Harvard University Area

Harvard University Area IRB Monthly Newsletter

July 2023

Hot off the Press! DRAFT Limited IRB Review Guidance Ready for Your Review

The Office for Human Research Protections (OHRP) has just released draft guidance on the new provision of Limited IRB Review. Limited IRB Review came about with the revision in the human subject protection regulations in January 2019, also known as the “2018 Requirements”.

Limited IRB Review is designed to dovetail with several of the exempt

categories. In essence, the limited review provides a safeguard for activities that fall slightly outside the spirit of the exempt categories. By conducting a limited review, the IRB can weigh in on research that may include potential risks and ensure that safeguards are in place prior to confirming the exempt determination. Without Limited IRB Review, many of these now-exempt studies would be required to be reviewed at a higher review level.

The guidance highlights how Limited IRB Review is to be conducted as well as answers some questions that many IRB folks have been wondering about for some time. Interested in learning more about Limited IRB Review? You can check out the guidance on the OHRP website here.

It’s Summer and the IRB is Open for Business

Although the campus is quiet this time of year, the Harvard University Area IRB office is open and ready for your submissions. In fact, we’ve already been quite

busy this summer!

To ensure a smooth review process, we recommend the following resources:

- If this is your first time submitting to the IRB, check out our First Time Submitters page found here.
- Not sure how long it will take to have your study reviewed? You can find our most current metrics in our Report on Operations here.
- Interested in tips on how to speed up your IRB application review? Check out information on this here.
- For an overview of all aspects of research compliance that may affect your IRB submission, review the "Quick Guide for Researchers: 12 Essentials Every Researcher Should Know" found here.

Some great information and related resources from our friends at Harvard Catalyst

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NIH Toughens Enforcement of Delayed Clinical Trials Reporting

Investigators, don't forget to register and report your clinical trials on clinicaltrials.gov.

Under the law, sponsors running clinical trials of drugs and devices—including those funded by the National Institutes of Health (NIH)—are required to register them on **ClinicalTrials.gov** within 21 days of enrolling the first volunteer. The problem? Many do not register studies or report their findings. **Read about recent efforts by the NIH** to fix this issue, including successfully bringing more than 200 tardy investigators into compliance.

Write Effectively: Plain Language

Researchers: Using plain language in your papers and presentations is key to ensuring your audience understands what you're communicating the first time they see or hear it. Check out our **Writing and Communication Center** for resources including checklists, tools, and guides to help you **incorporate plain language** into your research materials.

To find out more information about Harvard Catalyst or to access more great resources, go to the Harvard Catalyst website here.

Do You Speak IRB?

Payments to Research Subjects

Adapted from the HUA IRB News October 2018

Paying research subjects in exchange for their participation is a common and, in general, acceptable practice. However, difficult questions must be addressed by the IRB. For example, how much money should research subjects receive, and for what should subjects receive payment? Their time, inconvenience, discomfort, or some other consideration?

IRBs must also be sensitive to whether any aspect of the proposed remuneration will be an undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent.

Remuneration for participation in research should be just and fair. However, the specifics of each protocol will influence how those determinations are made. Both researchers and IRBs need to be familiar with the study population and the context of the research to make reasonable judgments about how compensation might affect participation.

Here are some things to keep in mind when paying for study subjects:

- For some individuals, the amount of the payment might make a significant financial difference. Socioeconomic factors may play a role in this assessment. Payments should not be so high that they create an "undue influence" or offer undue inducement that could compromise an individual's evaluation of the risks or affect the voluntariness of their choices.

- The consent process should include a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment (e.g., what will happen if he or she withdraws partway through the research, or the investigator removes a subject from the study for medical or noncompliance reasons).
- According to Massachusetts State law, it is permissible to use a raffle or lottery as a method to compensate study subjects if the study subject does not pay to be in the raffle or lottery.
- When research involves U.S. military personnel, there are limits on how individuals are compensated as well as for what.
- Don't forget to consult the Harvard University Financial Policy on Human Subject Payments.
- Refer to "WORKSHEET: Payments (HRP-316)", found in the ESTR Library for an overview of best practices in paying research subjects.

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