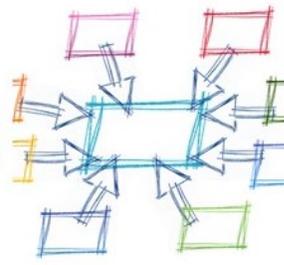


HUA IRB NEWS

Brought to You by the Committee on the Use of Human Subjects



In This Month's Issue!

November 2019

- Changes to Data Security at Harvard - Coming Soon!
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Changes to Data Security at Harvard - Coming Soon!

*Data Safety Application – the *NEW* tab that will join the “ESTR” tab and the “Agreements” tab!*

The Research Administration Systems team is working with the Office of the Vice Provost of Research and Harvard University Information Technology to develop a Data Safety system to support the review and implementation of research data management plans.

What is Data Safety? It is a new application intended to support tracking, monitoring, and compliance associated with the data security requirements for research data sets (sensitive information collected as part of research or obtained or shared under a Data Use Agreement or

sponsored award).

Please visit the [Research Administration and Compliance Systems](#) page for system, policy, and informational session details beginning in November!

Research Data Management Resource

Need more information on data security at Harvard? The Office of Vice Provost of Research has developed a great resource on data management for our research community that includes information on data management practices, policies, [which tools meet which data security level](#), and who to contact with questions. You can check it out [here](#).



External IRB Requirements

IRBs used to think that once they ceded review (don't know what a cede review or reliance agreement is? Go [here](#).) we were done. Basically, cede and forget about it! Well, that is no longer the case, my friends. With the various federal requirements (NIH's sIRB policy and OHRP's cooperative research mandate) to reduce administrative burden and prevent duplication of effort, knowing what is going on at the institution providing IRB review (also known as the "Reviewing IRB") as well as what is going on at the local research site (relying IRB) is an expectation.

We have enlisted our trusty e-submission system, ESTR, to provide you with an annual reminder of what you need to tell the Harvard IRB when your research is being reviewed by another IRB:

- **ESTR will send you an annual reminder.** This reminder will be sent on either 1) the date of the continuing review of the institution providing IRB review (e.g., if the Reviewing IRB determines an approval period of January 1, 2019 through December 31, 2019, the annual reminder will hover around the 12/31/2019 date), or 2) if there is no continuing review date because the research is being reviewed under those fancy new regulations, a reminder will be sent on the date that the reliance was confirmed (e.g., if the reliance

agreement between the Reviewing IRB and the Relying IRB was completed on June 1, 2019, the annual reminders will hover around June 1, 2020).

What the ESTR reminder will tell you to do:

- **Continuing Review.** You will be required to provide the continuing review of the Reviewing IRB, if applicable. If there is no continuing review, you don't have to do anything. You can report the continuing review by completing the "Report Continuing Review Data" (on the left side of the workspace). Note that this activity is only visible to the Harvard Principal Investigator - Only the PI can report continuing review.
- **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. Instructions on how to do so may be found [here](#) (scroll all the way down the page to "Updating External IRB Review").
- **Report RNIs.** If something unexpected happened, let us know by submitting a Report of New Information (RNI). Complete steps to "Report New Information" (on the left side of the workspace). Instructions on how to do so may be found [here](#).
- **IMPORTANT FACT!** RNIs should be submitted when you find out about them. Don't wait until the anniversary notification. The anniversary notification is merely a gentle reminder of your responsibilities.
- **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 do so, click on "Create site modification/Update study" details (on the left side of the workspace).

To ensure the status and context of the Harvard External IRB record remain accurate, researchers will receive this notice three times annually 30 days prior to the anniversary date, on the anniversary date, and 30 days after, and until the project is complete and the study is closed.



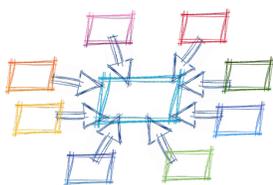
Repository Application

Repositories collect, store, and distribute data and/or other materials for research purposes. Repository activities involve three components: (i) the collection of data/materials; (ii) the repository storage and data management center; and (iii) the distribution of data/materials to the recipient investigators.

While repositories do not conduct research, they are considered a resource to facilitate research. Because of this, repository activities are required to be reviewed by an IRB. While the main IRB application is great for collecting information on most research activities, it is not well suited to collecting repository information.

Wondering what form to use for your repository? Fear not! We have created a special form that debuted in April 2019, the “HRP-504-Repository Protocol”. The Repository Protocol guides researchers through the various parts of the repository architecture: collection, oversight and governance, and distribution. This form may be found in the ESTR Library in the tab “Templates and Forms” [here](#) (just be sure that you are signed in to ESTR when accessing it). And, be certain to choose the one with “HUA” in the name!

Have more questions about repositories or thinking about creating a repository? Contact us – we’re happy to help!



Distribution Revision

IRB staff are assigned as the point of contact for specific Harvard schools and departments. On December 1, 2019, we will be rolling out some revisions to this department distribution to better serve our research community. Beginning on this day, you can check out the updated [distribution page](#) to find your IRB contact. IRB staff will also be contacting those schools and departments where there has been a change. But why keep this a secret? Here are the changes that will be taking place on December 1st:

Harvard Kennedy School

- Faculty submissions will be reviewed by [Elizabeth Parsons](#)
- Non-faculty (incl. PAE/SYPA) submissions will be reviewed by [Alicia McGovern](#) or [Katie Bean](#)

Harvard Law School

- All submissions will be reviewed by [Elizabeth Parsons](#)

Harvard FAS Psychology Department

- All submission will be reviewed by [Amanda O'Brien](#) or [Mikaela Niemasz-Cavanagh](#)

Harvard Graduate School of Education

- Faculty submissions will be reviewed by [Jonathan Girard](#)
- Non-faculty submissions will be reviewed by [Amanda O'Brien](#)



Undergraduate Research Ethics Training

The Undergraduate Research Training Program (URTP) is a comprehensive platform to create better prepared undergraduate researchers. As part of the program, in-person training sessions are held at various dates throughout the academic year. The in-person training sessions are an alternative to the standard online CITI training. The sessions have been developed with students in mind: they are 90 minutes in length, interactive, and developed with enthusiasm and energy. Here are some upcoming dates:

Thursday, November 7, 2019

5:00 pm – 6:30 pm

Emerson Hall Room 210

Please sign up for the November 7th training by clicking [here!](#)

Wednesday, November 13, 2019

4:30 pm – 6:00 pm

Emerson Hall Room 305

Please sign up for the November 13th training by clicking [here!](#)

Friday, November 22, 2019

3:30 pm – 5:00 pm

Emerson Hall Room 101

Please sign up for the November 22nd training by clicking [here!](#)

Monday, November 25, 2019

5:00 pm – 6:30 pm

Lamont Library Forum Room

Please sign up for the November 25th training by clicking [here!](#)



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