Upcoming Revised Rule presentation dates/AAHRPP training preparation

Did you know that we are only a couple of months away from the implementation date for our revised federal regulations?

If you didn’t – surprise!

In order to get our research community up-to-speed and in-the-know on the revised regulations, as well as how it may affect your research now and in the future, we are holding one-hour drop-in sessions. Please stop by and learn everything you wanted to know about the upcoming revised regulations!

**Tuesday, November 6, 2018**
9:30 a.m. - 10:30 a.m.
Smith Campus Center
Isaacson Room, 2nd Floor

Harvard ID is needed to use the elevator to access the 2nd floor

**Monday, November 26, 2018**
New NIH training alternative for non-affiliates

The National Institutes of Health (NIH) discontinued their very popular online ethics training “Protecting Human Research Participants” on September 26, 2018. For study team members that were not affiliated with Harvard University or did not have a Harvard Key, the Harvard University Area (HUA) IRB offered the NIH training as an alternative to completion of the CITI ethics training. As the CITI training is only available to Harvard affiliates, the discontinuation of the NIH training left non-Harvard affiliates with few-to-no options.

Realizing this problem, the HUA IRB adapted the NIH online training to a standalone pdf training document with mastery of the content demonstrated through successful completion of an online Qualtrics survey.

Starting October 12, 2018, the HUA IRB office began to accept the Harvard Non-Affiliated PHRP Training as documentation of completion of the Harvard ethics training requirement.
Have you met the Wizard?

We are still looking for volunteers to spend a few minutes to help us with a pilot project that is designed to reduce the amount of time researchers will spend on completing IRB submissions in the future.

Intrigued? Want to know more?

Harvard University has chosen to participate in a test of an electronic “wizard” that would allow investigators to self-determine if their project requires review by an IRB or if it meets the federal definitions of “exempt.” When you submit an IRB submission through ESTR, our online system, the IRB reviewer will place a comment in the study space with Exempt Wizard instructions.

Please know that your participation in the “wizard” will have no effect on the determination that your ESTR submission receives from the Harvard IRB office. As this is a demonstration project, the determination from the Harvard IRB is your official determination.

We realize that this is extra work for you and we appreciate your efforts. If this project succeeds, it will allow large reductions in the amount of work for investigators and IRB staff on reviewing exempt projects.

Agreements - DUA submission system coming in early December 2018

Through a partnership between the Harvard University Vice Provost for Research (OVPR) and Financial Administration (FAD), and as part of a larger initiative to improve and increase transparency into research compliance processes, Harvard will soon have a tool for submission and review of your Data Use Agreement (DUA)* requests. Researchers that share data between organizations can use the system as one place to:
• Request a DUA review;
• Correspond with the DUA reviewer;
• Track the status of review; and
• Manage active DUAs (including extension requests).

Please visit the OVPR/FAD Agreements-DUA support site to:

• Register for informational drop-in training sessions in your area (starting the first week of November);
• View system guidance materials; and
• Plan for the date of system availability in your area.

This site will be updated regularly through December. Please visit often for updated information on these topics (and more!).

* A Data Use Agreement (DUA) is a binding contract between organizations governing the transfer and use of data. DUA terms and conditions vary depending on the laws and regulations governing the particular type of data as well as the policies and/or requirements of the Provider. A DUA must be signed by a Harvard Institutional Signatory.

Do you speak IRB?

Speaking of the revised regulations (remember those cool presentations that we mentioned earlier?), one area where major changes are taking place is in the informed consent form ("ICF" for those in the know).

The new rule states that the informed consent must begin with a "concise and focused presentation of the key information" that would help assist subjects to understand the reason why they may or may not participate in the research.

According to our friends at the Office for Human Research Protections (OHRP; ahem, our federal regulators) the goal of these revisions is, “To improve consent forms and the process of
obtaining consent.” And, “Among other things, they will require that prospective participants be given the information that a “reasonable person” would want to have in order to make a decision about participating (a standard that is commonly used for consent to clinical care); that sufficient detail be provided regarding the research; and that the consent form be organized to facilitate understanding of why one might or might not want to participate.”

You will see in our ICF that there is a special section titled, “Key Information.” The Key Information section is a brief summary of the “Detailed Information” found in the rest of the ICF. The Key Information is not optional – it needs to be included as our federal regulators now consider this as an element of the informed consent process. PLEASE DO NOT DELETE THIS SECTION.

Should you have any questions about the updated informed consent form, please do not hesitate to contact us at the IRB!

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