Addendum A
Supplemental Conditions for Institutional Assurance

This Addendum to Institutional Assurance provides mandatory terms and conditions for the performance of research activities conducted by Principal Investigator ("PI") and its research staff using the University Health System ("Health System") services and/or facilities. This Addendum is attached to and made a part of the Institutional Assurance document for the approved IRB protocol. The PI shall execute the Institutional Assurance document and this Addendum prior to initiation of research activities.

1. RECORDS RETENTION. PI agrees to provide Health System and federal, state, and local governmental authorities having jurisdiction, upon request, access to all books, records and other papers (including, but not limited to, medical and financial records) and information relating to this Agreement and to those services rendered by PI pursuant to this Agreement, and to maintain such books, records, papers and information for the longer of six (6) years after termination of this Agreement, or the period required by applicable state law. All requested information shall be supplied within fourteen (14) business days of the receipt of the request, where practicable.

2. EMPLOYMENT OF PERSONNEL. PI agrees to employ, at its own expense (or shall have employed by and at the expense of a third party), all personnel (referred to hereinafter as "PI Research Staff") required in performing the research services under this Agreement. PI Research Staff employed by PI (or a third party) shall not be employees of, nor have any contractual relationship with the Health System and any and all claims that may arise from the Workers Compensation Act on behalf of said PI Research Staff while so engaged, and any and all claims made by any third party as a consequence of any act or omission on the part of PI Research Staff (or the third-party employer's) employees while so engaged in any of the work or services provided to be rendered herein, shall be the sole obligation and responsibility of PI (or the employing third party). All PI Research Staff engaged in the research shall be fully qualified and shall be authorized or licensed to perform such work as required. This relationship does not create an employment relationship, partnership, or joint venture between the PI, its subcontractors or employees (or the employing third party) and the Health System. Neither the PI nor its subcontractors or employees (or the employing third party) shall be deemed employees of the Health System for any purpose whatsoever, and neither shall be eligible to participate in any benefit program provided by the Health System.

3. COVENANT AGAINST CONTINGENT FEES. The PI warrants that no person or selling agency has been employed or retained to solicit or secure this research assignment upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the PI for the purpose of securing business. For breach or violation of this warranty, the Health System shall have the right to terminate the relationship without liability or at its discretion, to deduct from the contract price or consideration, or otherwise recover, the full amount of such commission, percentage, brokerage, or contingent fee.

4. COMPLIANCE WITH LAWS AND REGULATIONS. PI shall comply, and upon request, PI shall submit evidence of such compliance, with all State and federal certifications, regulations, or licensure requirements pertaining to the services provided hereunder. Evidence of such compliance shall be submitted to the Health System consistent with applicable JCAHO standards. PI agrees to give immediate notice to the Health System in the case of suspension or revocation, or initiation of any proceeding that could result in suspension or revocation, of licensure or of any circumstance that would cause PI to be noncompliant with any such statutes, rules, regulations, standards, or directives. Further, PI shall provide all services in accordance with applicable Medicaid and Medicare requirements.

5. CONFIDENTIAL INFORMATION. PI acknowledges that, in connection with the services to be performed under the research protocol by PI and PI Research Staff, PI and PI Research Staff may acquire and make use of certain confidential information of the Health System which includes, but is not limited to, management reports, financial statements, internal memoranda, reports, patient lists, and other materials or records of a proprietary nature ("Confidential Information"). Therefore, in order to protect the Confidential Information, PI and PI Research Staff shall not after the date hereof use the Confidential Information except in connection with the performance of services pursuant to the approved research protocol, or divulge the Confidential Information to any third party, unless the Health System consents in writing to such use or divulgence or disclosure is required by law.

