

TITLE: HUMAN PROTECTIONS ADMINISTRATION PROGRAM

PURPOSE: To outline the Human Protections Administration (HPA) program that provides education, ongoing review and monitoring, record-keeping and reporting of research for the University Health System. The processes for use and disclosure of Protected Health Information in research will be detailed. This is a revised departmental policy and supersedes the policy dated 4/10/03. [Key words: Informed Consent, Protected Health Information, Limited Data Sets, Preliminary Research, Adverse Events, Conflicts of Interest, Research Misconduct, Vulnerable Populations].

POLICY STATEMENT:

The HPA program will provide assurance that all human subjects involved in research are adequately protected.

POLICY ELABORATION:

I. DEFINITIONS

- A. "Clinical Research Director" is the head of the Research Department and acts as the Human Protections Administrator by serving as the OHRP's primary institutional contact person. The Clinical Research Director has administrative responsibility for the program within the University Health System.
- B. Protected Health Information (PHI) shall mean the subset of Individually Identifiable Health Information that is (i) transmitted by electronic media; (ii) maintained in any medium constituting Electronic Media; or (iii) transmitted or maintained in any other form or medium.

“Protected Health Information” shall not include (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g, (ii) records described in 20 U.S.C. §1232g(a)(4)(B)(iv), and (iii) employment records held by a Covered Entity in its role as employer.

- C. “Informed consent” is the voluntary choice of an individual to participate in research based on an accurate and complete understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.
- D. “Institutional Assurance” is the documentation of an institution’s commitment to comply with Federal regulations and maintain adequate programs and procedures for the protection of human subjects.
- E. “Research Committee” is the committee established by the Medical/Dental Staff Bylaws with responsibility for oversight and policy matters related to Human Subject Research. The committee is charged with the promotion of quality clinical research within the Health System.
- F. “Assent” is a child’s affirmative agreement to participate in research.
- G. Adverse Drug Reactions (ADR’s) include: New, rare or previously undocumented reactions, Serious, Life-Threatening or fatal reactions, Congenital anomalies potentially associated with drug administration, Suspected drug interactions, Suspected bioavailability problems, ADR’s requiring hospital admission, ADR’s requiring increased length of hospitalization.
- H. “Research Pharmacist” is a Registered Pharmacist in the Pharmacy Department who manages the Investigational Drug Studies (IDS).
- I. “Pre-Research” is the review of PHI preparatory to research and applies to investigations that are preliminary in nature and done in order to formulate a hypothesis that may be a topic for research at a later time or to collect data to write a research proposal.

- J. Conflicts of Interest” means a situation where the individual has the opportunity to influence the University Health System business, administrative, academic, research, or other decisions in ways that could lead to personal financial gain or advantage or could cause or appear to cause bias in the design, conduct or reporting of research.
- K. “Conflict of Commitment” means a situation where the individual undertakes external commitments that burden, interfere, or detract from the member’s primary obligations and commitments to the University Health System.
- L. “Good faith allegation” means an allegation of scientific misconduct made with a belief in the truth of the allegation which a reasonable person in the whistleblower’s position could hold based upon the facts. An allegation is not in good faith if made with reckless disregard for or willful ignorance of facts that would disprove the allegation.
- M. “Research Misconduct” means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.
- N. “Retaliation” means any adverse action or credible threat of an adverse action taken by a covered institution, or member thereof, in response to a whistleblower’s good faith allegation of scientific misconduct. It does not include an institution’s decision to investigate a good faith allegation of scientific misconduct.
- O. Significant Financial Interest” means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:
 - (1) Salary, royalties, or other remuneration from the applicant institution;

- (2) Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program;
 - (3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
 - (4) Income from service on advisory committees or review panels for public or nonprofit entities;
 - (5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
 - (6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10, 000.
- P. "Vulnerable Populations" means subjects that could be enrolled in a study are likely to be vulnerable to coercion or undue influence, such as pregnant women, prisoners, children, mentally or decisionally impaired, persons recruited or enrolled in emergent care settings, staff and students, or economically or educationally disadvantaged persons.
- O. "Whistleblower" means an individual who makes an allegation or demonstrates intent to make an allegation (or what is perceived to be an allegation) while a member of the institution at which the alleged scientific misconduct occurred.

