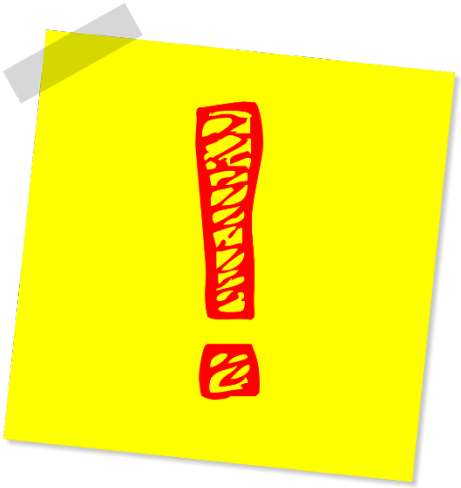
Harvard University Area

Harvard University Area IRB Monthly Newsletter

May 2022



Important Things to Know

Lotteries and Raffles as a Form of Subject Compensation

“Participants that take part in this study are entered into a lottery for a chance to win a new iPad!”

It is not uncommon to have a lottery or raffle as an incentive to take part in the research. However, there are restrictions on how you ***use*** a raffle or lottery in

your research.

According to Massachusetts State law, it is permissible to use a raffle or lottery as a method to incentivize or compensate study subjects as long as the study subject does not pay to participate in the raffle or lottery.
There are general Massachusetts statutes that restrict or prohibit the operation of a “raffle,” or a “lottery,” defined as “an arrangement for raising money by the sale of tickets.” If a research study is using a raffle as an incentive to participate, rather than a means of fundraising, it is not a raffle or lottery under the Massachusetts statute. Guidelines published by the Attorney General’s Office also emphasize that charging money is what brings a raffle or lottery within the statute: “If no money is charged, anyone may legally operate a raffle (and lottery) …”.

See more at the Massachusetts State website - Frequently Asked Questions About Nonprofit Gaming Events, https://www.mass.gov/service-details/frequentlyasked-questions-about-nonprofit-gaming-events.

We Love to Hear from You, but We Don’t Need To!

“I submitted a modification or continuing review for my study, why are you sending it back to me?” The IRB office sometimes receives modifications to exempt studies and continuing review submissions when they are not needed. Here is an overview of the “you don’t need to submit that” items:

Modifications on Exempt Determinations

Did you know that 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. So, when should an Exempt study submit a modification?
Here are a few examples:

- 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? Sometimes, it might be helpful to include changes in your study, either just to keep track or because of funder requirements. If there is ever any question about what requires a modification to your exempt determination, feel free to contact the HUA IRB office.

Continuing Review for Studies that follow the 2018 Requirements

If your study received an expedited review on or after January 21, 2019, there is an excellent chance that you do not need to submit an annual continuing review for your study. Why? Well, in early 2019, the long-anticipated (and delayed) “2018 Requirements” went into effect.

The 2018 Requirements removed the requirement for continuing review for many, if not all, studies that are reviewed by the expedited procedure. How do you know if this applies to you? If you are uncertain if your study was reviewed under the 2018 Requirements, check the main page of your study in ESTR. Located at the top right side of the page, you will see an overview of information for your study. One of those listed is “Regulatory Oversight”. This item indicates if a submission is/was subject to review under pre-2018 Common Rule or 2018 Common Rule. Go to pages 36 and 37 of the ESTR Submission Guide to find out more - https://estrsupport.fss.harvard.edu/files/estr/files/irb_study_submission_guide.pdf

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Do You Speak IRB?

Multi-Site/Collaborative versus Single-Site versus Location - what is the difference?

So many choices! ESTR prompts you to describe the type of study that you are conducting. Here is the low-down on each choice:

Multi-site/Collaborative versus Single-Site

Select Multi-Site or Collaborative to allow for the entry/addition of information about study sites and if the project may involve more than one site conducting the study (completely or in part), or collaborators with primary affiliation with other institutions, or if it is unclear if there will be additional sites.

Select Single-site Study if the project only involves work at Harvard, by Harvard-affiliated researchers.

Location

Location is where you indicate where the study is taking place. Conducting your research in another state? Another country? A hospital? Somewhere else? This is the place that you let the IRB know.
The important thing to keep in mind with this question is that the location only pertains to where the ***Harvard researcher*** will conduct or oversee the research.

For example, let's say that you are part of a research study that is taking place in five states across the country. Your role in the overall research study is to analyze data that is collected at the sites and transferred to your lab at Harvard. You should complete the "Locations" question by indicating where you are

conducting/overseeing the research, in this example, you would respond “Harvard University”.

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