IRB NEWS

Brought to you by the Harvard University Area IRB,
Committee on the Use of Human Subjects

September 2019

AAHRPP Highlight of the Month – AAHRPP Tip Sheets

The Association for the Accreditation of Human Research Protection Programs (that's a lot to say – we'll just refer to it as "AAHRPP" for the rest of this entry) has created a series of "tip sheets" to help guide organizations in creating a better HRPP (you know, our "Human Research Protection Program"). The tip sheets cover topics such as the IRB criteria for approval, data confidentiality considerations, as well as conflicts of interest for IRB members and researchers. The tip sheets embody the AAHRPP standards and elements and provide insight into how the IRB works and what information is considered when reviewing research studies. You can check out all of the tip sheets here - http://www.aahrpp.org/apply/resources/tip-sheets

Is Identifiable Data Getting a Bad Rap?

Collecting, analyzing, and storing identifiable data is permissible. Say what? Yes, you heard me – it is completely permissible. But aren't there IRB regulations that prohibit collecting, analyzing, or storing identifiable data? Nope - but there are specific precautions that need to be taken if you are collecting, analyzing, or storing identifiable data. In fact, two of the IRB Criteria for Approval pertain specifically to data: (1) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, and (2) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
Here are some things to keep in mind:

- As there is always some risk when collecting identifiable data, it is always a good idea to contemplate if it is necessary to collect identifiers.
- Keep identifiers separate from the study data. It is best practice to keep identifiers in one database, study data in another database, and then create a "crosswalk" that links the two.
- Think ahead – what will you be doing with the data at the end of the study? No, you don't have to destroy your data at the end of the study. However, one must always ensure that data are kept in a safe and secure location. If data will be retained as identifiable after the study closes, this is especially important. And just a reminder that while it is acceptable to maintain data as identifiable when a study closes, if at any time you (or another researcher) wishes to access the data, you will need IRB approval prior to doing so. Why? Identifiable data is considered a "human subject".

Interested in learning more? Check out the Harvard Research Data Management website here -https://researchdatamanagement.harvard.edu/

IRB Office Hours – Now Open for Questions at a Location Near You

Have questions about the IRB process, the ESTR system, or want some general assistance with protocol submissions? IRB Office Hours provide the research community with access to IRB staff at a convenient location near you. IRB Office Hours are comprised of reserved 20-minute time slots per person, so please sign up for the date and time most convenient for you.

- Serving the Harvard Kennedy School: 3rd Wednesday of each month from 9:00 a.m. – 11:00 a.m. in the RAO conference room – please email Carrie Kachoria if you would like to reserve a spot.
- Serving the Harvard Psychology Department: 3rd Tuesday of each month from 1:00 p.m. – 3:00 pm in WJH 226 conference room – sign up here – https://calendly.com/cuhs/20min
- Serving the Harvard Graduate School of Education: 1st Tuesday of each month from 10 a.m. to 12 p.m. in the Read House 1st floor conference room – sign up here - https://calendly.com/irbofficehours/irb-office-hours-at-gse

Do You Speak IRB? Benefit of Participation

According to the federal regulations at §46.111 “Criteria for IRB approval of research”, an IRB must determine that:

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

An IRB's assessment of risks and potential benefits is central to determining that a

research study is ethically acceptable and would protect participants, which is not an easy task.

In an article by Nancy King, there are three types of benefits that may occur in the context of clinical research (J Law Med Ethics. 2000 Winter;28(4):332-43):

- Direct Benefit: Defined as benefit arising from receiving the intervention being studied; According to the National Commission, "[t]o be considered 'direct,' the possibility of benefit to the subject must be fairly immediate [and the expectation of success should be well-founded scientifically.
- Indirect Benefit, Collateral Benefit: A benefit arising from being a subject, even if one does not receive the experimental intervention (for example, a free physical exam and testing, free medical care and other extras, or the personal gratification of altruism);
- Indirect Benefit, Aspirational Benefit: Or benefit to society and to future patients, which arises from the results of the study.

What about compensation? Is compensation a benefit? There is a continuing debate about whether the reimbursement subjects receive for their time and inconvenience constitutes a direct or indirect benefit of research participation. The benefits of financial incentives for those that participate are indirect in the sense that they do not stem from the research interventions themselves, but the subject may view them as very important. There are many, many discussions (here is an interesting one) surrounding this however, as noted by our federal regulators, compensation for participation in research is not considered a benefit of participation.

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