6. CONFIDENTIAL PATIENT INFORMATION. PIs who will have access to patients and patient records shall adequately instruct all personnel on PI Research Staff that may provide research services pursuant to the research protocol, regarding the confidentiality and privacy of patients and patients' medical records. All such instructions shall be in accordance with the formal policies and rules of the Health System and with all federal and state laws and regulations regarding patient and medical record confidentiality. PI assumes full responsibility for any breach of confidence by PI Research Staff with regard to the access to confidential patient information.

7. NO THIRD PARTY BENEFICIARIES. Nothing in herein, express or implied, is intended or shall be construed to confer upon any person, firm or corporation other than the parties hereto and their respective successors or assigns, any remedy or claim under or by reason of this document or any term, covenant or condition hereof, as third party beneficiaries or otherwise, and all of the terms, covenants and conditions hereof shall be for the sole and exclusive benefit of the parties hereto and their successors and assigns.

8. REPORT OF FRAUDULENT ACTIVITIES. PI understands and acknowledges that PI and PI Research Staff have an affirmative duty to report to the University Health System Integrity Office any suspected or known "fraudulent activities" that may come to their attention. "Fraudulent Activities" shall have the same meaning as defined in University Health System Policy No. 2.10 "Fraud" as may be revised or amended from time-to-time. A copy of Policy No. 2.10 shall be available from the Purchasing Department or the Integrity Office on the 1st Floor of University Hospital. PI and PI Research Staff may at its option choose to report Fraudulent Activities through the Integrity Hotline 1-877-225-7152.

9. INSURANCE. The UTHSCSA non-physician employees providing services pursuant to this Agreement (including Principal Investigator) will have liability coverage to the extent provided in Chapter 104 of the TEXAS CIVIL PRACTICE AND REMEDIES CODE. Pursuant to Chapter 59 of the TEXAS EDUCATION CODE, the UTHSCSA shall provide and maintain at its own expense, medical professional liability indemnity coverage for its faculty. The UTHSCSA shall provide the Health System with a current copy of such coverage, annually, and give the Health System thirty (30) days prior written notice of any material change or cancellation in such coverage. Any persons performing research that are not employed by the UTHSCSA shall provide and maintain, at its own expense, the following types and amounts of insurance for the term of the research:

TYPE	AMOUNT
Worker's Compensation	Statutory Amount
Professional Liability (if applicable)	$200,000 each occurrence $600,000 aggregate

With respect to the above insurance the Health System shall:

(a) Be provided with thirty (30) days advance notice, in writing, of cancellation or material change.

(b) Be provided with a copy of the insurance policy(ies) in effect for all subcontractors evidencing the above requirements prior to commencement of the research.

(c) Be provided written evidence of professional liability coverage to cover claims based on acts or omissions that occurred during the term hereof, for any professionals rendering

patient care services. Such professional liability coverage shall include “tail” coverage of the same limits as stated above for any “claims-made” policy as necessary to continue coverage until any applicable statute of limitations has expired.

10. VENUE and APPLICABLE LAW. The parties agree that venue for any litigation arising from this relationship shall lie in San Antonio, Bexar County, Texas. This relationship shall be governed by the applicable laws of the State of Texas.

11. DATA USER AGREEMENT. During the performance of the research, the PI will receive from the Health System, certain confidential health or medical information ("Protected Health Information" or "PHI" as further defined below). This PHI is subject to protection under and it is the intent of the parties to be in full compliance with state and federal law, including the Health Insurance Portability and Accountability Act, Texas Health and Safety Code Chapter 181, and implementing regulations issued pursuant thereto (collectively "HIPAA" herein). The provisions described in this section are intended to comply with requirements for establishment of a Data Use Agreement between the parties, securing satisfactory assurances that the PI and all PI Research Staff will only use or disclose the PHI for limited purposes related to research, public health and healthcare operations. The PI shall ensure that only approved PI Research Staff have access to PHI and the Limited Data Set, and that PI and PI Research Staff comply with all provisions described herein.

(a) **Definitions.** Capitalized terms in this Article have the same meaning set forth in HIPAA. Without limitation:

(1) "Data User" means anybody that is receiving PHI through a Limited Data Set pursuant hereto.

