

**Tulane University Accreditation  
with  
Association for Accreditation of Human  
Research Protection Programs (“AAHRPP”)**



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# What is AAHRPP?



- Voluntary accreditation for organizations that conduct or review research on human subjects.
- Seeks to ensure compliance with regulations and enhance protection standards.
  - Performance standards that surpass the threshold of state and federal requirements.
  - “Gold Seal” accreditation signifies commitment to the most comprehensive human subject protections.



# AAHRPP Mission & Methods



- Mission:

- Protect the rights and welfare of research participants.
- Promote scientifically meritorious and ethically sound research by:
  - Fostering and advancing the ethical and professional conduct of persons and organizations that engage in human subjects research.

- Achieves mission by using an accreditation process based on:

- Self-assessment
- Peer-review
- Education



# Why AAHRPP Accreditation is Important?



- Mandated by the University President.
- To ensure that scientific research can continue to grow and flourish in an environment where the best interests of research participants will be protected.
- Recent federally mandated closures of research programs around the country underscore the need to ensure consistency in meeting high standards for the protection for human research participants.
- Self-accreditation rather than additional federal oversight.



# Benefits of AAHRPP Accreditation



- Makes Tulane's research programs more competitive
- Improves research quality
- Builds public trust
- Assures regulatory compliance
- Credibility - helps in recruiting participants
- Gauges over-interpretation of regulations



# Who is Accredited?



- Over 10,000 entities have an FWA (i.e., conceivably could be accredited)
- 189 entities are AAHRPP accredited worldwide
  - 186 entities in U.S.
  - 3 entities abroad
- 60 universities & colleges accredited
- 3 entities in Louisiana accredited
  - LSU—Shreveport
  - VA—Shreveport
  - VA—New Orleans

# Structure of AAHRPP Standards

- 5 Domains of Standards

- Organization
- Research Review Unit (IRB)
- Investigator
- Sponsored Research
- Participant Outreach

- Each Standard is divided into Elements
- For each Standard and each Element, Tulane's Human Research Protection Program needs a written policy/procedure/item to demonstrate that our program meets standard/element



# Sources for Accreditation Standards



- Based on U.S. federal regulations for conducting human subjects research
  - Department of Health and Human Services 45 CFR Part 46
  - Food and Drug Administration 21 CFR 50, Part 56
- ICH Good Clinical Practice Guidelines
- Common Sense



# What Do The Standards Evaluate?

- **Structure**
  - What we have
- **Process**
  - How we do it
- **Outcome**
  - What we achieve



# Focus on Outcomes



- Look to the outcomes
- Do we meet the outcome described or implied by the element?
- AAHRPP is flexible on the process
- ***Protection***, not perfection is the focus



# AAHRPP does not:



- “Audit” decisions made by the IRB
- Critique researcher’s proposals
- Report “findings” to regulatory agencies
- *The entire accreditation process is confidential!*



# Accreditation Process



- ***Self-Assessment***

Evaluation and improvement of Tulane's Human Research Protection Program

- ***On-Site Evaluation***

A team of experts reviews Tulane's materials and schedules an on-site visit.

- ***Council Review***

AAHRPP's Council of Accreditation reviews the report, deliberates on the team's findings and determines your accreditation status.

- ***Notification of Accreditation Status***

Organizations that achieve accreditation must be re-evaluated every three years in order to remain accredited.



# Where is Tulane Now?



- **Self-Assessment:**
  - Organized the Site Visit Core Team in January 2009:
    - ✦ IRB Members
    - ✦ Human Research Protection Office
    - ✦ Office of General Counsel
    - ✦ Office of Research Administration
    - ✦ University Research Compliance Officer
- Application and supporting documentation will be submitted on September 30, 2009.
- Site Visit dates: tentatively first quarter 2010.



# Nature of Site Visit



- 3 to 4 site visit team members plus one AAHRPP administrative person.
- 4 to 5 day site visit with interviews of roughly 100 individuals:
  - Senior Leadership: President, Provost, General Counsel, Associate Senior Vice President for Research, Dean of School of Medicine & Dean of School of Public Health and Tropical Medicine
  - IRB Chairs
  - ***IRB members***
  - HRPO Staff
  - Investigators and Coordinators
- Record Review of HRPO Files, Forms, Checklists; Full Board IRB minutes of last 12 months
- Contracts, MOUs, Institutional Agreements, etc.



# What Happens After Site Visit?



- Tulane receives written report.
- 30-day response period for Tulane to address questions or deficiencies.
- Site Visit Team Report and Tulane response submitted to AAHRPP Council on Accreditation.
- AAHRPP Council renders a decision:
  - Full Accreditation
  - Qualified Accreditation
  - Accreditation Withheld
  - Accreditation Pending



# Questions???

