AAHRPP Training Series

Basic Information

1. What is the TAMU Human Research Protection Program (HRPP) and what are the components?

The TAMU Human Research Protection Program (HRPP) is the institution's program that is charged with oversight responsibilities for all human subjects research conducted under its authority. Responsibility for carry out the HRPP's mission is a team effort. The major components of the team include the following:

Institutional Official (IO) within the VPR office
IRB/HRPP staff
IRB members
Research Administration
Department Chairs
Affiliate member representatives
Investigators and research staff
Office of General Counsel
Sponsored Research Services

2. Who is the Institutional Official for Texas A&M University?

The Vice President for Research serves as the Institutional Official. The current IO is the interim VPR, Dr. Karen Butler-Purry. She serves as the Institutional Official for the purposes of AAHRPP Accreditation and as the Signatory Official on TAMU's Federalwide Assurance.

3. What is the Federalwide Assurance (FWA)?

The FWA is the agreement that TAMU signs with HHS OHRP that allows us to receive federal funding for research. It states that all of the Institution's human subjects research activities, regardless of whether or not the research is subject to Federal Policy will be guided by the institution's ethical principles (Belmont Report, Declaration of Helsinki).

By signing the FWA the Signatory Official recognizes the institutions responsibility to:

- Provide research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections to help ensure that the requirements of the Assurance are satisfied.
- Provide protections for human subjects
- Ensure the IRB(s) upon which this institution relies will comply with the **Terms of the Federalwide Assurance** when reviewing research covered by this Assurance and possess appropriate knowledge of the local context requirements in which this Institution's research will be conducted.

4. What is AAHRPP accreditation and why is it important to TAMU?

AAHRPP accreditation is a gold standard recognizing adherence to a rigorous set of human subjects protection standards that go beyond federal and state requirements. It communicates to the public the university's commitment to the protection of human participants in research and instills trust amongst our research collaborators.

The accreditation process involves an evaluation of the TAMU Human Research Protection Program (HRPP) and its standard operating procedures as well as the site visit which is focused on interviews with selected members of the HRPP, including IRB members.

Accreditation largely depends on how well TAMU's policies and procedures address the AAHRPP standards and the interviews which involve tough questions about research policies, process, and training. AAHRPP will check our practices by going through our records, first. Then they will check our knowledge through interviews.

5. What does the IRB do?

The main mission of the Institutional Review Boards is to protect the rights, safety and welfare of research subjects. The IRB is given authority through federal regulations to:

- approve, modify or disapprove research,
- conduct continuing review of already approved research,
- suspend or terminate approval of research,
- to observe or have a third part party observe the consent process and the research.

IRBs review and approve research in accordance with Department of Health and Human Services (HHS) regulations in 45 CFR 46. For studies involving products regulated by the Food and Drug Administration (FDA), the IRBs review research according to the requirements in 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812. The IRBs also comply with HIPAA regulations in 45CFR 160 and 164.

6. What is the Common Rule?

In 1991, many federal departments and agencies adopted a common set of regulations governing human subjects research. This is known as the Common Rule or 45 CFR Part 46. It was designed to create a uniform human subjects protections system for all federally supported human research. The core regulation is found in Subpart A which describes the authority and function of the IRB.

Subpart A of 45 CFR 46 includes:

- Definitions,
- IRB membership,
- IRB authority, functions and operations

- Review of Research
- Criteria for Approval
- IRB Records
- Requirements for Informed Consent and Documentation of Consent
- Use of federal funds requires a Federal Wide Assurance (FWA)

Extra protections for vulnerable populations are found in:

Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates
Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners
Subpart D - Additional Protections for Children Involved as Subjects in Research

7. What information is found in the Belmont Report and the Declaration of Helsinki?

The 1974 National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in response to the Tuskegee Syphilis Study which was terminated around 1972 after nearly three decades of carrying out very unethical research practices. This Commission drafted the **Belmont Report** in 1979 to identify the basic ethical principles that should underlie the conduct of human research. (The act also established the need for Institutional Review Boards).

The primary objective of the **Belmont Report** is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects. The three guiding principles of the Belmont Report are (1) Respect for Persons, (2) Beneficence, and (3) Justice.

This document provides the basis for Common Rule's criteria for approval. Specifically, the principle of *respect for persons* underlies the need to obtain informed consent; the principle of *beneficence* underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of *justice* requires that subjects be fairly selected.

In 1964 the **Declaration of Helsinki** was adopted by the World Medical Association to establish international ethical principles and rules for clinical research (medical research combined with clinical care) and non-therapeutic bio-medical research involving human subjects or their identifiable materials or data. It is the basis for Good Clinical Practices (GCP) used today.

8. Who should you contact for help with regulatory or ethical issues?

The first point of contact for general questions is normally the HRPP Director and staff or the IRB Chair. The federal regulatory agencies such as OHRP and the FDA are generally available for guidance. At times it may be necessary to contact the Office of General Counsel and the VPR's office.