



HUA IRB Newsletter - January 2021



We're Accredited!

The Harvard University Area Human Research Protection Program has received Full Accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP accreditation indicates that our organization follows rigorous standards for ethics, quality, and protections for human research.

Many thanks to all involved in this accreditation process. It took a lot of hard work, patience, and perseverance – especially during this unprecedented year!

Interested in learning more about AAHRPP accreditation? Check out the AAHRPP website here - <https://www.aahrpp.org/learn/considering-accreditation/value-of-accreditation>

IRB Office Hours Now at Harvard Law School

Starting Wednesday, January 21st, the IRB office will be providing a new opportunity for Harvard Law School researchers to connect with their IRB Staff representative.



IRB Office Hours provide our research community with an opportunity to discuss questions about the IRB process, the ESTR system, or general assistance with protocol submissions.

IRB Office Hours will be held via Zoom on the third Wednesday of each month, from 1-3 pm. We will reserve 20-minute time slots per person, so please sign up using our poll for the time most convenient for you. The poll may be found here: <https://calendly.com/irb-office-hours/hls>.



Do you Speak IRB? *Repositories*

What the heck is a repository and why do IRB's need to review them? Repositories collect, store, and distribute data and/or other materials for research purposes. 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. In fact, our federal regulators have had specific guidance on this topic for some time which you can check out here - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/issues-to-consider-in-use-of-stored-data-or-tissues/index.html>

Repository activities involve three components: (1) the collection of data/materials; (2) the repository oversight and governance; and (3) the distribution of data/materials to the recipient investigators. The IRB's review will focus on specific aspects according to the component of the repository, which may include (but not limited to):

1. Collection of data/materials: Where are these data or materials coming from? Will informed consent be obtained? Will specific research be conducted with these materials? Any other limitations?
2. Oversight and governance: How will the data or materials be stored? Will these data or materials be combined with other data or materials? What level of security is needed? What are the policies and procedures for the functioning of the repository?

3. Distribution: What is the process for a researcher to request data or materials? Is there a vetting process for requests? Are there limitations on use and if so, how is this maintained?

Repositories sometimes are referred to by other names such as a registry or a database. While each of these may include different information and be used for different purposes, the function remains the same – to collect, store, and distribute data and/or other materials for research purposes.

Does this mean that any collection of data or materials is a repository? The answer is “no”. However, if the purpose of the collection of data or materials is to be used for research purposes by other researchers, the answer is “yes”. We know that this can be a tricky area to navigate, so please let us know if you have any questions about what or what may not be considered a repository subject to IRB review.

Wondering what form to use for your repository? Fear not! We have created a special form to capture all the necessary information, the “HRP-504-HUA Repository Protocol”. The HUA 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”. And, be certain to choose the one with “HUA” in the name!

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

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