Association for the Accreditation of Human Research Protection Program

IRB OCR FORUM
MARCH 8, 2017
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
How does accreditation work?

Self-assessment

On-site evaluation

Council of Accreditation

Self-study that leads to application
Initial preparations began June 2015
June – December all policies and practices reviewed and updated

Tailored to setting
Expert Site Visitors

March 2017

Determines accreditation category
Draft report of site visit April 2017
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

Legal Office
Education Programs
Institutional Official
Conflict of Interest
Pharmacy Services
Human Subjects
Investigators and Research Staff
Institutional Review Board
Compliance Oversight
Communications Systems
HRPP Steering Committee
Contracts and Grants
Safety Offices
Clinical Trials Office
Institutional Official
Compliance Oversight
Legal Office
Education Programs
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?
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
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
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
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?
  - CTRC Protocol Review Committee (PRC)
Recruitment

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

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

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

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

[http://research.uthscsa.edu/irb/Policy/Identification_Recruitment_Policy.pdf](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—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)
- How would you define a UPIRSO?
  - Unexpected
  - Related
  - Places subjects or others at greater risk of harm
- What is the IRB policy on reporting UPIRSOs?
- In what time frame for reporting?
  - 7 days internal
  - 14 days external
- What has shorten time frames for reporting?
  - Life-threatening or fatal
  - 48 hours

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/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)

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/