A. *UTHSCSA specific module will contain information/policies including but not limited to:*

1. Links to
   a) [Belmont Report](#)
   b) [UTHSCSA IRB website](#)
   c) [Declaration of Helsinki](#)
   d) [Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46)](#)
   f) [OHRP Human Subjects Document Library](#)

2. An agreement including statements consistent with the following that the researcher must agree to in order to complete the training:
   a) Individuals engaged in research are responsible for
      
      (1) protecting the rights and welfare of research participants and others associated with the study.
      
      (2) understanding the ethical standards and regulatory requirements governing research activities and complying with all applicable human research and privacy regulations (e.g., use and disclosure of protected health information and confidentiality) and the provisions of their institution's Assurance (including but not limited to meeting requirements for Medical-Dental Staff privileges and provide a signed Scope of Practice, if required). (For some sites additional forms (e.g., self study orientation form, supplemental conditions form and even possibly a separate protocol) may need to be completed)
(3) ensuring that no portion of the research work that involves a human subject is started without prior written approval from the Institutional Review Board (IRB). [Note this does not included emergency medical care: a physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see Section 116[f]). However, such activities will not be counted as research nor the data used in support of research.]

(4) maintaining written records related to the study including IRB reviews and decisions. These records are subject to review by the appropriate federal, state and institutional authorities. Copies of certain documentation (e.g., protocols, ICD’s, advertising, annual reports, final reports) may be required by appropriate institutional officials of affiliated institutions.

(5) obtaining valid (as applicable by DHHS, FDA, JCAHO, HIPAA) informed consent and authorization under HIPAA of subjects before the subject is involved in the research, if applicable. Provide a copy of the IRB-approved and signed informed consent document/HIPAA authorization to each subject at the time of consent, if applicable. [Note: applicable unless the IRB has specifically waived or approved alteration of these requirements].

(6) using the currently approved (stamped by the IRB with an approval and expiration date) consent form (in studies where consent forms are required). (Some affiliated institutions may require a local copy of the consent form in all languages approved.)

(7) ensuring unlicensed research personnel working as research coordinators or research fellows (excluding those in an ACGME approved program) do not use their educational degree after their signature on Institutional Review Board approved consent forms or on Research Staff Contact lists although they may obtain informed consent if competency verification has occurred on the Research Scope of Practice form.

(8) maintaining all signed consent documents in a manner approved by the Office of the Institutional Review Board (OIRB).
(9) obtaining the appropriate HIPAA waiver prior to a record review or database search to identify potential subjects. Appropriate accounting for disclosure is the responsibility of the institution/covered entity. Research personnel may be required to place a copy of the waiver in each record reviewed if under 50 records especially if the researcher is not allowed to record identifiable information as part of the research.

(10) recording consent for research in the patient’s inpatient and outpatient record (as appropriate) as defined by the institution’s policy.

(11) reporting proposed changes in previously approved human subject research activities to the IRB, through the OIRB. The proposed changes will not be initiated without prior approval, except where necessary to eliminate apparent immediate hazards to the subjects.

(12) monitoring deadlines and submit a fully completed Progress Report to IRB prior to expiration of the study approval.

(13) monitoring subject safety or ensuring mechanisms for safety monitoring are in effect (some involved institutions may have specific requirements for a medical monitor to be able to access the facility, making the principal investigator responsible for lost badge replacement fees, etc.)

(14) ensuring the confidentiality and security of all information obtained from and about human subjects.

(15) submitting a final report when the study is complete.

(16) prompt reporting to the IRB (and other applicable agencies) any unanticipated problems involving risks to subjects and others.

(17) following applicable Food and Drug Administration (FDA) regulations for all research involving drugs, biologics and medical devices.

(18) if the individual is the principal investigator they are responsible for the entire study and all research personnel (e.g., including staff adherence to policies and procedures of the
institutions involved – department and unit policies can be accessed via internet)

(19) disclosing all requirements of research studies that could result in charges being generated that are not standard care and those expected to be paid by the study sponsor. Agreements may be required by affiliated institutions where charges are to be generated.