumping right into this month's vocabulary lesson! If you've been through the [IRB review process](#) before, your reviewer may have explained that sometimes research needs review from members of the Harvard community outside the IRB—what we usually call an Ancillary Review. These reviews focus on matters that intersect with human subjects research, like financial conflict of interest, biosafety, and data security, among others.

This additional review happens through the Ancillary Review function in our submission system, ESTR. The IRB reviewer assigned to your study will notify you of the additional review and triggers a notice through ESTR to that reviewer. This typically does not require additional action by the research team, and this review is usually performed in parallel with IRB review. Ancillary Review may be initiated at the time of an initial or continuing review of research, or in modification request depending on the nature of the proposed changes.

If there are questions for the research team, either the reviewer assigned to your study or a representative from the relevant Ancillary Review office will contact you. Keep in mind that some Ancillary Reviews may need to be completed before the IRB can grant final approval. Let's look at a few important examples...

Faculty Sponsor Assurance

If you are required to list a Faculty Sponsor (see PI eligibility requirements), the IRB reviewer will trigger an action via ESTR for that person to provide assurances that they have reviewed and are in support of your study. The Faculty Sponsor will be notified via email that their action is required. Once sign-off is complete, the review will begin. See our May 2023 newsletter for more information.

Data Safety Review

Per the Harvard Research Data Security Policy, any protocol assigned a Sensitive data designation by the IRB requires review/approval by a School Security Officer (SSO) prior to IRB approval. If you're looking for a deep dive, the complete policy may be found here.

The IRB will assign a Sensitive designation for studies that use or collect data that could be damaging to a research participant's financial standing, career or economic prospects, personal relationships, insurability, reputation, or be stigmatizing; data that could place the participant at risk of significant criminal or civil liability; or data that requires stronger security measures per a relevant law. Spins your head a bit!

Your IRB reviewer will inform you and your SSO why your data was deemed Sensitive. If this happens, visit <http://researchsafety.harvard.edu/> to create and submit your Data Safety submission for review, and use the "Manage Related Projects" activity there to link your IRB and Safety submissions.

PRO TIP: Linking the IRB and Data Safety projects is very important to ensure that everyone involved in the review of your study is notified when reviews are complete. Do not forget to do this!

Provostial Review

The Provostial Review process provides review and oversight of major projects and programs or studies that pose management challenges and/or reputational risk for the University.

For more information on Provostial Review and the characteristics of a project that may trigger it, our colleagues within the Office of the Vice Provost for Research (OVPR) provide helpful resources.

In most cases the IRB will trigger Ancillary Review for Provostial Review when a study takes place internationally and is being reviewed by the IRB at the Expedited or Convened IRB levels. Keep this in mind if you are working internationally, or with collaborators outside the US. As with all Ancillary Reviews, your IRB reviewer will inform you of the requirement and share any feedback from OVPR.

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