

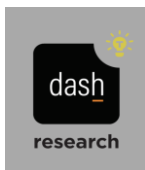
PRINCIPAL INVESTIGATOR RESPONSIBILITIES AND CHAIRMAN APPROVAL

In submitting a *Single or Multi-Site & External SmartForm* or a revision to include a new investigator via the *Modification and Continuing Review SmartForm* for approval by your local IRB, as PI you agree to assume the following responsibilities and to faithfully execute them in accord with applicable federal regulations for the protection of human subjects and your local IRB policies and procedures:

- A. To conduct the research according to your local IRB-approved protocol.
- B. To obtain and document the informed consent and/or assent of subjects or subjects' legally authorized representatives, using your local IRB approved informed consent process and documents, prior to the subjects' participation in any research procedures, unless these requirements have been altered or waived by your local IRB.
- C. To obtain prior approval from your local IRB for any modifications of previously approved research.
- D. When conducting FDA-regulated research, uphold all responsibilities delineated in the UTHSC Com C IRB SOP, FDA-Regulated Research.
- E. To ensure that progress reports and requests for continuing review and approval are submitted in the time frame and the manner prescribed by your local IRB.
- F. To provide your local IRB with prompt reports of any unanticipated problems involving risks to subjects or others, including adverse events and protocol deviations.
- G. To provide your local IRB with prompt reports of serious or continuing noncompliance with the federal regulations or with the requirements of your local IRB.
- H. To collect, where possible, information regarding gender and racial/ethnic origin of all subjects and to report this information to the IRB as requested.
- I. To request closure of the study from the IRB when all research activities including identifiable data analysis are complete.
- J. **Before** separating from UTHSC Com C or Erlanger Health, to either request (a) closure of the study from the IRB, OR (b) replacement of the Principal Investigator (PI) so that a local UTHSC COMC PI is maintained, OR (c) request a consult with the IRB if you wish to remain involved in the study in any way at your new institution (including receiving data/specimens that are de-identified or identifiable).
- K. To retain study/project records according to the applicable regulation or if more than one regulation applies, the longest applicable period:
 - 1. **OHRP Requirements:** For all research that is regulated by HHS and reviewed under 45 CFR 46, records relating to the research must be retained for a least three years after the completion of the research, including consent forms and all correspondence with the IRB and other entities involved in conducting and supporting the research
 - 2. **FDA Requirements:** An investigator conducting research that is regulated by the FDA and involves drugs or biologics being tested in humans must retain the research records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated or, if no application is being filed or the application is not approved for such indication, until 2 years after the investigation is discontinued and the FDA is notified.

An investigator conducting research that involves a medical device shall maintain the research records for a period of 2 years after the later of the following two dates: (i) the date on which the investigation is terminated or completed; or (ii) the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

- 3. **HIPAA Requirements:** Research that involves collection of protected health information (PHI) is subject to the HIPAA regulations. Research records including signed consent forms that



- contain the HIPAA authorization must be retained for six years after the date on which the subject signed the consent form or the date when it was last in effect, whichever is later
4. **Sponsor Requirements:** If a research project is sponsored, then the investigator must comply with the terms for record retention outlined in the contract with the sponsor.
 5. **Questions of data validity:** If there are questions or allegations about the validity of the data or appropriate conduct of the research, the investigator must retain all the original research data until such time as the questions or allegations have been completely resolved,
- M. To assure that all collaborating investigators and other key research personnel involved in the research study are fully informed regarding: (i) the study procedures; (ii) informed consent requirements; (iii) the potential adverse events associated with study participation and the steps necessary to minimize potential risks; (iv) reporting requirements for unanticipated problems; and (e) data collection and record-keeping requirements.
- N. To assure that all key research personnel personally complete required training regarding the protection of human subjects prior to their initiation of study activities.
- O. To disclose to the IRB all conflicts of interest as defined in institutional policy that may relate to the conduct of the research
- P. To permit inspection and audit of all records related to the conduct of the study by authorized representatives of the IRB and departments or agencies supporting or conducting the research.

PRINCIPAL INVESTIGATOR SIGNATURES:

Principal Investigator Name	Signature Date
Investigator Printed Name	Date
Investigator Signature	

As Department Head, I certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that I have approved for this project to be conducted within my Department .

CHAIRMAN SIGNATURE (only for UTHSC COMC Investigator Initiated studies):

Chairman Signature	Signature Date
Chairman Printed Name	Date
Chairman Signature	