
AAHRPP and the UIC Human Subjects Protection Program: Shared Goals, Shared Responsibilities



Designed for Principal Investigators, Research Staff, IRB
Members, and OPRS Staff (version 1.0, 08/10/09)

Goals of the UIC Human Subjects Protection Program

To ensure a comprehensive Human Subjects Protections Program (HSPP):

- Utilizing the highest ethical and professional standards
- Affording the highest possible protections for our human subjects
 - Minimize risk to subjects; and
 - Maximize benefits of the research

Key Concepts



- AAHRPP accreditation is a process, not an event. It is the vehicle taking us where we want to go (optimal HSPP), NOT the destination itself.
- Protecting human subjects is a Shared Responsibility of all parties involved in the research!
- As part of the HSPP, you must have:
 - ❑ Basic understanding of the HSPP; and
 - ❑ Clear understanding of your role in the HSPP.

What AAHRPP Expects from Organizations

- Protecting the rights and welfare of research participants must be an organization's first priority. An organization should promote a research environment where ethical, productive investigation is valued.
- Protecting research participants is the responsibility of everyone within an organization and is not limited to the Institutional Review Board (IRB). Accreditation examines whether the policies and procedures of the organization as a whole result in a coherent, effective system to protect research participants and that all individuals know their roles and responsibilities.
- Striving to exceed the federal requirements and continually seeking new safeguards for protecting research participants while advancing scientific progress must be integrated into an organization's mission.

The Benefits of Accreditation (1 of 2)

- **The highest possible standards and protections.** AAHRPP's high ethical and professional standards provide the most comprehensive protections for research participants. These standards exceed federal requirements for safeguarding participants and extend to all research studies overseen by an organization's HRPP.
- **An assurance of quality.** Accreditation is evidence of a quality research program. The AAHRPP seal indicates not only that an organization safeguards research participants but also that data are reliable and credible and the organization has made a commitment to continuous quality improvement.
- **Improved efficiency, effectiveness.** AAHRPP requires organizations to take an unprecedented view of their research protection programs — to make sure not just that policies and procedures are in place but also that they are documented and translated into practice. As a result, accredited organizations tend to have more streamlined and effective policies and procedures. These organizations also typically keep better records and are more likely to avoid costly shutdowns and problematic inspections.

The Benefits of Accreditation (2 of 2)

- **A competitive edge.** Sponsors and other funding agencies recognize that accredited organizations have more efficient operations, provide more comprehensive protections, and produce high-quality data. Increasingly, accreditation is expected to be a condition of research support.
- **Government recognition.** Federal agencies acknowledge the value of accreditation. They have begun seeking accreditation for their own HRPPs and using accreditation status to guide decisions. Regulators are more likely, for example, to target non-accredited organizations for inspections. With its commitment to quality and accountability, accreditation also is a viable alternative to further regulation.
- **Public trust, confidence.** Prospective participants, and the public in general, are looking to the research enterprise to take responsibility for ensuring that research is conducted safely and ethically. Since accreditation is a voluntary, objective measure of quality, participants are more likely to choose organizations that have earned the AAHRPP seal.

Protecting Human Subjects is a Shared Responsibility

AAHRPP Domains:

- Organization
- IRB
- Investigator
- Sponsored Research
- Participant Outreach



Link to responsibilities of each domain:

<http://www.aahrpp.org/www.aspx?PageID=23>

Example: How Investigators, IRB and OPRS Share Responsibility

Investigators:

- Direct protection of human subjects in the research by following the IRB approved research protocol

IRB:

- Provides support to Investigators:
 - Ensure Investigators have adequate resources needed to protect human subjects
 - Apply all applicable regulations and institutional policies and procedures to the review of the research protocols

Office for the Protection of Research Subjects (OPRS):

- Support both Investigators and IRB:
 - Help Investigators submit applications to IRB and communicate IRB determinations to Investigators
 - Ensure IRB has material needed to review the research protocols

Understanding how the IRB Reviews a Protocol

In the Initial Review process, IRBs must ensure that the scientific validity of a research protocol is considered as well as the risks and potential benefits to participants and benefits that might accrue to society:

- The IRB Chair, along with OPRS staff determine and document IRB has appropriate expertise to review protocol.
- The IRB utilizes a “Primary Reviewer” system (convened IRB review):
 - 2-3 assigned primary reviewers for each research protocol
 - All IRB members receive the same information (via packets)
 - All IRB members are equally responsible for review of all protocols
 - When needed, outside resources are utilized (e.g. Ad Hoc Reviewers)
- Continuing Review
 - IRBs are also responsible for reviewing research on an ongoing basis, monitoring reports of new information affecting risks and potential benefits, and assuring that the interests of research participants are protected.
 - Thus Continuing Review of research is not cursory, it is as substantive as Initial Review

IRB Approval Criteria:

1. 45 CFR 46.111: Criteria for IRB Approval of the Research
2. 45 CFR 46.116: General Requirements for Informed Consent

Note: Other approval criteria (e.g. FDA Regulations, HIPAA) may also apply, depending on nature of the research and the subject population.

45 CFR 46.111: Criteria for IRB Approval of the Research

- IRB must apply the correct review process (expedited or convened).
- In order to approve research the IRB must determine and document that all of the following requirements are satisfied:
 - 1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

45 CFR 46.111: Criteria for IRB Approval of the Research

- 2) 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).
 - The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

45 CFR 46.111: Criteria for IRB Approval of the Research

- 3) Selection of subjects is equitable. In making this assessment the IRB must take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Note: IRB must consider both who is targeted and who is excluded from the research.

45 CFR 46.111: Criteria for IRB Approval of the Research

- 4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
- 5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
- 6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

45 CFR 46.111: Criteria for IRB Approval of the Research

- 7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Privacy applies to the Person (Remember: “PP”); and
 - Confidentiality applies to the Data (Remember: “CD”)

Note: In addition to 1-7, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

- Key consideration: Diminished Autonomy

45 CFR 46.116: General Requirements for Informed Consent

A. Basic elements of informed consent:

- 1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- 2) A description of any reasonably foreseeable risks or discomforts to the subject;
- 3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

45 CFR 46.116: General Requirements for Informed Consent

- 4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- 5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- 6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

45 CFR 46.116: General Requirements for Informed Consent

- 7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- 8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

45 CFR 46.116: General Requirements for Informed Consent

- B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- 1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 - 2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

45 CFR 46.116: General Requirements for Informed Consent

- 3) Any additional costs to the subject that may result from participation in the research;
- 4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- 6) The approximate number of subjects involved in the study.

Summary

- Protecting human subjects is a shared responsibility.
- You must have a basic understanding of the HSPP and a clear understanding of your role in the HSPP
- The IRB must apply the correct review process and all applicable regulations and policies to ensure Investigators have adequate resources to protect human subjects.
- Investigators are responsible for the direct protection of human subjects. Conduct research as stipulated by IRB to ensure human subject protections.
- OPRS staff supports both the IRB and Investigators.