Form A

HUMAN USE RESEARCH

SIGNATURE ASSURANCE SHEET

Study Title:	

Principal Investigator's Assurance Statement:

I understand my institution's policies concerning research involving human subjects and the IRB's policies for protection of human subjects. I will:

- protect the rights, safety and welfare of the subjects involved in this research
- ensure research is conducted in an ethical manner and in accordance with all laws, regulations, or policies applicable to the protection for human research subjects and requirements and determinations of the IRB
- personally conduct or oversee those who conduct this research
- supervise study personnel to whom tasks are delegated. Ensure that study personnel: 1) are qualified by training and experience and licensure to perform study-related tasks that have been delegated to them; 2) have an adequate understanding of the research; and 3) follow the IRB-approved protocol, including the recruitment and consent procedures described in the protocol summary
- ensure that study subjects are provided with: 1) reasonable medical care for any adverse events, including clinically significant laboratory values, related to the research; 2) a qualified contact to answer questions or provide care during the conduct of the research; and 3) the study plan is followed, such as inclusion/exclusion criteria, safety assessments, safety monitoring and reporting of unanticipated problems, and procedures to protect privacy of subjects and confidentiality of identifiable data, in order to minimize risks to subjects
- obtain, document, and maintain records of informed consent from each subject or when approved by the IRB the subject's legally authorized representative using the consent document(s) approved by the IRB
- conduct the research in accordance with the protocol approved by the IRB
- initiate changes in the research, including the approved consent form(s), only after IRB approval, except where necessary to eliminate apparent immediate hazards to subjects
- report promptly to the IRB and to the subjects, any significant findings or new information that becomes known in the course of the research that might change the risk of or justification for the research or may otherwise affect the willingness of subjects to participate or to continue to participate in the research
- report promptly to the IRB, any unanticipated problems involving risks to subjects or others in research
- operate within the parameters that have been defined in the authorization portion of the consent regarding Protected Health Information (PHI)
- comply with all applicable FDA regulations, including the Good Clinical Practices Guidelines, and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 & 812
- control drugs, biological products, and devices used for research purposes
- submit a progress report for continuing review prior to expiration of IRB approval in accordance with UTHSCSA Policy;
- halt all research activities should IRB approval lapse, until the IRB re-approves the research or until special permission is obtained from the IRB to continue previously enrolled subjects if determined to be in their best interests to do so
- promptly submit a final report when the research has been completed or is being closed out prior to completion
- maintain adequate and accurate research records in accordance with institutional and, when applicable, the sponsor or FDA requirements

FORM A
SIGNATURE ASSURANCE SHEET

Completion of Section 1, Section 2, & Section 3 is REQUIRED. Complete Section 4 if PI is in an academic program.

Section 1	
Study Title:	
Select the type of signatures provided: *(select the signature options below that apply)*	**Method of Submission**
☐ **Option A.** A **scanned copy** of an original signature	Print, obtain signatures, then scan and submit an **electronic (PDF) file** of this signed form
☐ **Option B.** **Electronic signature** applied to this document	When final digital signature is applied, lock the document & submit this Adobe Acrobat version.

Section 2: Principal Investigator's Assurance Statement: I understand my institution's policies concerning research involving human subjects. I understand the IRB's policies for protection of human subjects. I have read and understand my institution's policy on conflict of interest or commitment. I understand it is my responsibility to ensure that others engaged in this research report any potential conflicts of interest or commitment.

P.I. SIGNATURE: →_____ **DATE:**_____

P.I. NAME (typed)**:** _____

>> **If there is a Co-P.I., a justification for sharing the PI responsibilities must be attached to the proposal & s/he must sign below:**

Co-P.I. SIGNATURE: →_____ **DATE:** _____

Co-P.I. NAME (typed)**:** _____

Section 3: Department Chairperson's/Division Chief's (or equivalent) Assurance Statement: This is to certify that I have reviewed this research protocol and that I attest: to the soundness of the design and its ability to answer the research questions; to the competency of the investigator(s) to conduct the project; and to the presence of sufficient resources required for the research and for protecting research participants' safety. **Due to concerns of a potential conflict of interest, if the Department Chair is the PI, this section will need to be signed by a deputy chair/division chief or equivalent.**

I confirm that the principal investigator is either: (choose one)
☐ An employee or agent of this institution (the Chair's/Division Chief's institution) **OR**
☐ Not an employee/agent of this institution (the Chair's/Division Chief's institution) and I support extending the institutional assurance to this investigator *(submit a signed* IIA *[Individual Investigator Agreement])*
The Chair's/Division Chief's Institution is:
☐ UTHSA; ☐ STVHCS; ☐ University Health; ☐ CSRHC; ☐ TBRI; ☐ SWRI; ☐ Other:

Chair/Division Chief SIGNATURE: _____ **DATE:** _____

Chair/Division Chief Name (typed): _____

Chair/Division Chief email (if not UTHSA): _____

Section 4: Academic Program Information Complete the following *if the PI is in an academic program*:

- Specify PI's academic program (e.g. resident) _____ and Date Academic Program Ends:_____
(The protocol's expiration date will be based on this date.)

- And include the signature of the PI's Faculty Advisor (or Mentor):

Faculty Advisor's Assurance Statement: I have reviewed this protocol and attest to its scientific merit and the competency of the PI. I will provide guidance as appropriate.

Advisor SIGNATURE: _____ **DATE:** _____

Advisor Name (typed): _____