



THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER
AT HOUSTON

ACCREDITATION OF HUMAN SUBJECTS PROTECTION PROGRAM BY AAHRPP

SITE VISIT

March 10 – 12, 2009
UT Professional Building Conference Room 1100.55

CONTACT

Dr Sujatha Sridhar
Director, Regulatory Unit CCTS
sujatha.Sridhar@uth.tmc.edu
Phone: (713) 500 7909

1. **What is a Human Subjects Protection Program (HSPP)?**

Maintaining a robust program of clinical research is one of the key requirements to achieving the UTHSC-H's mission which is to treat, cure and prevent disease. The University and its investigators share an unwavering commitment to the ethical and responsible conduct of human subjects research. This commitment is founded on the principles of respect for the rights of the individual, the goal of minimizing the risk of harm and maximizing the potential benefits of research to the participants and society and the incorporation of the principles of justice and fairness into all aspects of research conducted under the auspices of the University. Dr Peter Davies, Executive Vice President for Research is in charge of the Human Subjects Protection Program at UTHSC-H.

2. **Why are we seeking accreditation of the UTHSC Human Subjects Protection Program?**

Many universities, including our own, have taken steps to insure our research practices meet these lofty goals by instituting comprehensive human research protection programs. These programs are designed to put in place policies, procedures and practices that are designed to insure that all aspects of our institutional activities are configured to support the safe and ethical conduct of human subjects research. In 2001, Public Responsibility in Medicine and Research, Association of American Medical Colleges, Association of American Universities and other organizations established a not-for-profit entity, the Association of Accreditation of Human Research Protection Programs (AAHRPP) to advance accreditation as a means of ensuring excellent, ethically sound research. It has been AAHRPP's responsibility to first formalize so-called "best practices" for the design and operation of human research protection programs and then to implement a program of voluntary accreditation.

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

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 09. The AAHRPP site visit will occur in from March 10 – 12, 2009. Besides reviewing records, the Site Visit team will interview several 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.

AAHRPP selects individuals who reflect the ranges of experience, protocol volume, types of ongoing research, and research risk levels at the organization to be interviewed. The site visitors will interview a wide range of individuals including University officials, CPHS members, CPHS staff, researchers, study coordinators, research nurses, grants and contracts staff etc.

4. **What is research?**

A systematic investigation that leads to generalizable knowledge is called research. There are many research-like activities that are conducted as part of quality improvement, infection control, disease management etc, that may not qualify as human subject research and hence do not need CPHS review and approval. New innovative therapies are used by many doctors during their

clinical management of patients. These may not meet the definition of research. Sometimes the boundary between research and not research may not be clear, at these times, it is best to request CPHS to make a determination.

5. What is ethical research?

Research that upholds the core ethical principals of respect for persons, beneficence and justices is considered to be ethical research.

Ethical research protects rights, safety and well being of human subjects.

Ethical research is also compliant with all applicable regulations and guidelines.

6. What are the core ethical principles for human subjects research?

The core ethical principles for human subjects research, as described in the Belmont Report are:

- a. Respect for persons - Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy, e.g. the need to obtain informed consent.
- b. Beneficence - entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm, e.g. the need to engage in a risk/benefit analysis and to minimize risks.
- c. Justice - requires that the benefits and burdens of research be distributed fairly, e.g. the need to have a reasonable inclusion and exclusion criteria.

7. Describe the process of declaring and managing conflict of interests.

Reserachers must reveal on the application to the CPHS and in the Review and Approval form whether they or any other person (including his or her spouse and dependant children) responsible for the design, conduct, or reporting of the research has significant financial interest related to the research study.

UTHSC-H considers any significant financial arrangements (Significant financial interest includes anything of monetary value of \$10,000 or more) related to a research study as having real or potential investigator conflict of interest. Concerns are raised when financial considerations may compromise or have the appearance of compromising an investigator's professional judgment and independence in the design, conduct or publication of research. Possible resolution of the conflict may include, but is not limited to:

- i. Disclosure of the conflict in the consent document,
- ii. Possible modification of research plan,
- iii. Divestiture of financial interest, and / or
- iv. Severance of the relationship that creates the conflict.

