

**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 (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 12/28/08. [Key Words: Research, Protocol, Institutional Review Board, Research Committee, Institutional Assurance, Informed Consent, Human Protections, Belmont Report Protected Health Information, Health System Mission, Affiliation Agreement, Conflicts of Interest, Research Misconduct, Vulnerable Populations].

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**POLICY STATEMENT:**

All human subject research activities are guided by the ethical principles in the Belmont Report and other ethical standards known as the Common Rule. Human Protections Administration promotes and maintains compliance through education, ongoing review and monitoring, record-keeping and reporting. The Health System supports the ethical conduct of non-human research when using anatomical and animal specimens.

**POLICY ELABORATION:**

**I. DEFINITIONS**

- A. Anatomical Services** – within the Department of Cellular and Structural Biology at the University of Texas Health Science Center at San Antonio, which oversees research studies proposed on an anatomical specimen.

- B. Senior Clinical Research Director** – 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 Senior Clinical Research Director has administrative responsibility for the human protections program within the Health System.
- C. Conflict of Interest** – a situation where the individual has the opportunity to influence 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** – a situation where the individual undertakes external commitments that burden, interfere, or detract from the member’s primary obligations and commitments to the Health System.
- E. Engaged in Research** – 1) Health System employees or agent intervene or interact with human subjects for purposes of research; 2) Health System employees or agents obtain individually identifiable private information about human subjects for purposes of research; or 3) Health System receives a direct award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.
- F. Federal-Wide Assurance (FWA)** – the documentation of an institution’s commitment to comply with Federal regulations and maintain adequate programs and procedures for the protection of human subjects.
- G. Good Faith Allegation** – an allegation of scientific misconduct non-compliance, serious non-compliance, and unethical behavior

made with a belief in the truth of the allegation which a reasonable person 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.

- H. Human Subject** – 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.
- I. Informed consent** – a person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information (purpose, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate) to participate in research. “Legally effective informed consent’ is obtained when a subject or a subject’s legally authorized representative as outlined in Texas Health & Safety Code Ann. § 313.001 et. seq. (Vernon 2008) agrees to participate.” The informed consent process requires three elements: information, comprehension and voluntariness.
- J. Institutional Review Board (IRB)** – 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. The University of Texas Health Science Center at San Antonio Institutional Review Boards and National Cancer Institute Central Institutional Review Board are designated under the Health System’s Institutional Assurance as IRBs that review the largest percentage of research. The Health System relies on approval of research that was reviewed and approved only by an Institutional Review Board (IRB) at an institution that holds an FWA.
- K. 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.

- L. Investigator** – 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.
- M. Legally authorized representative** – 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.
- N. Noncompliance** – conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human subjects’ research. Noncompliance with IRB and /or federal requirements may involve a range of issues from relatively minor or technical violations which result from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff to more serious violations, which pose risk to subjects and /or violations of their rights and welfare.
- O. Non-Research** – activities that do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. Examples include quality improvement, health surveillance, and program evaluation.
- P. Non-Human Research** – conducted with the use of animal specimens, cadaver, left-over, de-identified specimens, or specimens/data from a repository (de-identified to recipient). These studies cross 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. Support of research for anatomical or animal specimens are specific types of non-human research.

**Q. Office for Human Research Protections (OHRP)** – 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.

**R. Protected Health Information** – 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 must 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.)

**S. Research** – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [See, 45 CFR 46.102(d) for a complete regulatory definition].

**T. Research Misconduct** – fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. To constitute research misconduct, the behavior must 1) represent a significant

departure from accepted practices of the relevant research community; 2) be committed intentionally, knowingly, or with reckless disregard for the integrity of the research; and 3) the allegation is proven by the preponderance of evidence. [See, 42 CFR 93.103-04 (2008) for a complete regulatory definition]

- U. **Research Committee** – 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.
- V. **Research Scope of Practice** – the duties and responsibilities of each investigator or study staff. Each individual is specifically authorized to conduct research involving human subjects with the responsibilities approved in conjunction with approved research protocols.

The Research Scope of Practice is governed by policies and procedures of the Health System. Research Scope of Practice is required for all non-licensed personnel credentialed by the Health System, residents and students (medical, nursing, allied health), research assistants, non-licensed physicians and other professionals, such as PhDs. Research Scope of Practice is not required for licensed personnel credentialed by the Health System (MD, RN, RRT, RPh, etc.) and Health System employees. Research Scope of Practice is documented within the Health System Research Protection Program to ensure that research personnel are qualified to conduct research in the Health System.

- W. **Retaliation** – 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.

