AAHRPP Founding Members 2002

Association of American Medical College
Association of American Universities
Consortium of Social Science Associations
Federation of American Societies for Experimental Biology
National Association of State Universities and Land Grant Colleges
National Health Council
Public Responsibility in Medicine and Research
What is AAHRPP accreditation and why is it important?

Gold standard recognizing adherence to a rigorous set of human subjects protection standards that surpass state and federal requirements.

Process involves an evaluation of the Human Research Protection Program (HRPP) and a site visit focused on interviews with critical members of the HRPP.

Accreditation largely depends on these interviews which involve tough questions about research policies, process, and training.
Who Seeks Accreditation

- 85% research intensive universities
- 80% independent IRBs
- 75% academic medical centers
- 50% NCI-funded cancer centers
- 30% independent teaching hospitals
- 27% independent children’s hospitals
- 13% research institutions
- 12% universities with only behavioral/social science programs
- 10% contract research organizations
AAHRPP Accreditation History

Accredited since 2009
Re-accredited 2012
Accredited until 2017
AAHRPP Accreditation Preparations

Initial preparations began June 2015
- June – December all policies and practices reviewed and updated

Application process began January 2016
- January – June preparation of Step 1 application

July 2016 received Step 1 application review

August 2016 submission of Step 2

Site visit preparations began Sept 2016
- Individual training
- Group training
- Staff retreat
- Question of the week

Site visit March 2017

Draft report of site visit April 2017
How does accreditation work?

Self-assessment

On-site evaluation

Council of Accreditation

Self-study that leads to application

Tailored to setting Expert Site Visitors

Determines accreditation category
Five Domains of Responsibility

I. Organization - Human Research Protection Program (HRPP)
II. Institutional Review Boards
III. Researcher and Research Staff
IV. Sponsored Research
V. Participant Outreach
Human Research Protection Program (HRPP)

- OIRB staff, IRB directors, IRB chairs, IRB vice chairs, IRB members
- VPR Office, Institutional Official (IO)
- HRPP Steering Committee, Community Outreach Programs
- Office of Clinical Research (OCR), Office of Regulatory Affairs & Compliance (ORAC), Clinical Trials Office (CTO), Office of Sponsored Programs (OSP), Conflict of Interest (COI), Technology Transfer and Commercialization
- Legal office, affiliate research offices
- Investigators, study team members.
Human Research Protection Program
What is the guiding philosophy of the Human Subjects Protection Program at UT-Health San Antonio?

UT-Health San Antonio is committed to conducting its biomedical and behavioral research involving human subjects under rigorous ethical principles.

The IRBs have been established to comply with existing regulations of the federal government in accordance with U.S. Department of Health and Human Services (HHS) regulations (46 CFR Part 46), the Food and Drug Administration (FDA) regulations (21 CFR 50, 56), and with the Federalwide Assurance accepted by the DHHS. Office for Human Research Protections (OHRP).

The University has also agreed to adhere to the statements of ethical principles as described in The Belmont Report: Ethical Principles and Guidelines for the Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The IRBs also meet the International Conference on Harmonization Good Clinical Practice Consolidated Guidelines as adopted by the FDA regarding organization and operation of Institutional Review Boards.

This fundamental commitment to the protection of human subjects applies to all UT-Health San Antonio research involving human subjects regardless of whether the research is funded through Government, non-profit or industry sponsors, through University funds, or not funded at all, and regardless of the location of the research.
Accreditation Standards

Does the organization have policies and procedures that meet accreditation standards?

Is the organization following their policies and procedures?

Do staff know the policies and procedures?
Records Review

Minutes last 12 meetings of each IRB

Protocols – Cross Section of Research Portfolio

Other Records which could be requested

- IRB files
- Training Records
- Affiliation/MOU Agreements
- COI Minutes
- Clinical Trial Agreements
- Scientific Review Committee Minutes
- Radiation Safety, Radioactive Drug Use, IBC
- Reports to Regulatory Agencies (does not include research misconduct)
On-Site Interviews

VPR Leadership
IRB Chairs, Members
IRB, OCR, CTO, COI staff
Principal Investigators
Research Staff
Sponsored Program/Contracts
Regulatory Affairs & Compliance
Investigational Pharmacy
Legal
Environmental Health and Safety
Office of Technology and Commercialization
Form A Signature Assurance Sheet

Department Chair /Section Chief/Center Director Verification

- Soundness of the research design
  - Ability to achieve goals of protocol

- Competency of the Principal Investigator

- Sufficient resources to safely conduct the trial
  - Personnel, funding
  - Lab/Equipment
  - Potential Subjects

- Who else performs this function for the IRB?
  - CTRC Protocol Review Committee (PRC)
PI Interviews

Background

Training to do Research
- CITI on-line course
- Clinical Research Course

Role in Research
- Role of Staff – Scope of Practice Policy

Choice of Studies
- Design
- ?Turn Down
Research Staff Interviews

What is your role as a research nurse, research coordinator, or research assistant?

