Association for the Accreditation of Human Research Protection Programs
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
UT Health San Antonio receives Accreditation

2009

Re-accredited

2012

Re-accredited

2017

Accredited until

2022

AAHRPP Accreditation History
How does reaccreditation work?

**Re-assessment**
Preparations began June 2020
June – December all policies and practices reviewed and updated

**On-site evaluation**
Tailored to setting
Expert Site Visitors
February 2022

**Council of Accreditation**
Determines accreditation category
*Draft report of site visit March 2022*
Human Research Protection Program (HRPP)

- VPR Office, Institutional Official (IO)
- Investigators and study team members
- OIRB staff, IRB directors, IRB chairs, IRB vice chairs, IRB members
- VPR Executive Leadership
- Community Outreach Programs
- Office of Clinical Research (OCR)
- Institutional Compliance and Privacy
- Clinical Trials Office (CTO)
- Office of Sponsored Programs (OSP)
- Conflict of Interest (COI)
- Office of Technology and Commercialization
- Safety offices
- Legal office
- Affiliate research offices
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?
Domains of Responsibility

I. Organization - Human Research Protection Program (HRPP)

II. Institutional Review Boards

III. Researcher and Research Staff
The Site Visit

HELD VIRTUALLY ON FEBRUARY 2-3, 2022
Virtual Interviews

VPR Leadership
IRB Chairs, Members
IRB, OCR, CTO, COI staff
Principal Investigators
Research Staff
Sponsored Program/Contracts
Institutional Compliance and Privacy
Investigational Pharmacy
Legal
Environmental Health and Safety
Office of Technology and Commercialization
Records Review

Minutes last 3 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)
PI Interviews

- Background
- Training to do Research
  - CITI on-line course
  - GCP Training
  - Mentoring
- Role in Research
  - Role of Staff – Scope of Practice Policy
  - Staff oversight – Delegation of duties
- 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 them?
Soundness of the research design

- Department Chair / Section Chief / Center Director Verification
  - Form A Signature Assurance Sheet
  - 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?
    - MCC Protocol Review Committee (PRC)
Recruitment

How to identify possible subjects
• HIPAA and Informed Consent
• IRB requires approval of ads

How to recruit/approach possible subjects
• Who has initial contact
• Is cold calling allowed

VA policy regarding recruitment of veterans in non-VA Research

Compensation for recruitment
• Bonuses - prohibited
• Finders Fee – prohibited
• Compensation for services rendered
Informed Consent

Process

Appropriate Language; Level

Time to Consider

Documentation of consent

Non-English Speakers; short-form

Consent and Legally Authorized Representatives

Legally Authorized Representatives (LAR) Under Federal and Texas Law - IRB Guidance
### How COVID Has Changed How We Obtain and Document Informed Consent

<table>
<thead>
<tr>
<th>Ensuring that the study has been approved to waive documentation of informed consent</th>
<th>Consent through telephone or virtual meeting platform</th>
<th>Providing the subject an information sheet or the informed consent document electronically</th>
</tr>
</thead>
<tbody>
<tr>
<td>For subject’s unable to consent for themselves, use of LAR</td>
<td>Documenting discussion and method subject agreement in the research record</td>
<td>An impartial third party should witness the entire consenting process and sign the consent document</td>
</tr>
</tbody>
</table>

Including specific language in the consent form regarding risks associated with use of virtual meeting platform
Contact Information for Research Team and Others

How do participants receive contact information?

Questions comments, concerns, complaints

Complaints IRB Policy

Information for research participants

Clinical Trials

Compliance hotline

Institutional Compliance and Privacy
Conflict of Interest

All research team members or immediate family
  iDisclose system
  Form X

Management Plans
  Developed by the COI committee
  IRB—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

**How would you define a UPIRSO**
- Unexpected
- Related
- Places subjects or others at greater risk of harm

**What is the IRB policy on Reporting UPRISOs?**
- Report events which meet all three criteria (in the order listed above)

**What is the time frame for reporting**
- 7 days – Internal Events
- 14 days – External Events

**Which events have shortened reporting time frames?**
- Life-threatening or fatal events
- 48-hour reporting
- 24-hour reporting (VA studies)

**Possible Noncompliance**
- Serious Noncompliance
- Continuing Noncompliance

**Deviations and Adverse Events**
Safety Monitoring

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)
Additional HRPP Terms and Concepts to be Familiar With

- Education (CITI/license/scope of practice/forums)
- Communication (IO/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/neonates/others)
- Populations with added protections within the regulations (prisoners/children/pregnant women)
- Where do you go for information specific to a project? Regarding general ethics? Regarding compliance issues?
AAHRPP Resources

https://uthealthsa.sharepoint.com/VPR/AAHRPP/Forms/AllItems.aspx

http://www.aahrpp.org/