IRB NEWS

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

March 2019

AAHRPP Update

We are entering the next phase of the AAHRPP accreditation process – putting together our AAHRPP application!

There is quite a bit of work in this process:

- Putting together a list of supporting documents for each AAHRPP Element ("…most Elements can be supported by one to five documents, and some Elements may not have any supporting documents. In general, no more than 10 documents are necessary.");
- Putting together all our "Policies and Procedures" ("…policies, procedures, standard operating procedures, checklists, guidelines, job descriptions, memoranda, forms, templates, strategic plans, websites, charters, by-laws, mission statements.");
- Constructing an Element-by-Element index to the supporting documents ("…List the supporting document for each Element. Reference the document's number and provide a brief explanation. Use page numbers, paragraph numbers, line numbers,

item numbers, chapter titles, and section headings to pinpoint the supporting information.")

- Making a copy of each document authored by our Organization and cited in the list of supporting documents ("…Include copies of Web sites, educational materials, and slide presentations.");
- And finally, formatting the ENTIRE application!

Once our application is received by AAHRPP, they will let us know whether our application is satisfactory or if additional information is needed. Typically, AAHRPP provides feedback on application materials within 45 days. Once the written documents are complete, AAHRPP staff will schedule a site visit. Stay tuned!

Leaving Harvard?

As the end of the academic year will be here before we know it, and some of you may be leaving Harvard, we thought this might be a good time to remind the Harvard research community about what to do with studies before you leave.

As you know (because you are all serious readers of the IRB News), all ongoing research involving human subjects approved before January 21, 2019 that is expedited or greater than minimal risk requires continual oversight by an IRB.

But what if you are leaving Harvard? What do you do with your research studies?
There are a few options available to you:

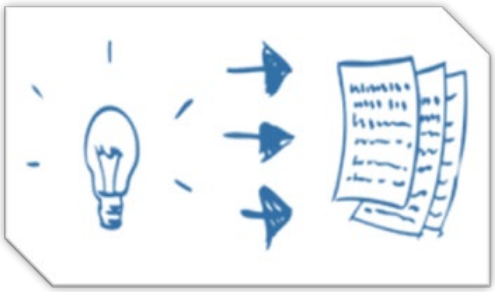
- Transferring your studies to another institution – The Harvard IRB will work with your new institution to ensure that there is continued coverage for your research study. As soon as possible, please let your IRB Reviewer know that you are leaving Harvard and that you wish to have your study transferred to your new institution

- Transfer to another PI – If taking your study with you is not an option, the study may remain open if another Harvard University Area PI is identified. The first step is to determine if the identified individual is "PI eligible." If not, you will need to also identify a Faculty Sponsor for this individual. Once the new PI is ready, you will submit a modification to change the PI on

your study. Information on how to submit a modification to change the PI may be found here. Of note, to change the Principal Investigator on an approved study, select the “Other parts of the study” Modification scope.

- Close the study – If you are not interested in continuing with your study or are just not able to carry on for various reasons, you will need to close your study. If your study is funded, it is always a good idea to check in with your funder about whether closing your study is possible. You will also want to think about what you will do with the data that has been collected. And a friendly reminder – if the data are identifiable, it is not permissible to analyze these data without current and active IRB approval. Information on how to close an IRB study may be found here.

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 some of our forms due to the recent regulation revisions. To take advantage of these changes, always use the version that is found in the ESTR library.

Do you speak IRB?

Exculpatory (ik-skuhl-p*uh*-tawr-ee) tending to clear or charge from guilt.

According to the federal regulations that protect human subjects (45 CFR 46.116), “No informed consent, whether oral or written, may include any **exculpatory** language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.”

The central purpose of the informed consent form is to provide enough information for an individual to make an informed decision about whether they wish to voluntarily participate in a research study.

An informed consent form should not give the impression of a legal agreement or include any statements that the individual may lose or “give up” something if they participate. The IRB has encountered some research submissions that include a Term of Service (TOS) agreement or other binding agreement that is meant to substitute for an informed consent form. There have also been requests to imbed text from a related permission form or release form in the informed consent form. This is not permissible.

For example, a research study may require the release of information from another institution’s records. While the information may be used in the research study, the release form could be a legally binding agreement between the institution that holds the records and the individual that signs the form; the agreement is not between the researcher and the individual as the researcher does not “own” the records.
What is one to do in this situation? Using the above scenario as an example, the study informed consent form should mention that the research team will be asking the participant for a release of information and that this release will require a separate signature. The researcher would then obtain the signature using the separate release form.

What does **exculpatory** language look like? Here are some examples according to our federal regulators:

- “By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.”

“I waive any possibility of compensation for injuries that I may receive because of participation in this research.”

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Harvard University Area IRB, Committee on the Use of Human Subjects (CUHS)

Smith Campus Center, 1350 Massachusetts Ave, Suite 935 Cambridge, MA 02138

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