

TITLE: SUBMISSION AND REVIEW OF PROPOSAL FOR RESEARCH PROTOCOL APPROVAL

PURPOSE: To outline the policy and procedure for submission, review and approval of research conducted within the University Health System. This is a revised departmental policy and supersedes policy dated 4/10/03. [Key Words: Research Proposals, Health System Approval, Institutional Assurance, Conditions]

POLICY STATEMENT:

It is the policy of University Health System that all research conducted within the Institution and departments providing individual support be reviewed and approved by the Research Department. The Health System will evaluate and determine the extent of its support for each proposed research protocol with consideration for compliance with IRB requirements, state and federal regulatory requirements, for the protection of human subjects, and the feasibility of providing the services or facilities requested the financial impact of participation. The Health System may disapprove any proposed research based on its evaluation.

POLICY ELABORATION:

I. DEFINITIONS

- A. “Research Projects Coordinator” is the individual responsible for coordinating the review of proposed research studies within the University Health System and serves as the liaison between the Health System and investigators wishing to conduct studies within its facilities. The Research Projects Coordinator is the primary contact to facilitate research.
- B. “Investigator” is an individual who assumes responsibility for conducting a research study to develop or contribute to generalizable knowledge.
- C. “The Institutional Review Board (IRB)” is a committee established to protect the rights and welfare of human research

subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

- D. “Institutional Assurance” is the documentation of an institutional commitment to comply with Federal regulations and maintain adequate programs and procedures for the protection of human subjects. The principal mechanism for compliance oversight is by the Office for Human Research Protections. (OHRP).
- E. “Research Pharmacist is a Registered Pharmacist in the Pharmacy Department who manages Investigational Drug Studies (IDS).
- F. "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium (including demographic information that is collected from an individual) that (1) relates to the past, present or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual, and (2) identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. “Protected Health Information” or "PHI" 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 University Health System as a covered entity or any Affiliated Covered Entity in its role as employer.
- G. “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.

- H. Financial Category A: Patient seen/admitted for medically indicated care but participating in research. The patient's insurer/patient is responsible for the costs of care including physician fees excluding that which is research and the cost of the research is the responsibility of the grant.
Financial Category B: Patient / subject seen / admitted for research. The patient/subject is not responsible for any costs. All costs are the responsibility of the grant.
- I. "The Research Department" through its Clinical Research Director, is responsible for developing and implementing a Human Protections Administration program and management of the billing for research with the assistance of the Financial Accounting Department.
- J. "Clinical Research Director" is the head of the Health System Research Department who acts as the Human Protections Administrator (HPA) by serving as the OHRP's primary institutional contact person. The Clinical Research Director has administrative responsibility for the human protections program within the Health System.

II. SUBMISSION OF PROPOSALS

- A. All Principal Investigators and Co-Investigators performing clinical functions, as defined in the Scope of Practice (Scope of Practice Attachment VII) must be credentialed by the Medical-Dental Staff prior to implementation of a research study. Research Personnel working under the Principal and Co-Investigators that are not involved in direct patient care or a Residents and Faculty member performing research as part of their appointment will not be required to obtain credentialing privileges through the Medical-Dental Staff Office. University Health System Staff performing research on employees or employees performing administrative duties will not be required to obtain credentialing privileges.

(Confidentiality Statement Attachment V)

- B. A research proposal should be submitted to the Health System only after the final written IRB approval. All consent documents, in English and Spanish (if the IRB requires a Spanish language translation) must be approved by the IRB. All HIPAA related acknowledgments and/or waivers of acknowledgement for use and disclose of Protected Health Information (PHI) must also be approved by the UTHSCSA IRB. No research will be conducted without all these requirements being met and copies of these documents forwarded to the Health System Research Department.
- C. Prior to initiation of any research within the Health System, the Investigator is required to submit an application to perform research at the Health System to the Research Department. This will include a protocol and abstract with other applicable documents to the Research Department (Guidelines for Research Posters Attachment IX). This submission can be hard copy or submitted electronically to research@university-health-sys.com These documents include:
1. Proposal for Research Protocol Approval Form (Attachment I)
 2. Abstract/Summary (Research Committee Review)
 3. Drug Form (BCHD#7-516) (Attachment II) (Research Protocols that require an investigational drug, including those drugs being studied off label, will submit an Investigational Drug Information form)
 4. Device Form (Attachment III)
 5. Cover for Consent Form (BCHD#7-455) (Attachment IV) (For each University Health System patient enrolled in the study a Cover Sheet for Research Consent must be completed and attached to the signed consent document)

6. IRB Approval Letter (Scanned or paper copy)
 7. Consent document bearing an IRB stamp and Spanish language consent document (if required by IRB) (Scanned or paper copy)
 8. Confidentiality Agreement (Attachment V)
 9. Assurance/Supplemental conditions (Attachment VI)
Scope of Practice (Attachment VII)
 9. Physician Order sets (Attachment VIII)
- D. The submission documents can be located on the Research Department Website. The intranet address is <http://home/research/default.html> or the internet address is <http://www.universityhealthsystem.com/research/default.html>
Paper copies of these instructions and required forms may also be obtained from the Research Department.
- E. Devices being purchased by the University Health System and **not** being reimbursed by the investigator/research project will be required to go through the Physician Product Evaluation Committee prior to approval (Product Evaluation Attachment X). The Investigator can obtain paperwork from the website or paper copies from the chair of the Product Evaluation Committee. Forms should be submitted to the Product Evaluation Committee two weeks prior to their monthly meeting date. All devices utilized for direct patient contact entering the Health System to include those that are supplied by vendors/sponsors and those that go through the Product Evaluation Committee will need to go through Biomedical Engineering for clearance prior to use within the University Health System facility. (See Quality Risk Management policy section 5.07 Attachment VI section II and III)

