

TITLE: PROTECTION OF HUMAN SUBJECTS IN RESEARCH AND THE CONDUCT OF RESEARCH WITHIN THE UNIVERSITY HEALTH SYSTEM

PURPOSE: To establish the process by which the research Mission of the University Health System and its affiliate University of Texas Health Science Center will support research to advance knowledge and improve delivery of patient care. This is a revised policy and supersedes policy dated 07/08/03. [Key Words: Research, Protocol, Institutional Review Board, Research Committee, Institutional Assurance, Informed Consent, Human Protections, Protected Health Information, Health System Mission, Affiliation Agreement, Conflicts of Interest, Research Misconduct, Vulnerable Populations].

POLICY STATEMENT:

It is the policy of University Health System to protect human subjects in research and to establish a Human Protections Administration in order to promote and maintain compliance through education, ongoing review and monitoring, record-keeping and reporting. University Health System supports the ethical conduct of translational research using anatomical and animal specimens.

POLICY ELABORATION:

I. DEFINITIONS:

- A. “Anatomical Services” is within the Department of Cellular and Structural Biology at the University of Texas Health Science Center San Antonio which oversees research studies proposed on an anatomical specimen.
- B. “Clinical Research Director” is the head of the Health System Research Department who acts as the Human Protections

Administrator (HPA) by serving as the Office of Human Research Protections (OHRP) primary institutional contact person. The Clinical Research Director has administrative responsibility for the human protections program within the Health System.

- C. “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.
- D. “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.
- E. “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.
- F. “Human Subject” is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual and/or access for review of an individual’s identifiable personal information.
- G. “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.

- H. “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.
- I. “The Institutional Review Board (IRB)” is a committee established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. There are three University of Texas Health Science Center at San Antonio Institutional Review Boards designated under the Health System’s Institutional Assurance;(1) Full Board (2) Continuation (3) Cancer.
- J. Institutional Animal Care and Use Committee (IACUC) at the University of Texas Health Science Center at San Antonio and Southwest Research Institute which oversees the animal care and use programs of each institution.
- K. “Investigator” means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research to develop or contribute to generalizable knowledge. For purposes relating to financial interests, “Investigator” includes the investigator’s spouse and dependent children.
- L. “Legally authorized representative” is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in a particular research protocol.
- M. The “Office for Human Research Protections (OHRP)” is the federal agency responsible for developing and monitoring, as well as exercising compliance oversight for the protection of human subjects in any research conducted or supported by any

component of the Department of Health and Human Services and for establishing criteria for and negotiation of all Institutional Assurances.

- N. “Protected Health Information” 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. (Note that Highly Confidential Information is a subset of Protected Health Information.)
- O. “Research” is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Criteria used to determine whether a planned activity is research includes (1) The collection of data with the intent to report them in scientific publications (2) Use of a standard procedure or medication if it is influenced by any consideration other than the direct welfare of the patient, even if both therapies seem equal to the physician in charge (e.g., a selection between different though widely accepted therapies according to a predetermined plan such as randomization) (3) Innovative or newly-introduced therapies when they involve "research" activities (e.g., the systematic collection of data with the intent to evaluate the effectiveness of the therapy, use of an experimental drug or device, or use of any procedure such as randomization which is not done solely for the benefit of the patient). The definition of research does not include activities for “health care operations”. Health care operations generally means any of the following activities of

the Health System: 1) conducting quality assessment and improvement activities; 2) reviewing the competence qualifications of health care professionals, evaluating practitioner and provider performance, conducting training programs, accreditation, certification, licensing or credentialing activities; 3) conducting or arranging for medical review, legal services and auditing functions, including fraud and abuse detection and compliance programs; 4) business planning and development; and 5) business management and general administrative activities. [See, 45 CFR 164.501 for a complete regulatory definition].

- P. "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.
- Q. "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.
- R. "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.
- S. "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.
- T. "Specimen" is either an anatomical specimen (corpse or tissue or fluid from a corpse) or a human/animal sample of blood, urine, other body fluid or tissue.
- U. "Translational Research" crosses boundaries between basic science and clinical application. It is the conversion of pre-clinical studies into information, resources or tools that can be used by health professionals and can lead to clinical trials. The support of research for anatomical animal specimens is a

specific type of translational research.

- V. “University Health System” or “Health System” is the Bexar County Hospital District d/b/a University Health System and all operating components over which it has legal authority, as identified in the Health System’s Institutional Assurance, as well as the facilities associated with it.
- W. “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.
- X. “Whistleblower” means an individual who makes an allegation or demonstrates an 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. Organizational Structure and Responsibility for Human Subject Research and Translational Research.

The protection of human subjects within Health System facilities is a shared responsibility among the UTHSCSA IRB, the Health System, the Medical-Dental Staff, and the Investigator.

