

Accreditation of UTHSC-H Human Subjects Protection Program by AAHRPP

SITE VISIT

Date

TUESDAY, MARCH 10, 2009
WEDNESDAY, MARCH 11, 2009
THURSDAY MARCH 12, 2009

Venue

CCTS CONFERENCE ROOM 11.55 AND 11.11
UT PROFESSIONAL BUILDING

1. What is AAHRPP ?

AAHRPP is a non profit organization that accredits Human Subject Protection Programs. It was founded in 2001 by a group of seven non profit American universities, medical schools, and teaching hospitals; biomedical, behavioral, and social scientists; IRB professionals; and patient and disease advocacy organizations.

AAHRPP's accreditation process is voluntary, peer-driven, and educationally focused, and aims to foster a culture of conscience and responsibility within institutions seeking its services. AAHRPP has accredited over 129 organizations representing 550 entities:

- 42% of nations research intensive universities
- 36% of US medical schools
- 52% of Department of Veteran Affairs facilities

2. How would accreditation help UTHSC-H?

Accreditation of the human subjects protection program is a gold standard to ensure that human subjects are protected while encouraging investigators to engage in cutting edge research. When achieved, accreditation will place our cluster amongst the leading healthcare organizations that conduct safe and responsible research. In order to be accredited, we must demonstrate that we provide research subjects safeguards that surpass the threshold of regulatory requirements

3. What is the process of accreditation?

For the last several months a team of UTHSC-H faculty and staff has been actively engaged in preparing our institutional AAHRPP application. An 800 page application was submitted to AAHRPP in September. The AAHRPP site visit will occur early next year. Besides reviewing records, the Site Visit team will interview many of the individuals involved in our human subjects research program to assess their familiarity with and commitment to UTHSC-H policies and procedures governing human subjects' research.

4. How are site visitors selected?

Site visitors are selected based on the research knowledge and expertise they bring to the process. AAHRPP conducts a computer-based training program with all site visitors in

the interpretation and use of the Evaluation Instrument for Site Visitors. In the field, new site visitors are matched with experienced ones for hands-on practice.

5. What happens during the site visit?

After introductions between the site visit team and members of the organization, site visitors review records and conduct interviews of Senior Management, IRB members, staff, and chairs, as well as investigators and research staff. Site visitors also interview key organizational officials, such as those who review contracts, manage financial conflicts of interest, lead departments involved in research, and provide legal advice.

6. How are investigators selected for interviews? Does AAHRPP select them or does the organization?

AAHRPP selects interviews, although sites may suggest individuals to be interviewed. Investigators are selected who reflect the ranges of experience, protocol volume, types of ongoing research, and research risk levels at the organization. In addition to investigators, site visitors will interview coordinators, co-investigators, students, and other research staff.

7. What executive level officials need to attend the site visit?

Individuals who are responsible for overseeing the human research protection program should be present for interviews during the site visit. Dependent upon the organization's structure site, visitors may interview the Institutional Official, the President for Research, the CEO of the organization, Vice President for Research, or Executive Director.

8. Where are the interviews conducted?

All the interviews will be conducted at Conference Room 1100.55 at UT Professional Building.