- X. Serious Noncompliance** – non-compliance judged by the IRB to be a behavior that may adversely affect subject safety; increase risks to subjects (may also be an unanticipated problem); affect the integrity of the data (may also be scientific misconduct); violate the rights and welfare of participants; or affect the subject’s willingness to participate in research.
- Y. Specimen** – 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.
- Z. Study Staff** – individuals who 1) intervene or interact with subjects; 2) obtain identifiable private information about subjects; or 3) perform research activities and/or research procedures listed in protocol that have been identified by the investigator to the institutional review board and Health System.
- AA. University Health System (Health System)** – 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.
- BB. Vulnerable Populations** – individual subjects with limitations in mental capacity or voluntariness. They are likely to be vulnerable to coercion or undue influence, such as pregnant women, prisoners, children, mentally or decisional impaired, persons recruited or enrolled in emergent care settings, staff and students, or economically or educationally disadvantaged persons.
- CC. Whistleblower** – an individual whom makes a good faith allegation, as defined herein, or whom demonstrates an intent

to make an allegation (or what is perceived to be an allegation) while being a member of the institution at which the alleged scientific misconduct, non-compliance, serious non-compliance, unethical behavior occurred.

## **II. Organizational Structure and Responsibility for Human Subject Research and Non-human Research.**

The protection of human subjects within Health System facilities is the responsibility of the Health System. The University of Texas Health Science Center San Antonio Institutional Review Board (UTHSCSA IRB) provides review and continuity oversight as detailed in 45 CFR 46, 21 CFR 50 and 56. The investigators share responsibility.

### **A. IRB Responsibility**

1. The Health System assures that it will rely upon only IRBs registered with the Office of Human Research Protections (OHRP) and designated under an assurance of compliance approved for federal-wide use (i.e., an FWA) by OHRP. The UTHSCSA IRB serves as the primary IRB of record 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 IRB will review all human research that will be done at the Health System; and have the authority to approve, disapprove, or require modification in all human research activities, including proposed changes in ongoing, previously approved 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 IRB 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 requirements or that has been associated with unexpected, serious harm to subjects.
4. Research that has been approved by one of the IRB's 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. 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 must 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 policies.

## **B. Health System Responsibilities**

1. When the Health System is engaged in human subjects research it provides assurance to satisfactorily comply

with the Code of Federal Regulations for Protection of Human Subjects<sup>4</sup>, applicable Food and Drug Administration (FDA) regulations, the Health Insurance Portability and Accountability Act<sup>1</sup> and implementing regulations<sup>2</sup>, and applicable state statutes and regulations<sup>3</sup>. Institutional oversight for human subjects research and non-human research 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 Senior Vice President for Research and Information Management assumes on behalf of the Health System the obligations in the Institutional Assurance. As signatory for the Assurance he/she designates IRB's that review research covered by this institutions FWA and ensures that the Health System will maintain an institutional culture of respect for human subjects through establishment of human protections administration. The Senior Vice President provides effective institution-wide communication and guidance on human subjects research and requires investigators conducting research in the Health System to protect the rights and welfare of human subjects. He/she requires that staff engaged in conduct and oversight of human subjects research will complete mandatory educational training.
- b. The Senior Vice President for Research and Information Management 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 must have responsibility for supervision of the Clinical Research Director and the Health System Research Department and must 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 Senior Research Director and 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 Senior 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. The Clinical Research

Director is the point of contact for notification of unanticipated problems in research regarding serious or continuing non-compliance, suspension or termination of research allegations of scientific misconduct. The Clinical Research Director is delegated authority to take immediate action to protect safety of human subjects at 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.
  - 1) Review of research protocols
  - 2) Human protections administration program
  - 3) Emergency research drugs and devices
  - 4) Procedures for Non-human Research
  - 5) Fiscal management of research
- 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. Additional safety evaluation of each protocol may lead to additional required protections prior to implementation. 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. Non-human 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.

### **C. Medical-Dental Staff Responsibilities**

1. The Research Committee shares in the oversight responsibility for all human subject and non-human 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.
2. 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 non-human 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 review studies for monitoring focused on risk and vulnerable populations. Based on the

risk assessment the committee will recommend additional monitoring, protections or could recommend that study not be considered at University Healthy System. 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 non-human research.

3. A designated subcommittee will review conflict of interest disclosures for the 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. Investigators and study staff from the UTHSCSA, Veteran's Administration, and the Health System will complete the integrated Research Scope of Practice and obtain approval for requested roles and responsibility from appropriate clinical site(s).
3. All principal investigators and their co-investigators that are not employed by the Health System will be credentialed by Medical-Dental Staff prior to implementation of research study. The Health System 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 Research Scope of Practice to the institution. Each will sign a confidentiality statement. Health System employees must complete departmental competencies if supporting or implementing a research protocol in their area.
4. Investigators and their study 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 Health System employees implementing a research protocol in their 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. 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. 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.
  6. 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 of this policy, an investigator may not involve a human being as a subject in research unless a legally effective informed consent from the subject or the subject's legally authorized representative is obtained. An investigator or research employee/staff is specifically authorized to perform this duty/responsibility; i.e. the informed consent within their Research Scope of Practice. They will 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 must 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.<sup>1</sup>
2. Appropriate documentation of informed consent per federal regulations is required unless an exception to the

documentation requirement has been approved by IRB.