A. UTHSCSA IRB Responsibility

- 1. The UTHSCSA IRB serves as the IRB for the Health System and is primarily responsible for ensuring that research proposals submitted to the Health System meet the substantive and procedural requirements of the applicable state and federal regulations, and that the rights and welfare of the human subjects are adequately

protected.

2. The UTHSCSA IRB will review all research that will be done at the Health System; and have the authority to approve, disapprove, or require modification in all research activities, including proposed changes in ongoing, previously approved, human subjects research. The IRB staff will also review and make a determination of research proposals that will be exempt from IRB review. All non-exempt research that is to be done at the Health System must have the approval of the IRB either through review at a convened meeting or through expedited review.
3. The UTHSCSA IRB-2 will conduct continuing review of ongoing approved research either through review at a convened meeting or through expedited review. The IRB has the authority to suspend or terminate the approval of ongoing, previously approved research that is not being conducted in accordance with the IRB-2 requirements or that has been associated with unexpected, serious harm to subjects.
4. Research covered by this policy that has been approved by one of the IRB is subject to further appropriate review and approval or disapproval by the Health System. However, the Health System may not approve any research that has not been approved by the IRB.
5. UTHSCSA IRB provides safeguards in the review of applications for research to protect the rights and welfare of vulnerable subjects. In addition to the responsibilities prescribed for the IRB under 45 CFR Part 46, Subpart A, the Board shall follow special procedures with respect to pregnant women, fetuses, neonates of uncertain viability,

prisoners and children. These federally recognized vulnerable populations and the requirements for inclusion of these populations are discussed in 45 CFR 46, Subparts B,C, and D. Other vulnerable populations are considered by the UTHSCSA IRBs and are discussed in further detail in their operating manual.

B. Health System Responsibilities

1. The Health System is responsible for human subjects research conducted within their assurance and studies conducted for translational research. Institutional oversight will be accomplished through a designated Health System administrator and the Health System Research Department, in conjunction with the Medical-Dental Staff through its Research Committee.
 - a. The CEO assumes on behalf of the Health System the obligations in the Institutional Assurance. As signatory for the Assurance he/she ensures that the Health System will maintain an institutional culture of respect for human subjects, provides effective institutional-wide communication and guidance on human subjects research, requires investigators conducting research in this assurance to fulfill their responsibilities and affords human subject education activities for staff.
 - b. The CEO designates an administrator to assist him/her in accomplishing these responsibilities and providing him/her with timely communications in regards to research activities in the Health System. The designated administrator shall have responsibility for supervision of the Clinical Research Director and the Health System Research

Department and shall serve as an ex-officio member of the Research Committee.

- c. The Research Department facilitates the processing of and the Health System's approval of proposed research protocols. The Department further serves as a liaison between the Health System, the Investigator, the IRB office, Anatomical Services Department of Cellular and Structural Biology, Institutional Animal Care and Use Committee and the Research Committee.
- d. The Department, through its Clinical Research Director, is responsible for developing and implementing a Human Protections Administration program. Oversight functions will include those relating to education, credentialing, recordkeeping and reporting, monitoring of the informed consent process and use and disclosure of PHI in research processes as well as compliance with key protocol elements, and coordination of financial responsibility. Health System policy 7.09 Fiscal Management of Research Protocols details this process. Audit and monitoring information obtained by the Clinical Research Director will be shared with the Principal Investigator, the Research Committee and the IRB office in order to ensure human subjects protection and protection of the resources of the Health System.
- e. The Clinical Research Director is responsible for developing and maintaining departmental policies and procedures consistent with this policy as well as federal and state laws. These departmental

policies and procedures will address in greater detail the following matters as well as other matters that are identified by the Clinical Research Director as appropriate for policy or protocol development:

- Review of research protocols;
- Human protections administration program; and
- Emergency research drugs and devices
- Procedures for Translational Research; and
- Fiscal management of research

Additionally the Clinical Research Director is responsible for maintaining copies of policies and procedures from all departments within the Health System that directly support the research standards as specified by the Joint Commission on the Accreditation of Health Care Organizations.

2. Prior to initiation of any research within the Health System, an investigator will submit each research protocol to the Research Department for review and approval in accordance with Health System policies. The Health System will evaluate and determine the extent of its support for the proposed research protocol with consideration for compliance with IRB requirements, state and federal regulatory requirements, the protection of human subjects, the feasibility of providing the services or facilities requested, and the financial impact on the Health System of participation. Priority for procedures and treatment will first be to the treatment of patients. Procedures for human subjects' research will be given the highest priority after patient care. Translational research

will be conducted in a manner that will not interfere or conflict with the direct patient care mission.

The Health System may disapprove implementation of any proposed research based on its evaluation.