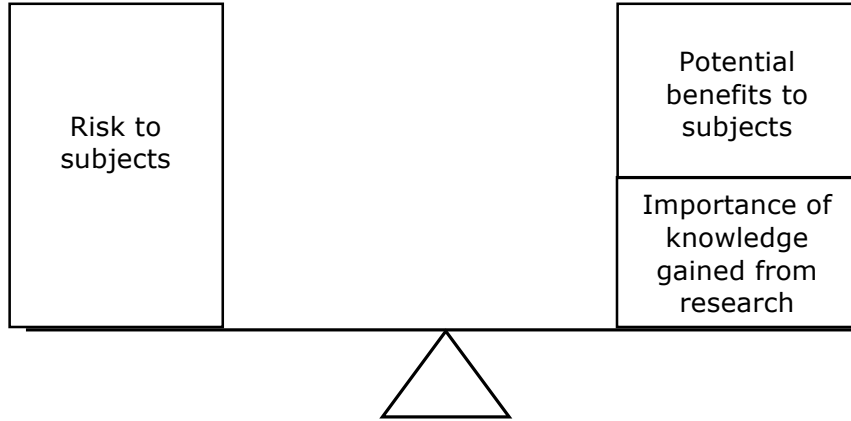
8. What is the difference between privacy and confidentiality?

Privacy - Privacy is about people. For example, to protect a patient's privacy only health care professionals who have access to the patient for their clinical care should make contact with the patient for inviting to participate in a research.

Confidentiality_- Confidentiality is about data. For example – to avoid breaches in confidentiality, investigators should store identifiable data in a secure location with access controlled to only members of the research team on a need to know basis.

9. What is risk benefit ratio?

The anticipated benefit, either to new knowledge or improved health of subjects should justify their taking the risk to participate in the research study.



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10. What are the different types of risks that research subjects may be exposed to?

The risks to which subjects may be exposed to can be classified as physical, psychological, social, economical and legal. Some examples of the various types of risks:

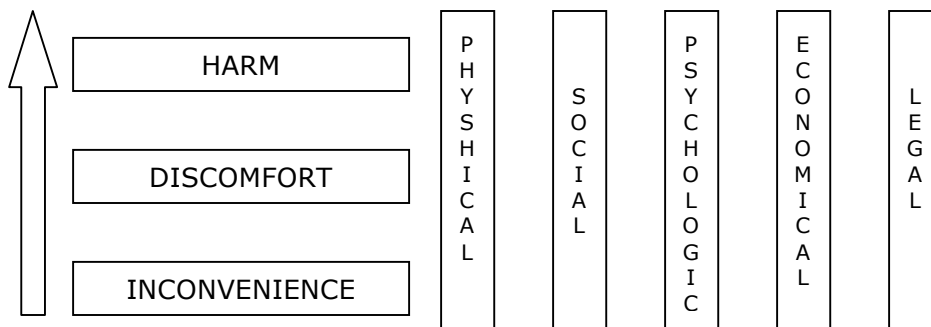
Physical: bruising after blood draw, study drug related adverse events.

Psychological: psychological effects following survey asking sensitive questions.

Social: breaches in confidentiality revealing that a subjects suffers from a psychiatric illness.

Economical: additional expenses to be borne by subject due to participation in research.

Legal: mandatory reporting of child abuse discovered during the research may cause legal problems for the subject.



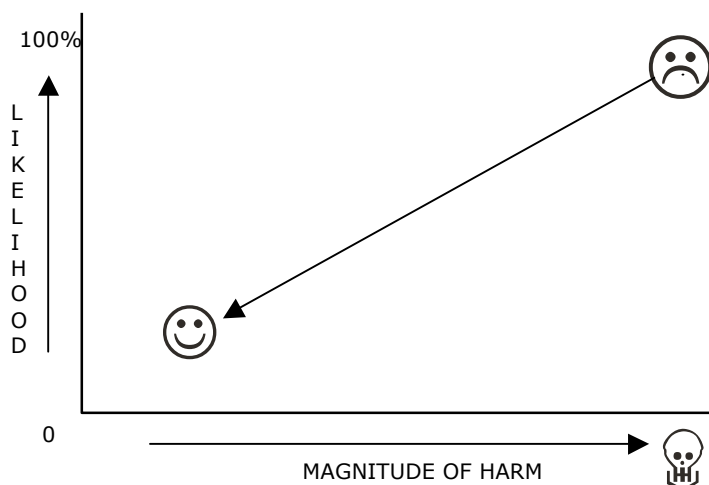
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11. What are the possible ways to minimize risks?

The investigator should constantly strive to minimize both the magnitude as well as the likelihood of the possible harms.

Magnitude– Possible harms may range from a mere inconvenience (such as an extra visit to the clinic) to a serious harm or even death.

Likelihood – The probability of occurrence of the harm.



Some examples of the ways the investigator can minimize potential harm are:

Physical: Procedures already being performed on the subjects for diagnostic or treatment purposes should be used, instead of performing additional tests for research. For example – extra blood drawn during a routine blood draw for treatment rather than requiring an additional needle stick.

