Harvard University Area

Harvard University Area IRB Monthly Newsletter

April 2023

Oh, We've Got Ethics Training!

Harvard University requires all individuals who are conducting human subjects research to have completed training in the ethical conduct of human research. This includes all study team members as well as faculty sponsors of non-exempt research.

To fulfill this requirement, there are several options available, depending on

your role.

Harvard Faculty, Staff, and Non-Undergraduate Researchers may complete one of the following:

- CITI (Collaborative Institutional Training Initiative) Social & Behavioral Research online training.
- Protecting Human Research Participants training. This training was previously supported by NIH but is now managed elsewhere and is fee-based.
- CITI training certificate that is still valid from a previous institution (must be comparable training and at the discretion of the IRB office)
- Other equivalent ethics training. Please know that the determination of equivalency is at the discretion of the HUA IRB.

Harvard Undergraduate Researchers may complete one of the following:

- An Undergraduate Research Training Program in-person training (see below for more information)
- CITI (Collaborative Institutional Training Initiative) Social & Behavioral Research online training

Don't forget that if you receive NIH funding for your research, you may have additional training requirements. Find out more on our website here.
See the full breadth of training options on our training page here.

Last Chance for Harvard Undergraduate In-Person Training for Spring 2023!

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 on various dates throughout the academic year. The in-person training sessions are an alternative to the standard online CITI training.

The last in-person URTP training will be held via Zoom on **Monday, April 10th from 4:30 pm to 6 pm.** You can sign up here.

Exempt Research – Everything You Wanted to Know

Our federal regulators created some confusing terms for us at the IRB to use. One of those words is “exempt”. With the change in the HHS federal regulations in 2019, there are many more research studies that may qualify as *exempt*.

Let’s start with some regulatory background about where *exempt* review fits in…

IRB review occurs on a continuum according to risk. Once an activity meets the definition of regulated research and involvement of human subjects, the level of review is determined. *Exempt* review is the lowest level of review which is then followed by Expedited review and then review by the Convened IRB/Full Board. See more about level of review in our IRB Lifecycle guide on our website here.

Below are some common questions that we encounter regarding *exempt*

research that we thought might be helpful.

Exempt research and not human subjects research mean the same thing, right?

Well, actually no. Unfortunately, terms used in the IRB world are not as straightforward as one might think. The IRB's use of the word *exempt* means that the research **does** involve human subjects however the activities that are part of the research fall into one (or more) of the federal regulatory designated *exempt* categories. Because of this, the research is **exempt** from the regulations.

What are the exempt categories?

The categories are activity focused. For example, *exempt* category 2 focuses on research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. While *exempt* category 3 focuses on what are called "benign behavioral interventions". You can find more information about some of the more popular categories on our website here.

Can I make my own exempt determination?

The federal regulations do not specifically state *who* should make *exempt* determinations however our federal regulators state, "OHRP recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is *exempt*." You can read more about OHRP's current guidance on *exempt* research here.

What if I need to make changes to my study that's been determined to be exempt?

Most *exempt* submissions do not require a modification if the *exempt* determination does not change. You also do not need to submit a modification when study team members change.

When should an Exempt study submit a modification?

- If including children, prisoners, or other protected populations.
- Study procedures that fall outside the *exempt* category. For example, an intervention was initially going to take place in one sitting, but the research team decides to include longitudinal effects, so they implement a follow-up treatment.
- Increase in risk.
- Ancillary policy/regulations: GDPR, collection of sensitive information requiring a Limited IRB review, change in data security assessment.
- Change in Principal Investigator.
- Change in Faculty Sponsor.
- If there is new funding.

What about other changes?

If an *exempt* study is changing the design of the study or a major revision to the procedures, a new exempt determination request should be submitted.

What template do I use for the consent process for my exempt study?
As studies that have been determined to be *exempt* are *exempt* from the regulations, the standard template for the informed consent form does not have to be used. Instead, you may use the “HUA Exempt Human Research Consent Script Template” (HRP-502-c in the ESTR Library). You will find the Exempt Script to be much shorter than the standard consent form but still include all of the elements that are needed.

What if I am working with a collaborator and my study is determined to be exempt? Can a reliance agreement be in place to cover my collaborator for their work on my study?

For our regular readers, the term “federalwide assurance” or “FWA” has been a feature in our newsletters of late. Well, here, we go – more FWA!

The FWA applies to all non-exempt research. Non-exempt means that the research must be reviewed at either the expedited level or by the convened IRB. Research activities that have been determined to be exempt, not engaged, or not human subjects research do not fall under the requirements and responsibilities of an institution’s FWA.

When more than one institution is engaged in non-exempt research, it is possible to have one IRB provide the review for both institutions. This “reliance” is documented by a reliance agreement. Our friends at HHS opine:

“*Whenever the Institution relies upon an IRB operated by another institution or organization for review of research to which the FWA applies, the Institution must ensure that this arrangement is documented by a written agreement between the Institution and the other institution or organization operating the IRB that outlines their relationship and includes a commitment that the IRB will adhere to the requirements of the Institution’s FWA.*”

So, if you are conducting non-exempt research and more than one institution is involved, a reliance agreement may be possible and/or may be required if federally funded by way of the new single IRB requirement.

If you are conducting research that has been determined to be “exempt”, your collaborator will need to seek guidance from their own institution. Their

institution may either accept the exempt determination or provide its own exempt determination.

Do You Speak IRB?

Exculpatory

It's been a while since we revisited one of the best (and one of the most fun to say) terms used in the IRB world, **exculpatory**.

According to the federal regulations that protect human subjects (45 CFR 46.116), "No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence."

The central purpose of the informed consent form is to provide enough information for an individual to make an informed decision about whether they

wish to voluntarily participate in a research study. An informed consent form should not give the impression of a legal agreement or include any statements that the individual may lose or “give up” something if they participate. Moreover, the form should not appear to release those that are conducting the research from any liability if things go wrong.

As an example, the HUA IRB has encountered some research submissions that include a Term of Service (TOS) agreement or other binding agreement that is meant to substitute for an informed consent form. This is not permissible. Or the study may involve an informed consent form and a TOS for the use of a service, such as a mobile phone application. In these instances, the researcher must draw a line in the sand between what is research and what is not. And, to convey this line to the study participant.

Here are some examples of exculpatory language according to our federal regulators:

- “By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.”
- “I waive any possibility of compensation for injuries that I may receive because of participation in this research.”

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Check out our website at:

https://cuhs.harvard.edu