III. REVIEW PROCESS

- A. The Research Projects Coordinator will review the protocol and submit it to the Director (or designee) of each department and to the Clinical Nursing Director (or designee) of each nursing unit where institutional support is requested (Protocol Process Attachment XI). The Research Projects Coordinator will provide an electronic or hard copy of the research protocol to the Medical Director of each participating department and nursing unit. Reviewers with questions about protocols being reviewed are encouraged to communicate directly with the investigator for clarification and to resolve any other issues.

- B. Each Department Director or Clinical Nursing Director will determine and provide to the Research Projects Coordinator within 10 working business days:
 - 1. The feasibility of his/her department/nursing unit's participation.
 - 2. Any conditions or limits that will be placed on that participation.
 - 3. The expected cost/revenue associated with any participation in the research project beyond that which is required for the routine care of the patient to include additional labor costs.
 - 4. For Financial Category B, the expenses for bed costs, supplies, staff time, tools and equipment and miscellaneous charges related to the study.
 - 5. Charges cannot be less than the *actual costs* to the Health System. (Research fee schedule is set by director for their department areas. Fee schedules are accessible on the research home page.)

6. Whether to recommend approval or disapproval based on the financial impact of participating in the study.
- C. If a Director's response is not received within 10 working business days, the Research Projects Coordinator may notify the Associate Administrator by email. The Associate Administrator may contact that individual or their supervisor regarding the delay in response. The Research Department will track all responses in the Research Departmental database.
 - D. All research protocols involving investigational drugs are reviewed by University Health System Research Pharmacist. If University Health System pharmacy services are not required the Research Pharmacist will indicate that statement in his/her review. The Investigator must make arrangements with the Research Pharmacist for the initial visit from the sponsoring drug company prior to initiation of study. This appointment will be made through the website. The study will not be initiated until this initial visit is completed. The Research Pharmacist is available to assist offsite pharmacists or investigators with initial set up and handling of drugs. The Research Pharmacist should be contacted directly if such help is required.

IV. APPROVAL PROCESS

- A. The administration of the University Health System reserves the right to disapprove the implementation of any research protocol and to suspend or revoke its prior approval if the Research Department or Health System Administration determines it is in the best interest of the Health System, its patients and/or staff to do so.
- B. The Research Projects Coordinator will provide a summary of the study, the recommendations of the reviewers, and other information relevant to the impact of the study on finances and resource utilization at the Health System. Based on this summary the study will provide written documentation.

- C. Study related expenses negotiated by the investigator and the various departments and agreed to by the Directors of the associated departments will be outlined in a contract prepared by the Research Projects Coordinator, written by Legal Services. (Attachment Template Contract XVII). This agreement outlines research related expenses to the investigator. (1) Disapprove based upon recommendations; (2) Approve with no service charges required; (3) Approve with contracted services. The designated Health System Administrator and the head of grants management or other designated official will sign for the UTHSCSA. The designated official will sign for the Health System and UTHSCSA respectively. (Attachment Template Letter XV /Attachment Template Contract XVII)
- D. The Investigator must review and sign The University Health Systems Institutional Assurance. Supplemental Conditions will agreed to with this Assurance.
- E. Departments' Directors, Clinical Nursing Directors and other Health System staff that may be involved or may be called upon to assist in the implementation of the study will be sent a copy of the an internal memorandum stating the same information regarding the study as the Investigators Agreement by electronic mail.
- F. The status of all studies can be checked at the UHS Research Department website. Throughout the study Investigators should check this database to see the status of their study as expiration of approval from the IRB/UH will lead to termination of computer access, medical records access and billing access.
- G. The approval of the Health System is automatically suspended at any time the IRB's approval expires or is suspended.
- H. Studies requiring monitors will register for Health System badges at the Department. Monitoring visits will be requested on the website. (Monitor Workflow Attachment XXI)

- I. Clinical trial studies will be provided copies of “Participating in a Clinical Trial” for distribution of UHS Research Volunteers.

V. GENERAL RULES FOR CONDUCTING RESEARCH AT THE HEALTH SYSTEM

- A. All Investigators are expected to abide by the Agreement, University Health System Institutional Assurance and Supplemental standards while conducting research at the Health System.
- B. The Department of Research, the Integrity Office, Financial Accounting and the Privacy Officer are available to assist investigators with any questions or issues that arise during the study.
- C. Fiscal Management issues should be directed to the Research Department for initial management. The Department will work with Financial Accounting to assure that invoices are correct.

REFERENCES/BIBLIOGRAPHY:

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

University Health System Policy DRAFT “Fiscal Management of 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.

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Effective Date: 4/11/06

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.