Psychological or Emotional Wellbeing: debriefing after the completion of the research.

Social: ensure confidentiality is maintained especially while dealing with sensitive information.

Economical: ensure that the subject doesn't have to pay out of pocket for research related expenses and that institution covers treatment for research related injuries.

Legal: inform the subject during consent process if mandatory reporting of disease or abuse is required or employ a study design that assures anonymity.

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12. What is the role of the Committee for Protection of Human Subjects?

CPHS is an independent committee consisting of volunteers from various departments and the community who review research proposals and maintain oversight for ongoing research to ensure that human subjects' safety, rights, and well being are protected.

13. What are the various types of CPHS reviews?

Exempt – Studies that do not pose any risk for subjects such as anonymous surveys, research involving datasets / tissues which are stripped of identifiers may qualify for exemption.

Expedited Review – Studies that do not pose a greater risk than a subject would face in daily life may be reviewed by expedited review. This includes studies involving blood draws, investigations such as MRI, ultrasound, etc.

Full Board Review – Studies that do not qualify for exempt or expedited review are reviewed at a convened meeting of the CPHS.

- 14. What type of training did you receive in order to perform your duties as a researcher?**
Minimum training requirement for being PI on UTHSC-H projects is the CITI Program.
- 15. What type of training is available at UTHSC-H for study coordinators?**
UTHSC-H has a coordinator training seminar which is run twice a year, a monthly coordinator meeting and a course on regulatory issues.
- 16. What does informed consent mean?**
Consent is the process by which a subject voluntarily agrees to participate in a study after the he / she is given adequate information about the research study. Consent is documented by means of a written, signed, and dated consent document.
- 17. What are the points to keep in mind to conduct a good consent process?**
Consent should be obtained before initiation of the study i.e. before any procedures that are being performed solely for the research. Consent must be presented in a language that is understandable to the subject.
Subjects should be approached in a conducive environment, for example, it would not be appropriate to approach a subject immediately before a procedure or surgery, while in labour, while under sedation and any other situation where a subject might feel compromised. Subjects should be given adequate time to consider before making a decision whether or not to participate and should be encouraged to discuss participation with their family.
Consent discussion should be conducted by the PI, Co I , collaborator or a member of the study team who is listed in the CPHS Application Form as the designated person for conducting the Consent discussion. Consent is not a onetime single event prior to enrolling research subjects, but must be a continuous ongoing process. Investigators must inform subjects of any important new information that may affect their willingness to continue participation.
- 18. Other than the signing of the consent form, describe what method of documentation is used to record the informed consent process.**
Each subject or his/her legally acceptable representative must sign and date a copy of the CPHS-approved consent form prior to enrolment or any participation in any aspect of the study, unless the requirement is waived by the CPHS. The subject must be given a copy of the signed document. The person who conducted the informed consent discussion must sign and date the consent document and record the date of informed consent as well as the fact that a copy was given to the subject in the subject's medical record.
- 19. What methods help determine whether the subject understands the project, especially the risks involved?**
Assess the subjects' capacity to understand, appreciate consequences, make and communicate a decision and give subject opportunity to think about the study and ask questions. Address the subjects' questions. Ask subject questions about the study to assess comprehension.
- 20. What do you do when you encounter unanticipated problems involving subjects and others including adverse events?**
Assess the Event – Seriousness, expectedness and relation to study
Manage of Event - The investigator should ensure that adequate medical care is provided to the subject for treatment of adverse events.
Report the Event – Deaths within 24 hours, other unanticipated problems within 7 days.

Additional reading:

UTHSC-H Pages

1. UT Human Subjects Protection Program at <http://www.uth.tmc.edu/research/AAHRPP/>
2. Human Subjects Guidance at <http://www.uth.tmc.edu/orsc/>
3. The Investigator Handbook at <http://www.uth.tmc.edu/orsc/investigator/handbook/index.html>
4. Investigator Training at <http://www.uth.tmc.edu/research/training/index.html>
5. Research Conflict of Interest Policy – HOOP 23.10 <http://www.uth.tmc.edu/research/training/rcoi/index.html>
6. The Clinical Coordinator Newsletter at <http://www.uth.tmc.edu/research/clinical/news/Dec2008/Newsletterwinter08.html>
7. The Belmont Report at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

External Links

8. FDA Information Sheet - Guidances for Institutional Review Boards, Clinical Investigators, and Sponsors at <http://www.fda.gov/oc/ohrt/irbs/default.htm>
9. OHRP Policy Guidance at <http://www.hhs.gov/ohrp/policy/index.html>