II. INFORMED CONSENT

- A. The Health System shall be entitled to rely on the approval of the UTHSCSA IRB to assure that requirements for the consent form have been met. The Health System may require additions and/or revisions to the consent form for protection of human subjects. Investigators and research team members not employed by the University Health System providing informed consent must be credentialed by UHS and should be identified in the Scope of Practice. (Policy 9.000, Attachment VI)

- B. It is the investigator's responsibility to ensure that each potential subject understands the information and to take the appropriate steps necessary to gain that comprehension. Assessment of literacy and language preference must be completed prior to consent being signed. Spanish Consent form will be on file with the UHS Research Department prior to the initiation of any research study where IRB has required a Spanish Consent. Spanish speaking patients will not be consented until the consent form is approved by the IRB.
- C. All patients must be given a copy of the signed consent form. Copies of the consent document must be filed (as applicable) in the inpatient and outpatient medical records.
- D. The Health System expects that investigators enrolling patients from vulnerable populations will adhere to the strictest interpretation of all the appropriate federal and state regulations.
- E. Investigators must assess the need for subjects within their study to carry medical information regarding the study for presentation to other health care professionals who may not have access to the patients hospital or study records.
- F. The research Principal Investigator or the approved designee will document that the research informed consent process has been accomplished. This documentation will be accomplished in a research progress note in the subject's medical record. At a minimum, the consent progress note must include:
 - (1) The name of the study.
 - (2) The person obtaining the subject's consent.
 - (3) A statement that the subject or the subject's legally-authorized representative was capable of understanding the consent process.
 - (4) A statement that the study was explained to the subject.
 - (5) A statement that the subject was given the opportunity to ask questions or time for the participant to determine if they want to participate
 - (6) If Spanish or foreign language consent is used the translator for the consent process must be identified.

An entry must also be placed in the progress note when the subject is enrolled in the study (consent and entry note may be combined when occurring at same visit) and when the subject's participation is terminated.

A research note template will be available within the electronic medical records to enter the required documentation.

- G. Witnessing for consents is a function of staff within the clinical setting. The signature of witness attests only to the signature of the subject. He/she does not need to witness the consent process, unless the subject cannot read the consent for him/herself, or unless it is specifically required by the protocol and approved by the IRB. The witness should be an *impartial* person; not a member of the research team and not a family member of the subject. If the consent must be read to the subject (such as when a subject is illiterate or is blind), the witness must be present for the entire consent process and a special statement must be added to the consent form, regarding the meaning of the witness' signature.
- H. Community studies that incorporate non-patients across the Health System will be registered as non patients in IDX and a stored copy of the consent will be kept in the clinic site of the study.

To register a non-patient in IDX, staff will use XO IDX patient action code, then select XNBUC (clinical site code) patient type that is non-billable. This means charges cannot post to the visit. Staff should complete the visit as normal. Investigators of these studies will be required to provide copies of the consent forms to the administrator of the clinic to be kept on file per records retention schedule.

III. THE HPA; COMMUNICATION & EDUCATION, RECORDKEEPING & REPORTING, MONITORING & OVERSIGHT

A. Communication and Education

1. The Clinical Research Director, the Research Coordinators and members of the Research Committee will facilitate communication among department heads, investigators, clinical care staff, human subjects, and institutional officials, as a means of maintaining a high level of awareness regarding the ethical conduct of research, and safeguarding the rights and welfare of subjects.
2. The Clinical Research Director will maintain copies of the Institution's Assurance, pertinent Federal regulations, policies and guidelines related to the involvement of human subjects in research, as well as institutional policies and procedures.
3. The Clinical Research Director will develop an educational program for the Health system research community in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human subjects. (Resident/Patient Clinical Trial brochures Attachment I)
4. Any individual Investigator and their staff engaged in human research (intervening/interacting with humans or their private identifiable information) must complete the designated program from the UTHSCSA IRB on research ethics. After completing the initial training modules listed on the UTHSCSA Institutional Instruction page, continued education must be completed every three years using the designated Refresher Education modules.

University Health System Research Committee members, reviewers of research protocols, and UHS employees supporting or implementing a research protocol in their area must complete the basic designated program and the continued education every three years. Staff participating in research protocols in their clinical site may also complete this training, if desired.