3. An IRB must 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.<sup>2</sup>

#### **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.<sup>3</sup>
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.<sup>4</sup>
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.<sup>5</sup>

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.<sup>6</sup>
5. The informed consent requirements in 45 CFR 46.116 and 46.117 are inapplicable to research that is deemed "exempt" under applicable federal regulations.<sup>7</sup>

### **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 law<sup>8</sup>. 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
  - 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 and Health System policies.

#### **D. Conflicts of Interest**

1. Investigators and study staff must comply at all times with the Health System's Policy No. 2.12, Conflicts of Interest. Any actual, or potential, conflict of interest with respect to any proposed or ongoing research for which an investigator has responsibility must be disclosed by completing and submitting the Disclosure Statement Form to Integrity Services prior to implementation of any

research protocol. This duty of the investigator and study staff is an ongoing duty that exists through the term of the research, and any conflict of interest that arises after the research has been implemented must be reported to Integrity Services.

2. Health System staff paid by grant funds and assigned to design, conduct, or report research must also comply with the Health System's Policy No. 2.12, Conflicts of Interest Policy.

#### **E. Research Misconduct**

1. The 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 the Health System to the Clinical Research Director and/or members of the Research Committee.
3. Any actual, potential, or suspected significant misconduct must be reported to the Health System's Integrity Officer in accordance with the Health System's Policy No. 2.13, Reporting Errors and Incidents of Misconduct Policy, which outlines specific guidelines and reporting channels, to include the integrity hotline toll free number 1-877-225-7152. Integrity Services will investigate research

misconduct and will provide a fair and objective procedure for examining and resolving complaints, disputes and allegations of research misconduct and will limit disclosure of the identity of those reporting complaints of misconduct to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. Integrity Services will share its determinations and findings with appropriate collaborators, peer review boards and Health System Professional Staff Services and must take appropriate actions in concert with collaborators to inform publishers, grant funding agencies and other associates of the research of misconduct findings.

4. The Health System believes in the importance of protecting whistleblowers who make good faith allegations of research misconduct as defined in this policy. The Health System will not tolerate or engage in retaliation against good faith whistleblowers.

All whistleblower retaliation complaints will be taken extremely seriously and will be thoroughly investigated by Integrity Services upon written receipt of a retaliation complaint which must include a description of the whistleblower's scientific misconduct allegation and the asserted adverse action, or threat thereof, against the whistleblower. Integrity Services will timely conduct an independent investigation as to the basis of the retaliation complaint, and based upon its findings, will take any appropriate action.

5. Medical-Dental Bylaws Article VIII outlines Criteria for Initiation for Corrective Action: Whenever any practitioner, allied health professional or any other individual with clinical/research privileges engages in, activities or professional conduct, that is, or is reasonably likely to be detrimental to patients' safety, to the delivery of appropriate patient care, disruptive to Hospital operations, in disregard of the Staff Bylaws or the Staff Rules and Regulations, or Hospital policies, corrective action against such person may be requested by the Chair of any clinical department or standing Staff committee, or by the Chief Executive Officer.

#### **IV. Elements of Safety and Ethics in Conduct of Non-Human Research**

- A. Anatomical Specimens examined within clinical departments at University Health System 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 Board<sup>9</sup> 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 Health System clinical laboratory prior to being transported to Health System 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. Health System staff have the right to refuse participating in the testing of the specimens.

- C.** Only specimens from animal research will be tested at Health System 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.
- F.** Non-human research may involve non-identifiable private information such as de-identified left-over specimens. Data use agreements are established as appropriate.

#### **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 or online at  
[www.imc.gsm.com/demos/dddemo/consult/belm\\_all.htm](http://www.imc.gsm.com/demos/dddemo/consult/belm_all.htm))

Engagement of Institutions in Research [hhs.gov/ohrp/policy/engage08.html](http://hhs.gov/ohrp/policy/engage08.html)

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

"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, September  
24, 2013

Dunn, Cynthia and Chadwick, Gary. "Protecting Study Volunteers in Research," CenterWatch, Inc. 2012.

**University Health System Policies:**

- 7.09, Fiscal Management of Research Protocols
- 2.12, Conflicts of Interest
- 2.13, Reporting Errors and Incidents of Misconduct
- 2.14, Health Assurance and Portability and Accountability Act (HIPAA) Compliance Program Policy
- 2.14.01, Uses and Disclosures of Protected Health Information

**OFFICE OF PRIMARY RESPONSIBILITY:**

**Senior Vice President, Research and Information Management**

**ENDNOTES:**

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<sup>1</sup> 45 CFR 46.116.

<sup>2</sup> 45 CFR 46.109(b)

<sup>3</sup> 45 CFR 46.116(c)

<sup>4</sup> 45 CFR 46.116(d)

<sup>5</sup> 45 CFR 46.117(c)

<sup>6</sup> 61 Fed. Reg. 51531-51533 (attached as Appendix II)

<sup>7</sup> 45 CFR 46.101

<sup>8</sup> See HIPAA regulations, 45 CFR 164.512(i), and Texas Health & Safety Code §181.101 et seq.

<sup>9</sup> Texas Health & Safety Code Ann. § 691.001, et seq (West Supp. 2005)