3. The Health System complies with the Code of Federal Regulations for Protection of Human Subjects¹, applicable Food and Drug Administration (FDA) regulations, the Health Insurance Portability and Accountability Act² and implementing regulations³, and applicable state statutes and regulations⁴.

The Medical-Dental Staff

- a. The Research Committee shares in the oversight responsibility for all human subject and translational research conducted within the Health System. It is responsible for assuring protection of human subjects in research and for the safety of personnel engaged in research.
- b. The Research Committee's responsibilities will be accomplished through oversight mechanisms that ensure compliance with regulations and administration of the Human Protections Program and ethical conduct of translational research. Committee members will provide education to staff, investigators, and community members on the protection of human subjects and safety in research. They will review abstracts of all IRB- and Health System-approved research as well as audit and monitoring data presented by the research department. The Committee will

organize educational activities for Health System staff, investigators, and community members on the protection of human subjects in research as well as the conduct of ethical translational research. A designated subcommittee will review conflict of interest disclosures for the University Health System staff that conduct research under grant funding. The committee will report to the executive committee annually.

D. Investigator and Research Personnel Responsibility

1. The Investigator is obligated to separate roles as a researcher and clinician and follow the appropriate policies for each.
2. All Principal Investigators and their Co-Investigators that are not employed by the University Health System will be credentialed by Medical-Dental Staff prior to implementation of research study. UHS staff employed by UTHSCSA for purposes of research will be credentialed by Professional Staff Services. Administrative and research personnel who have knowledge of the subjects' protected health information, even if not in direct contact with the subject will be listed as authorized personnel on the investigators Scope of Practice to the institution. Each will sign a confidentiality statement. Ethics education for these personnel is the responsibility of the Principal Investigator. Health System employees must complete departmental competencies if supporting or implementing a research protocol in their area.
3. Investigators and their staff engaged in human research

(intervening/interacting with humans or their private identifiable information) must complete the designated program on research ethics from the UTHSCSA IRB. After completing the initial training, continued education must be completed every three years using the designated Refresher Education modules. Health System Research Committee members, reviewers of research protocols, and UHS employees implementing a research protocol in there area must complete the basic designated program as well as 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.

4. Investigators have the primary responsibility for protecting the rights and welfare of human research subjects and are responsible for complying with all applicable provisions of the Institutional Assurance.
5. Investigators will conduct their research according to the IRB-approved protocol and will comply with all IRB determinations. Investigators are expected to be knowledgeable about and committed to comply with the requirements of all applicable state and federal regulations, the Institutional Assurance, and all Health System policies and procedures that bear on the implementation of the research and the protection of human subjects.

III. Elements of Human Subjects Protection

A. General Rule - Informed Consent Required

1. In general, and subject to exceptions stated in III.B, an investigator may not involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights; or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.⁵
2. Appropriate documentation of informed consent per federal regulations is required unless an exception to the documentation requirements exists.
3. An IRB shall require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB judgment the information would meaningfully add to the protection of the rights and welfare of subjects.⁶

B. Exceptions to General Rule of Required Informed Consent

1. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 45 CFR 46.116(a) and (b), or waive the requirement to obtain informed consent provided the IRB finds and documents that:
 - (a) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
 - (b) The research could not practicably be carried out without the waiver or alteration.⁷

2. An IRB may also approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 45 CFR 46.116(a) and (b), or waive the requirements to obtain informed consent provided the IRB finds and documents that:
 - (a) The research involves no more than minimal risk to the subjects;
 - (b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

- (c) The research could not practicably be carried out without the waiver or alteration; and
 - (d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.⁸
3. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
- (a) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - (b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.⁹
4. In addition to the above, the IRB may approve research and an Emergency Research Consent Waiver (ERCW) for a strictly limited class of research involving activities which may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained. Under an ERCW, the applicability of obtaining and documenting informed consent pursuant to 45 CFR 46.116 and 46.117 is waived. Because of special

regulatory limitations relating to research involving prisoners (Subpart C of 45 CFR 46) and research involving fetuses, pregnant women, and human in vitro fertilization (Subpart B of 45 CFR 46), ERCW's may not be used for these categories of research.¹⁰

5. The informed consent requirements in 45 CFR 46.116 and 46.117 may be inapplicable to research that is deemed "exempt" under applicable federal regulations.¹¹

C. Patient's Rights Regarding Use and Disclosure of PHI

1. No research involving uses or disclosures of a research subject's PHI may be conducted unless one of the following applies:
 - a. An authorization for use or disclosure of such information is obtained from the subject or the subject's legally authorized representative;
 - b. A waiver of authorization has been approved by one of the UTHSCSA IRB pursuant to the 45 CFR 164.512 (i) or approved by a privacy board pursuant to state and federal law¹². If a waiver is provided, disclosure and Accounting of PHI for Research purposes will be provided to the Research Department.
 - c. The health information has been de-identified;
 - d. The health information is used or disclosed in a limited data set in accordance with a data use agreement; or

e. One of the exceptions for disclosure under HIPAA applies.

