IRB NEWS

A monthly newsletter brought to you by the Harvard University Area IRB, Committee on the Use of Human Subjects

Revised Rule Presentation Dates

There are less than 50 days until the new Revised Rule takes effect. Are you ready? If you aren’t or you want to know everything there is to know about our cool new rule, stop by for one of our hour-long information sessions.

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<th>When</th>
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<tr>
<td>Wednesday, December 12, 2018</td>
<td>2:30 – 3:30 pm</td>
<td>William James Hall Room 105</td>
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<td>Monday, January 7, 2019</td>
<td>12:00 – 1:00 pm</td>
<td>Lamont Library Forum Room</td>
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<td>Wednesday, January 16, 2019</td>
<td>3:00 – 4:00 pm</td>
<td>Lamont Library Basement Room B-30</td>
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<tr>
<td>Thursday, January 24, 2019</td>
<td>10:00 am – 11:00 am</td>
<td>Lamont Library Basement Room B-30</td>
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Reminder - Don't forget to use the latest version of our forms.

For those of you that are looking on our website for the latest version of our forms – they were removed some time ago, so don't go there – go to the ESTR Library.

We made some big changes to our standard IRB template back in January 2018. However, did you know that we made some small but significant changes to our forms in August 2018? To take advantage of these changes, always use the version that is found in the ESTR library

Working with Native American Populations?

The Revised Rule calls out requirements when working with Native American Populations. Specifically, that IRBs and institutions should have processes in place that ensure research subject to tribal law is being conducted in accord with those laws. As such, any research that includes Native American populations must receive review by the Office of the Vice Provost of Research (OVPR) through the Provostial Review process. While the Provostial Review is specific to Harvard, if you are planning to conduct research with a Native American Population, please keep in mind that there are other aspects you may have to adhere to outside of the HUA IRB process (i.e. tribal law).

Below are tips to think about when planning your research that were developed by our friends at Colorado State University.

- Each tribe handles research review differently and each has their own time frame. Be sure to contact the tribe well in advance of your start date. Find out who you need permission from within the tribe, in addition to a review board, and whether you will you need a signed resolution.
• Remember to consider the data you are collecting and what you will be sharing. Will the data do the community harm? Will the research stigmatize the community?
• Work with a collaborator to make sure your materials are culturally appropriate.
• What benefit will help the tribe? Do not conduct your research as “helicopter” research; do not fly in and fly out with your data without giving back.
• Possible items to review with the tribe: who owns the data; should the community be named; what will happen with unused samples; who will review the material before published; how will the community be protected?

Do you speak IRB?

Sorry to let you know, but when the IRB informs you that you are engaged, it does not involve a diamond ring.

Engagement in the IRB world means that you are conducting activities that require IRB review. Engagement is a unique regulatory aspect in that there must be certain elements involved when engagement is contemplated. The first part focuses on who is involved and what the study entails. The second part focuses on what activities are involved.

Let’s start with the first part. The following items must apply:

#1. More than one institution is involved. If you are working on an independent research study, engagement does not apply.
#2. The overall research study must be non-exempt. Non-what? What this means is that the overall study (not just your part) must either be reviewed at the expedited or convened IRB level.

So now that we have that covered, let’s move on to the activities that would cause someone to be engaged, the second part. Here are the activities that would engage you:

#1. If you are the direct recipient of an award through a grant, contract, or cooperative agreement, even where all activities involving human subjects are carried out by employees
or agents of another institution. Yep, that's right, just receiving a direct award would engage you. Why? Well, the person (or institution) that receives a direct award is seen as the head honcho, the el jefe, the person that has the overall responsibility.

#2. Or, if you do the following activities for research purposes, you would be engaged:

- Intervene with any human subjects by performing invasive or noninvasive procedures,
- Manipulate the environment of any human subjects,
- Interact with any human subjects,
- Obtain the informed consent from human subjects, or
- any identifiable private information or identifiable biological specimens from any source.

If you are engaged, you must receive IRB review. If you are not engaged, it is a good idea to check in with the IRB too as there may be requirements by the funder to document what everyone is doing.

Interested in knowing more about engagement? You can check out our federal regulators overview here.

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Last but not least...

Happy Holidays to all from the Harvard University Area IRB.

We wish our Harvard research community a wonderful holiday season and a prosperous New Year!
Know someone who would be interested in subscribing to our newsletter?

It's easy! Just share this link with them:

http://calists.harvard.edu/mailman/listinfo/huairb