What role does your PI play in conduct of the trial?

What Education, Licensure, Training is required for your position?
Is PI available when you need him or her?

- Co-Investigators/Back Up
- Call Plan
Recruitment

➢ How to identify possible subjects
  o HIPAA and informed consent waivers
  o IRB required to approve advertisements

➢ How to recruit/approach
  o Who has initial contact?
  o Cold calling
  o Who has subsequent contact?

➢ VA Policy regarding recruitment of veterans in non-VA research

➢ Compensation for recruitment
  o Bonuses – Prohibited
  o Finder’s Fees – Prohibited
  o Compensation for services rendered

http://research.uthscsa.edu/irb/Policy/Identification_Recruitment_Policy.pdf
Informed Consent

- Process

- Appropriate Language; Level

- Time to Consider

- Documentation of consent
  - [http://research.uthscsa.edu/irb/Policy/Written_Documentation_of_Consent.pdf](http://research.uthscsa.edu/irb/Policy/Written_Documentation_of_Consent.pdf)

- Non-English Speakers
  - Short-form

- Consent and Legally Authorized Representatives
  - [http://research.uthscsa.edu/irb/Policy/IRBConsentpolicyattachment1.pdf](http://research.uthscsa.edu/irb/Policy/IRBConsentpolicyattachment1.pdf)
Contact Information for Research Team and Others

How do participants receive contact information?
- Questions comments, concerns, complaints
  [http://research.uthscsa.edu/irb/Policy/Complaints_Policy.pdf](http://research.uthscsa.edu/irb/Policy/Complaints_Policy.pdf)

Information for research participants
- [http://research.uthscsa.edu/irb/informationforparticipants.shtml](http://research.uthscsa.edu/irb/informationforparticipants.shtml)

Compliance hotline
- [http://uthscsa.edu/compliance/compline.asp](http://uthscsa.edu/compliance/compline.asp)
Conflict of Interest

➡️ All research team members or immediate family
  o iDisclose system
    https://vpr.uthscsa.edu/iDisclose/
  o Form X

➡️ Management Plans
  o Developed by the COI committee
  o IRB and R&D for VA research – Final Approval
Records

Where do you keep regulatory files?
Where do you keep consent documents?
What do you keep and what do you give to subject?
How long do you retain research records?
Prompt Reports

http://research.uthscsa.edu/irb/PromptReport.shtml

Unanticipated problems involving risks to subjects or others (UPIRSOs)
  o How would you define a UPIRSO?
    ✓ Unexpected
    ✓ Related
    ✓ Places subjects or others at greater risk of harm
  o What is the IRB policy on reporting UPIRSOs?
  o In what time frame for reporting?
    ✓ 7 days internal
    ✓ 14 days external
  o What has shorten time frames for reporting?
    ✓ Life-threatening or fatal
    ✓ 48 hours

Possible noncompliance
  o Serious noncompliance
  o Continuing noncompliance

Deviations and adverse events
What plans do you have for monitoring the data to ensure safety of participants?

How is this communicated to the IRB?
- Form R Monitoring Participant Safety and Data Integrity
- When is Form R required?
  - All studies considered greater than minimal risk
  - NIH or FDA requires a plan
  - IRB requests a plan

Discuss a safety monitoring plan for your study (not just DSMB)
General HRPP Terms and Concepts to be Familiar With

Education (CITI/ACRP/license/scope of practice/forums)

Communication (investigator and staff/IRB Director/OIRB staff/IRB members/OSP)

Handling Complaints (subjects/staff/research assistants/IRB/Compliance Office) IRB Policies, Procedures, Regulations (where to find them/availability)

Vulnerable populations (prisoners/children/pregnant women/neonates/others) Risk Levels (definition of greater than minimal/determinations)

Reportable events (study staff reporting/IRB discussion/Adverse Events/Privacy and Compliance/Unanticipated Events)

Informed consent (concepts/importance/practice)

Where do you go for information specific to a project? Regarding general ethics? Regarding compliance issues?
AAHRPP Resources

http://research.uthscsa.edu/irb/aahrpp.shtml

http://www.aahrpp.org/