AAHRPP Accreditation Spotlight

Accreditation involves a series of steps.

The first step toward accreditation is to conduct a self-assessment. The self-assessment involves a complete review and evaluation of our Human Research Protection Program (HRPP) and its compliance with the AAHRPP (Association for the Accreditation of Human Research Protection Programs) Accreditation Standards and Elements. We will be conducting the self-assessment of our HRPP from April 2018 through August 2018.

What are “Standard and Elements”?

AAHRPP uses a set of objective Standards to evaluate the quality and level of protection that an organization provides research participants. Each domain in a HRPP (Domain 1 = Organization, Domain 2 = Institutional Review Board, and Domain 3 = Researcher and Research Staff) has a set of Standards. The AAHRPP Accreditation Standards themselves describe what organizations can do to consistently act on these principles by applying them to the diverse organizational and cultural contexts in which research is
conducted and reviewed.

For each of these Standards, there are numerous Elements that must be met. If an organization meets the Elements for a particular Standard, it meets the Standard. Each Element contains four parts: Commentary, Regulatory and Guidance References, Required Written Materials, and Outcomes. So, in short, within each Domain are Standards, and for each Standard there are Elements that provide more specificity for the Standard. Whew – that was a lot of information!

If you are interested in knowing more about the self-assessment process, or the Domains, Standard and Elements that comprise accreditation, you can check out the self-assessment tool here.

**Department Distribution Revision**

As the IRB office will have two staff members on leave from mid-May to mid-August, 2018, we have made some minor revisions to our IRB review distribution. We have updated our distribution page to reflect these changes and those areas of the university that are affected by this revision have been notified by email. Questions? Feel free to contact us at (617) 496-2847 or cuhs@harvard.edu

**Do you speak IRB?**

**Deception vs. Incomplete Disclosure**

The following information is taken from our Investigator Manual which contains a lot of really helpful material. You can check out the Investigator Manual here.

**Deception** is the intentional misleading of a subject about the nature of the study. Withholding of full information is known as **incomplete disclosure**. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental. Deception increases ethical concerns and should be used with discretion, because it interferes with the ability of the subject to give informed consent. The IRB recognizes that deception or incomplete disclosure may be necessary for certain types of behavioral research. Because people act differently depending on circumstances, full knowledge by the subject might bias the results in some cases.

**Special requirements for deception or incomplete disclosure projects:**
Waiver of Informed Consent

Because participants are not provided with all the details of the proposed research at the time consent is obtained, deception projects must meet the criteria for waiver of informed consent including that the project poses no more than minimal risk to the subjects.

Debriefing

In most circumstances, subjects have the right to full disclosure as soon as possible after participation in deception or incomplete disclosure research; a post-participation debriefing is usually required. The debriefing should disclose the full or true purpose of the research and allow the subject to indicate that their data not be used in the study. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the data collection is complete. In such cases, subjects should not be exposed to undue stress or embarrassment and should have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected.

There may be circumstances when debriefing is not appropriate. This may be when disclosure of the information may cause more distress to subjects than if not disclosed or when disclosure may bias the scientific integrity of the study.