(2) "Limited Data Set" means PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
- (i) Names;
- (ii) Postal address information, other than town or city, State and Zip Code;
- (iii) Telephone and fax numbers;
- (iv) e-mail addresses;
- (v) Social security, medical record, account or health plan beneficiary numbers;
- (vi) Certificate/license numbers;
- (vii) Vehicle identifiers and serial numbers (including license plate numbers);
- (viii) Device identifiers and serial numbers;
- (ix) Web Universal Resource Locators (URLs);
- (x) Biometric identifiers (including finger and voice prints); and
- (xi) Full face photographic images and any comparable images.

(3) "Protected Health Information" or "PHI" means generally, any information, whether oral or recorded in any form or medium 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.

(b) **Scope of Prohibited Use of Protected Health Information.**

(1) The Data User shall not:
- (i) use or otherwise disclose PHI except as permitted or required pursuant to the approved research protocol referenced in the Institutional Assurance Document to which this is attached;
- (ii) use or otherwise disclose PHI for purposes independent of helping the Health System carry out its health care functions; or
- (iii) notwithstanding any other provisions of this Agreement, use or disclose PHI in any manner that violates or would violate HIPAA if such activity were engaged in by the Health System.

(2) In addition to (1) above, the Data User shall not:

(i) use or allow receipt of the Limited Data Set by anyone other than authorized persons performing services directly authorized pursuant to this Agreement;

(ii) use or otherwise disclose the Limited Data Set for purposes other than research, public health and healthcare operations;

(iii) re-identify the source data (such as, without limitation, discovering any of the direct identifiers described in the definition of Limited Data Set); or

(iv) contact the individuals, the subjects of the Limited Data Set.

(c) **Safeguards for the Protection of PHI.** The Data User has implemented and maintains, and by signature hereto, warrants that it will continue to implement, such safeguards as are necessary to ensure that the PHI is not used or disclosed by the Data User or PI Research Staff except as provided herein.

(d) **Reporting Of and Corrective Action Related To Unauthorized Use or Disclosure.** The Data User shall report to the PI (if the Data User is not the PI) and the PI shall report to the Health System any known use or disclosure of PHI or other Confidential Information not permitted or required herein, or any actual or suspected breach of security or intrusion, within 3 business days of such use, disclosure or breach and shall permit the Health System to investigate any such report and to examine the Data User's premises, records and practices and interview/examine personnel. The PI shall take prompt corrective action to cure any such deficiencies and any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations.

(e) **Use of Subcontractors.** To the extent that the PI uses one or more subcontractors or agents to provide services hereunder (Data Users other than the PI may not engage subcontractors or agents), the PI shall ensure that any agents, including subcontractors, agree to the same restrictions and conditions that apply to the Data User with respect to such information, and that such subcontractors and/or agents further sign an agreement with the PI containing substantially the same provisions as this Article and identifying the Health System as a third party beneficiary with rights of enforcement and indemnification from such subcontractors and/or agents in the event of violation.

(f) **Uses of Open Communication Channels; Encryption.**

(1) The Data User may not transmit PHI over the internet or any other insecure or open communication channel unless such information is encrypted or otherwise safeguarded using procedures no less stringent than those required by the Health System.

(2) If the Data User stores or maintains PHI in encrypted form, the Data User shall, promptly at the Health System's request, provide the Health System with the key or keys to decrypt such information.

(g) **Effect of Termination.** Data User shall extend the protections of this Agreement and HIPAA to the PHI and shall limit further uses and disclosures for as long as PHI is possessed by Data User and not otherwise returned to the Health System or destroyed.

12. INJUNCTIVE RELIEF. The parties agree that violation of any of the provisions contained in this Addendum would result in irreparable harm to the Health System.

13. SURVIVAL OF TERMS. The obligations of the parties relative to, and the provisions contained in, this Addendum shall survive termination and be ongoing.