2. All authorizations will comply with HIPAA regulations.
3. Investigators will understand and comply with the concept of limiting use and disclosure of PHI to the minimum necessary.
4. If the Investigator maintains a database containing PHI, the researcher is obligated to ensure that use and disclosure of PHI is compliant with HIPAA policies.

D. Conflicts of Interest

1. Investigators and research staff from the University of Texas Health Science Center must be in compliance with their Conflicts of Interest policy . Any actual or potential conflict of interest with respect to any proposed or ongoing research for which an Investigator has responsibility must be disclosed to the Health System's Clinical Research Director prior to implementation of any research protocol. This duty of the investigator is an ongoing duty that exists through the termination of the research, and any conflict of interest that arises after the research has been implemented must be reported to the Health System's Clinical Research Director.
2. University Health System staff that are grant funded to design, conduct, or report research will complete conflict of interest disclosure forms (Appendix III) for review by the Medical Dental Research Committee for determination of conflicts of interest. Integrity Services

will provide consult to the committee on any issues and resolve for these research conflicts of interest.

E. Research Misconduct

1. 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.
2. Any research subject, investigator, Health System employee, Medical Dental staff member or other person may express concerns about research policy matters, the approval, or implementation of a specific protocol, or concern over human protections of human subjects in research conducted within Health System's to the Clinical Research Director and/or members of the Research Committee.
3. 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.
4. 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.

IV. ELEMENTS OF SAFETY AND ETHICS IN CONDUCT OF TRANSLATIONAL RESEARCH

- A. Anatomical Specimens examined within clinical departments at UHS will be obtained through the Anatomical Services at UTHSCSA. The Service will provide evidence of the registration of each body or body part with the Texas Anatomical Board¹³ that indicates the donation was for medical education and research. Additionally, these specimens are non-reactive for major communicable disease and have been tested by UHS clinical laboratory prior to being transported to UHS for examination.
- B. The investigator and the receiving department will assure that the specimens are transported inconspicuously. They will coordinate this transport with the supervisor of the Anatomical Services. If specimens from the Anatomical Services have been removed to another laboratory, they need to return to the Anatomical Services for transport to the hospital. All examinations of specimens will be conducted out of the view of patients. UHS staff have the right to refuse participating in the testing of the specimens.
- C. Only specimens from Animal research will be tested at UHS clinical sites. Live animal studies are prohibited. Investigators obtaining testing of specimens will provide the Research Department with approval of the study from Institutional Animal Care and Use Committee (IACUC) and annual continuation.
- D. Infection Control procedures are followed prior to, during and

following testing to ensure equipment is free of any pathogens. Biological waste is managed in compliance with Institutional, State and Federal Regulations.

- E. Processing of applications and contracting for these services will be facilitated through the Research Department.

REFERENCES/BIBLIOGRAPHY:

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.

Anatomical Board of Texas Health and Safety Code of Texas Chapter 691

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

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

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

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

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.

University Health System Policy 7.09, Fiscal Management of Research Protocols

University Health System Policy 2.12, Conflicts of Interest

University Health System Policy 2.13 Reporting Errors and Incidents of Misconduct

University Health System Policy 2.14, Health Assurance and Portability and Accountability Act (HIPAA) Compliance Program Policy

University Health System Policy 2.1401, Uses and Disclosures of Protected Health Information

OFFICE OF PRIMARY RESPONSIBILITY:

Associate Administrator, University Hospital

APPENDICES:

Appendix I – The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

Appendix II – Waiver of Informed Consent Requirements in Certain Emergency Research - 61 Fed. Reg. 51531-51533

Appendix III – Conflict of Interest Disclosure Forms

ENDNOTES:

¹ 45 CFR 46.001 et seq. (the “Common Rule”)

² Section 1171 - 1179 of the Social Security Act (42 USC 1320d-1329d-8), as added by sec. 262 of Pub. L. 104-191, 110 STAT. 2021-2031 and sec. 264 of Pub. L. 104-191 (42 USC 1320d-2 (note)).

³ 45 CFR 160.001 et seq.

⁴ See Texas Health & Safety Code, 181.001 et seq.

⁵ 45 CFR 46.116.

⁶ 45 CFR 46.109(b)

⁷ 45 CFR 46.116(c)

⁸ 45 CFR 46.116(d)

⁹ 45 CFR 46.117(c)

¹⁰ 61 Fed. Reg. 51531-51533 (attached as Appendix II)

¹¹ 45 CFR 46.101

¹² See HIPAA regulations, 45 CFR 164.512(i), and Texas Health & Safety Code §181.101 et seq.

¹³ Texas Health & Safety Code Ann. § 691.001, et seq (West Supp. 2005)