Pilot of Updated Research Data Security Policy Guidance

An important announcement from the Research Management @ Harvard website: OVPR and HUIT are excited to announce that starting May 15th, 2020 the University will be implementing a partial rollout of the updated Research Data Security Policy Guidance! What do we mean by partial? Only certain requirements from the updated HRDSP Guidance will be effective in May, specifically:

- As part of their reviews, IRBs will begin assigning non-Sensitive/Sensitive determinations, as opposed to a specific Data Security Level (DSL). The content of the IRBs’ reviews will not change, just the specificity of their determinations.
- Related to the IRBs’ switch to a binary determination, information & school security officers (ISOs) will work with researchers to determine the applicable DSL. Researchers will submit a request for security review in the new Data Safety Application (go to - http://researchsafety.harvard.edu), and the request will automatically be routed to the cognizant ISO.
- All projects deemed “Sensitive” by the IRBs, and all research data that, based on HUIT guidance, appears to be DSL 3, 4 or 5, will be required to be submitted in the Safety Application for ISO review.
- Similarly, all data that is subject to a DUA will be required to be submitted in the Safety Application for ISO review (in addition to submitting a request in the Agreements-DUA Application).

Research Administration and Compliance Systems has done an amazing job developing a Summary of these reviews, and their website provides helpful guidance on using each of the Applications: Data Safety, ESTR-IRB and Agreements-DUAs!

Collaboration Tools Matrix

Wondering what collaboration tools are appropriate for a specific data security level? Or, if it is safe to use Zoom for Level 3 (or, “Sensitive” after May 15th) data collection? You no longer need to wonder! Behold – the HUIT Collaboration Tools Matrix is now available.

The Matrix provides a listing of what Harvard tools are available according to data security levels. And, it’s in an easy to understand format. Check it out here - https://security.harvard.edu/collaboration-tools-matrix

ESTR Upgrade Planned May 29 - June 1

ESTR will be getting an upgrade at the end of May. This upgrade brings some great improvements to Harvard’s increasingly integrated research administration systems. Highlights of the upgrade include:

- Integration with Office365 for easier viewing and editing of submission-related documents in Word, Excel, and PowerPoint;
- Modernized SmartForm design with updated navigation and reviewer options; and
- Improved guidance in select ESTR notifications.

TAKE NOTE that during the upgrade, ESTR will be unavailable from Friday, May 29 at 2:00 pm through Monday, June 1 at 8:00 am. This means that you will not be able to submit any IRB submissions during this time.

You can learn more about these changes by visiting the ESTR Support site here.

Everything You Wanted to Know about Documented Consent but were Afraid to Ask

As of this writing, face-to-face research interactions are not permitted at Harvard University. As more and more research studies are moving online, getting written documented consent may not be possible. While an inked signature is the standard for paper-based forms, there are multiple other ways to document consent, especially if you are conducting your research online. See all of the possibilities here.
Do you speak IRB?  Data Use Agreements

A data use agreement (also known as a “DUA”) is an “agreement” between two parties for the exchange of data. The agreement generally describes the type of data that are being exchanged, how data should be used, if there are any restrictions on the use of the data, as well as data security measures that are required to be in place.

Even though it is the researcher who will receive the data, a DUA is a contract between the institution (in this case, the President and Fellows of Harvard College) and the provider of the data. As such, DUA's are reviewed and signed by an authorized Harvard signatory in the Office for Sponsored Programs (“OSP”) for University area schools.

**NOTE!**  DUAs may not be signed by University faculty or staff members in the absence of institutional approval from the OSP.

So where does the IRB come into play with DUA’s?  Well, we don’t.  The IRB does not negotiate DUA’s, we do not comment on DUA’s, and we don’t hold up IRB approval for DUA’s.  So, why is it sometimes thought that the IRB is part of the DUA process?

Well, DUA’s can provide the IRB with important information about the nature of the data that is being used or other restrictions that may be in place. So, while IRB’s don’t have a role in the approval or negotiating of a DUA, nor are they required to be submitted along with your IRB submission, they do provide the IRB with additional information that may be used in the IRB review process when we come across them.

Now DUA curious?  You can get more DUA here - [https://vpr.harvard.edu/files/dua_guidance.pdf](https://vpr.harvard.edu/files/dua_guidance.pdf)

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

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