IRB NEWS

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

New SOPs, Templates, and Forms

The regulatory revisions that were to take place two weeks ago acted as a catalyst to review our entire suite of documents. Although a gigantic kibosh was placed on this regulatory revision by our federal regulators, we used this momentum to move forward with the positive progress that we accomplished with our forms, templates, policies, and procedures.

Collectively, this new and revised suite of documents is referred to as the Human Research Protection Program (HRPP) Toolkit. Included in the Toolkit are documents geared toward the research community and an overview of policies and procedures that demystify the IRB process. For example, the IRB Protocol Template has been revised to gather important information and reduce the back and forth that occurs from not having all the required information at the outset. Also, we've revised the Informed Consent Form Template that includes all required elements that may be needed.

Moving forward, it is recommended that these new forms and templates be used with your IRB submissions. And, as a reminder, it is always a good idea to check our website or the ESTR library for the most recent versions of IRB forms and templates.

Find out more about the Toolkit here.

Ethics training Check-in

Did you know that the most frequent delay in completing the review and approval process for an IRB submission is expired human subjects training for study staff?

Harvard University requires all individuals who are involved in human subjects research to complete training in the ethical conduct of human research. These individuals include Investigators, all study team members who have contact with human subjects or their identifiable data, and Faculty Sponsors of non-exempt research.

There are several training options available and the training is valid for three years.
Check out the human subjects training options here.

NIH Clinical Trial

As part of the NIH initiative to improve the quality and transparency of NIH supported research, a suite of initiatives have been launched. These initiatives include dedicated funding opportunity announcements for clinical trials, Good Clinical Practice training, enhanced registration and results reporting on ClinicalTrials.gov, and required use of single IRBs for multi-site studies.

Determining whether these initiatives apply to your research largely depends on whether your research meets the NIH definition of a clinical trial: “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes”.

The NIH has boiled down this definition down to some basic questions researchers need to ask and answer. These include:

1. Is your research funded by NIH?
2. Does the study involve human participants?
3. Are the participants prospectively assigned to an intervention?
4. Is the study designed to evaluate the effect of the intervention on the participants?
5. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is yes, then NIH considers your research a clinical trial.

Should you have any questions about this NIH policy and requirements, please contact the IRB office at (617) 496-2847 or cuhs@harvard.edu

Also, here are some additional resources that you may find helpful:

Frequently asked questions:
https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm

Definition of Clinical Trial Case Studies:
https://grants.nih.gov/policy/clinical-trials/case-studies.htm

Do you speak IRB?

Practicable (praktəkəb(ə)l): *adjective,* able to be done or put into practice successfully.

You might have heard the term "practicable" when a waiver of consent is requested for a research study. Specifically, an IRB reviewer may ask you why it is not practicable to conduct the research without the waiver of informed consent.

The basis for this question may be found in the federal regulations (45 CFR 46.116 (d) (3)for all you regulatory nerds out there) that distinctly lay out the criteria that must be met to *not* include an informed consent process in your study. As having an informed consent process is the "default," any deviation from the "default" has to be justified. In fact, this is not only the case with the informed consent process, but also for many other aspects of a research study. Another example is obtaining a signature on the informed consent document or not. Not having a signature requires justification.

So what would be considered "not practicable"?

Our friends at the Secretary's Advisory Committee for Human Research Protection (SACHRP), a think tank of IRB professionals, offer the following examples of when it would not be practicable to conduct a research study without the waiver of informed consent:

- *Scientific validity would be compromised if consent was required. Examples of this might include the following:*
    - *The sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.*
    - *The subjects for whom records would be reviewed are no longer followed and may be lost to follow-up. For example, the proportion of individuals likely to have relocated or died may be a significant percentage of the subject population and the research results may not be meaningful and lose statistical power.*
    - *The disclosure of the study purpose as part of the consent process would bias the research subjects so that the results will not be meaningful.*
- *Ethical concerns would be raised if consent were required. Some examples include:*

- *There is a risk of creating additional threats to privacy by linking otherwise de-identified data with nominal identifiers in order to contact individuals to seek consent.*
- *There is a risk of inflicting psychological, social or other harm by contacting individuals or families.*

- *There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.*

Practicability should not be determined solely by considerations of convenience, cost, or speed.

The complete text from SACHRP may be found here.

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