The Human Subjects Training program can be accessed from the Research Department website. Staff required to complete this training will forward a copy of their completed training certificates to Learning Resources for recording.

5. Specific UHS guidance has been developed for new research coordinators that include orientation to facility, orientation to the department, Safety JCAHO requirements, Information Systems guides and department policy. (Orientation Checklist Attachment II)

B. Recordkeeping and Reporting

1. Required Reporting to the UHS Research Department by the Investigator
 - a. The UTHSCSA IRB will and report to the Health System Research Department on all significant adverse events for studies conducted at the Health System.
 - b. Subject lists will be requested for studies in preparation for monitoring/auditing.
 - c. The investigator must submit to the Research Department a stamped copy of the IRB letters of continuing approval, the Annual Progress Report for review, and an updated personnel list under their written assurance.
 - d. At the study's conclusion of institutional support a memo of completion must be submitted to the Research Department.
 - e. All studies 90 days or greater that have expired will have a memo generated to each department chair of notification study closure with in 30 days.
2. Required Reporting of the HPA/Health System Research Department:

- a. The HPA program is responsible for ensuring prompt reporting to the IRB
 - any serious or continuing noncompliance with the regulations or requirements of the IRB, and
 - any suspension or termination of approval for research from UHS.

3. Research Misconduct

4. The University Health System is committed to conducting all of its research activities with integrity, adhering to both scientific and ethical principles. Compromise of these principles for conducting research will not be condoned.

- a. Any patient, Investigator, University Health System employee or Medical/Dental staff member may express concerns about research policy approval from the Health System, or implementation of a specific protocol within the University Health System to the Research Department, members of the Research Committee and/or to the Director of the IRB at UTHSCSA. (Complaint Workflow Attachment III)

Whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as defined in this policy. University Health System will not tolerate or engage in retaliation against good faith whistleblowers.

5. UHS policy 2.13 outlines specific guidelines and reporting channels, to include the integrity hotline for health system staff to report actual, potential or suspected significant misconduct. Integrity Services will investigate research misconduct.

They will provide a fair and objective procedure for examining and resolving the complaints, disputes and allegations of research misconduct. Integrity Services will share its determinations and findings with appropriate collaborators, peer review boards and UHS Professional Staff Services. Integrity Services will take appropriate actions in concert with collaborators to inform publishers, grant funding agencies and other associates of the research of misconduct findings.

4. Recordkeeping

- a. Records management policy 2.05 will be followed for record retention.
- b. Responsible precautions to protect intellectual property of sponsors will be implemented by the research department.

C. Monitoring and Oversight

1. All investigators will sign the Health System Institutional Assurance prior to initiation of their research. The Assurance outlines members of the research team, consent processes, documentation requirements, adherence to policy and supplemental conditions as well as monitoring (Research Departmental Policy Attachment VI). The Principal Investigator will ensure that only the specified research staff members on the Assurance will have access to Protected Health Information. The Principal Investigator will notify the Health System research department in writing, of any changes (Assurance Update Attachment IV) (additions/removals) in the research staff members. The Principal Investigator and research staff members must comply with all Health System Policies, including the policy on Uses and Disclosures of Protected Health Information, and have signed a confidentiality statement (Reference Departmental Policy Attachment V). The Research staff members will have access to information for the period of 13 months unless extended by the IRB continuation letter, or until the research performed pursuant to the approved research protocol is completed, whichever is earlier.

2. The HPA program provides an oversight mechanism to ensure that the determinations of the IRB have been implemented.

The Clinical Research Director will report to the Chairman of the Research Committee or the full Research Committee on the important issues or problems related to research at the Health System. The research committee will also regularly review the abstracts of protocols approved by the Health System.

3. The Health System Research Department will monitor studies to determine compliance with appropriate federal, state, and Health System policy. The Clinical Research Director will report the results of audits to the Research Committee.
4. Investigators are responsible for reporting to UHS Risk Management all adverse events, including investigational drugs. This includes notifying the primary physician (if not the investigator) and pharmacy, as well as completing the Adverse Drug Reaction Reporting Form.

