AAHRPP Update – Timing of Events/AAHRPP Site Visit

Following submission of the AAHRPP Step 1 Application which includes a basic overview of the program and supporting documents such as standard operating procedures, the AAHRPP Accreditation Team reviews the materials to ensure that the contents fulfill accreditation standards. Once this is determined, the Step 2 application which includes more detailed level documents such as IRB meeting minutes, the IRB membership roster, and listing of key personnel in the program is prepared and submitted to AAHRPP for review. At the same time, a site visit date is planned. The site visit will occur approximately two months after the submission of the Step 2 application.

During the two months before the AAHRPP site visit, we will be holding various training sessions to prepare our research community. What will this entail?

Training sessions will be focused on the several key research communities such as IRB staff, IRB members, and other “Key Personnel” from across the University such as representatives from the Office of Sponsored Programs, Office of the Vice Provost for Research, Office of General Counsel, and other offices that fulfill a research compliance
function. We are conducting these training sessions to familiarize and harmonize each of our roles in the oversight, roles, and responsibilities as part of the Human Research Protection Program (HRPP) as well as reduce some of the anxiety that is a natural part of a site visit.

AAHRPP staff are interested in knowing how these different parts of the University function together as a HRPP. AAHRPP staff will conduct a brief meeting with individuals designated as HRPP Key Personnel. AAHRPP has opined that these meetings are not an audit of the program but rather a discussion on how the program works together.

Got some extra time this summer? We would greatly appreciate your attendance at one of our AAHRPP Training Sessions - coming soon to a convenient location around campus!

**Cooperative Research**

Want some IRB “hot goss”? Well, you didn’t hear it from me, but word within the IRB inner circle is that there are some mumblings about what our federal regulators (i.e., OHRP) were thinking when they wrote the “Cooperative Research” single IRB requirement (“sIRB”). Most IRB folks thought that because the Cooperative Research sIRB requirement was effective January 20, 2020, that the requirement only applied to those studies approved on or after the sIRB requirement effective date in 2020. However, recent discussions and direct lines of questioning to OHRP has shown that our regulatory friends were thinking something completely different.

At the recent AAHRPP conference that took place late May, an OHRP representative all but said “yes” that the Cooperative Research sIRB requirement applies to all Cooperative Research approved on or after the implementation date of the revised regulations that became effective in **January 2019**.

So, why does the IRB community have “all the feels” about this? Well, Cooperative Research casts a wide net. Cooperative Research is defined as “those projects . . . that involve more than one institution.” (45 CFR 46.114). What this means is that if your research study is federally funded, receives either an expedited or convened IRB review, and involves more than one institution, and reviewed and approved on or after January 2019, you will be required to have one IRB provide review for your overall

We are doing our best to get ahead of this requirement by identifying studies that may be affected. Should this affect your study, you’ll be hearing from us. And, should any new “hot goss” pop up about this subject, we’ll let you know too.

Do You Speak IRB? – UPIRTSO

No, this is not a new addition to the Oxford English Dictionary, but it is another fun IRB initialism that stands for an “Unanticipated Problem Involving Risks To Subjects or Others. And no, we don’t know what the correct pronunciation of this initialism is either – we just pronounce it “you-PERT-so.”

So, why is an UPIRTSO important?

As the research has not yet taken place, when an IRB approves or provides a determination for a study, it is a “predictive” approval or determination based on the information provided in the IRB submission. During the conduct of the study, it is the responsibility of the study team to let the IRB know when something unexpected happens. By doing so, the study team keeps the IRB apprised on whether a re-evaluation of risks is needed. This is where the reporting of an UPIRTSO comes into play.

So, what events are considered an UPIRTSO and what needs to be reported?

Any incident, experience, or outcome that meets all of the following criteria must be reported to the IRB:

Is unexpected, serious, and would have implications for the conduct of the study, or is

a. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
b. related or possibly related to a subject’s participation in the research; and
c. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

This graphic might also be helpful in determining when an event meets the reporting requirements of an UPIRTSO.

So, let’s say an UPIRTSO happened, how soon do you have to report it? Harvard University Area IRB policy states that an UPIRTSO needs to be reported to the IRB within five business days; of course, the sooner the better.

Now that we know what an UPIRTSO is and when it has to be reported, how does one report it? A Report of New Information (RNI) is the method by which to do so. Instructions on how to complete a RNI may be found here.

Interested in more information? Check out these resources:

- HUA Investigator Manual – found in the ESTR Library under the “General” tab. Go to the section on “Prompt Reporting Requirements”.
- HRP-024 – New Information - also found in the ESTR Library under the tab “Standard Operating Procedures”
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