IV. Protected Health Information; Disclosures and Uses in Pre-Research and Research

- A. Authorization is required for all research related to use and disclosure of PHI. Exceptions are:
 1. When IRB approved waiver of authorization is given.
(Procedure for Authorization Wavier Attachment VI)

2. Use of decedent's information
 - a. Protected health information may be used by or disclosed to a researcher for research on decedents provided the researcher: (i) represents to the University Health System that the use or disclosure is sought solely for research on the protected health information of decedents, (ii) provides to the University Health System, upon request, documentation of the death of the research subject, and (iii) represents to the University Health System that the protected health information is necessary for the research.
 - b. All research studies on decedent's data must be approved by the Health System Research Department. Application will be made by submitting the "Authorization for Pre-Research and use of Decedent's PHI" form to the Research Department.
(Application Attachment VII) Investigators will be required to provide the Research Department the names of subjects whose PHI was accessed in this study for accountability to these patients or their personal representative on PHI access.
3. Use of information for review of PHI preparatory to research (pre-research)
 - a. Protected health information may be used by or disclosed to a researcher as necessary to prepare a research protocol or for similar purposes preparatory to research or provided the researcher represents to the University Health System that: (i) the use or disclosure is sought solely for such purposes, (ii) no protected health information will be removed from the University Health System premises by the researcher in the course of the review, and (iii) the protected health information for which use or access is sought is necessary for the research purposes.

- b. All preliminary research studies must be approved by the Health System Research Department. Application will be made by submitting the “Authorization for Pre-Research and use of Decedent’s PHI” form to the Research Department. (Application Attachment VII) Investigators will be required to provide the Research Department the names of subjects whose PHI was accessed in this study for accountability to these patients or their personal representative on PHI access.

- 4. Use of information is in a limited data set (Procedure for Limited Data Set Attachment VIII)

- B. There are no restrictions on use of health information that does not identify the individual. (De-Identification Data Attachment IX)

- C. 1. Researchers will be required to follow the accounting of disclosure procedure for waiver of authorization decedent and preparatory to research functions. The researcher will be responsible for disclosures on PHI accessed on 50 or less subjects. The researcher will not be required to submit monthly disclosures on PHI accessed on 51 or more subjects.

(Accounting of Disclosure Procedure Attachment X) (Disclosure Log Attachment XI)

- 2. The patient or the patient’s personal representative may request an accounting of all Accountable Disclosures of the patient’s Protected Health Information. Upon receipt of a written request the Health System will provide the requestor with an accounting of all Accountable Disclosures during the six (6) year period immediately prior to the date of the request for an accounting. The Health System will maintain a record of all research related uses and disclosures of PHI for which an authorization has not be obtained. Details of this process are outlined in the Health System Policy “Accounting of Disclosures of Protected Health Information”.

- D. University Health System will provide all patients with a copy of the Notice of Privacy, which includes a statement that their PHI may be used for research purposes.

V. Conflicts of Interest

- A. Grant funds will complete the “University Health System disclosure statement”.
- B. The research committee will designate a sub-committee to review and determine if conflicts of interest exist.
- C. Integrity services will provide consultation on all identified conflicts of interest.
- D. When conflicts of interests are identified but can not be resolved staff will not participate in research endeavor.

REFERENCES/BIBLIOGRAPHY:

University Health System Policy 9.01 “Protection of Human Subjects in Research” Effective Date

Health Insurance Portability and Accountability Act Section 1171-1179 of the Social Security Act (42U.S.C1320d-1329d-8)

HIPAA implementing regulations - 45 C.F.R. 160.001 et seq.

Protection of Human Subjects - the “Common Rule” – 45 C.F.R. 46.101 et seq.

University Health System Institutional Assurance filed with the Office for Human Research Protections.

VHA Handbook 1200.5, Appendix C, paragraph 3

Department of Health and Human Services, Final Guidance Document Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection

Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is Sought 42 CFR Part 50, Subpart A

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Public Health Standards for the Protection of Research Misconduct
Whistleblowers 42 CFR 94

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research - The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Washington D.C., April 18, 1979 (Federal Register Document 79-12065 (see Appendix or online at http://www.imc.gsm.com/demos/dddemo/consult/belm_all.htm)

"Affiliation Agreement" between University Health System and the University of Texas Health Science Center at San Antonio, dated June 11, 1992.

Bylaws of the Medical-Dental Staff, University Health System.

Dunn, Cynthia and Chadwick, Gary. "Protecting Study Volunteers in Research," CenterWatch, Inc. 1999.