1. POLICY

The Central Institutional Review Board (CIRB) Initiative is sponsored by the National Cancer Institute (NCI) in consultation with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The University participates in the NCI-CIRB Initiative for review and approval of NCI-approved Children’s Oncology Group (COG) Phase 2 and 3 protocols and pilot protocols and Adult Phase 3 Cooperative Group protocols.

The NCI CIRB serves as the IRB of record for the CIRB-approved studies conducted under the Authorization Agreement between the University and CIRB. The CIRB conducts initial and continuing review of these studies as well as review of local context considerations. The University with the cooperation with the HSC Component Institutions (Stephenson Cancer Center (SCC) and Jimmy Everest Center for Cancer and Blood Disorders in Children) is responsible for ensuring compliance with the NCI CIRB determinations and local institutional requirements and for monitoring the conduct of the research at the HSC affiliated sites named in the Authorization Agreement.

CIRB-approved research projects shall be reviewed by the HSC IRB if the HSC investigator plans to enroll prisoners; or if a participant becomes incarcerated during the course of the research, as the NCI CIRB is not constituted to review research projects involving prisoners.

Specific Policies

A. Local Context

1. The HSC HRPP Director and/or HRPP designee shall submit all Institutional Worksheets on behalf of the University as required to participate in the CIRB Initiative.

2. HSC HRPP shall provide CIRB a description of local context considerations through the submission of the CIRB Annual Signatory Institution Worksheet About Local Context and the Annual Principal Investigator Worksheet About Local Context. Local context considerations for the University include, but are not limited to, state and local laws, conflict of interest policies, boilerplate language for inclusion in the informed consent document, and any other University requirements.

3. The Investigator shall submit the Study-Specific Worksheet About Local Context to participate in an individual study. Local context considerations for University Investigators include, but are not limited to, resources available to support research; extent of existing research responsibilities; and informed consent process information, including descriptions of vulnerable populations eligible for enrollment and safeguards used to protect those populations.

B. HIPAA

1. For research projects conducted under the HSC IRB, the University requires that the informed consent form and HIPAA Authorization form be separate documents. Although CIRB accepts the University’s boilerplate language to be included in the informed consent form for HIPAA Authorization, CIRB does not serve as a Privacy Board. Therefore, the HIPAA Authorization
form for CIRB studies at HSC sites shall be reviewed by a designated HSC IRB chair on behalf of the HSC Privacy Board.

C. Monitoring

1. The HSC HRPP reserves the authority to monitor any aspects of the research conducted under the CIRB / University agreement.

2. SCOPE

This SOP applies to University investigators and their research staff participating in CIRB-approved research projects; to IRB staff; and to IRB members serving on behalf of the HSC Privacy Board.

3. RESPONSIBILITY

Division of Responsibilities

The Responsibilities of the NCI CIRB are to:

1. Maintain an NCI CIRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
   a. Post the roster of NCI CIRB membership on the public side of the NCI CIRB website;
2. Conduct initial, amendment and continuing review of studies as well as review of any other study-specific documents submitted by the Study Chair to the NCI CIRB;
3. Conduct review of local context considerations:
   a. As outlined in the following worksheets: the Annual Signatory Institution Worksheet About Local Context for NCI CIRB Review, the Annual Principal Investigator Worksheet About Local Context, and the Study-Specific Worksheet About Local Context.
4. Conduct review of potential unanticipated problems and/or serious or continuing noncompliance when the University or other entity reports an incident, experience, or outcome to the CIRB. The review includes the following step:
   a. Report any unanticipated problem and/or serious or continuing noncompliance determination to OHRP, the FDA, and the NCI Signatory Official;
5. Conduct a review of individual Adverse Event Reports for studies without a Data and Safety Monitoring Board (DSMB) or equivalent monitoring body;
6. Post all study-specific documents related to CIRB reviews to the restricted access side of the CIRB website;
   a. Notify research staff and University designees of all CIRB actions, per written procedures, via institution-specific correspondence, broadcast emails, and access to the restricted area of the CIRB website;
7. Notify HSC Institutional Official immediately if there is ever a suspension or restriction of the CIRB's authorization to review a study; and
8. Post the NCI CIRB Standard Operating Procedures on the public side of the CIRB website.

The Responsibilities of HSC are to:
1. Comply with the NCI CIRB’s requirements and directives as noted in the CIRB SOP’s and on the CIRB website.

2. HSC HRPP will report to the NCI CIRB the names of any Component or Affiliate Institutions that rely on the Signatory Institution’s IRB.
   a. Component Institutions are defined by the NCI CIRB as meeting all of the following criteria:
      • the Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the component Institution;
      • the FWA number for the Component Institution is the same as the Signatory Institution;
      • the local context considerations of the Component Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context;
      • the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet About Local Context; and
      • the conduct of research at the Component Institution is monitored by the same office as the Signatory Institution.
   b. Affiliate Institutions are defined by the NCI CIRB as meeting all of the following criteria:
      • the local context considerations of the Affiliate Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Institution Worksheet about Local Context;
      • the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Institution Worksheet about Local Context; and
      • the conduct of research at the Affiliate Institution is monitored by the same office as the Signatory Institution.

3. HSC HRPP with the cooperation of SCC and Jimmy Everest Center shall ensure the safe and appropriate performance of the research at the Signatory Institution and at all Components and Affiliates. This includes, but is not limited to:
   a. ensuring the initial and ongoing qualifications of investigators and research staff;
   b. overseeing the conduct of the research;
   c. monitoring protocol compliance;
   d. maintaining compliance with state, local, or University requirements related to the protection of human subjects;
   e. providing a mechanism to receive and address concerns from local study participants and others about the conduct of the research; and
   f. investigating, managing, and providing notification to the NCI CIRB of any study-specific incidence, experience or outcome that seems to rise to the level of an unanticipated problem and/or serious or continuing noncompliance. When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing non-
compliance, the University must provide a plan to manage the incident, experience, or outcome, including measures to prevent similar occurrences.

NOTE: As part of ensuring safe and appropriate performance of the University’s research, the University has the authority to observe any aspect of the research process including observing the consent process. The CIRB retains the authority to direct observation to be done when necessary.

4. Provide updates in a timely manner to the NCI CIRB whenever a HSC Principal Investigator is no longer the responsible party for a study under the purview of the NCI CIRB;

5. Notify the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review;

6. Complete and submit the Annual Institution Worksheet About Local Context, the Annual Investigator Worksheet About Local Context, and any other worksheets/forms required by the NCI CIRB for participation;

7. HSC HRPP shall determine on a study-by-study basis whether to open the study through the NCI CIRB or to conduct its own local IRB full Board review. Indicate the decision to open a study through the NCI CIRB by submitting a Study-Specific Worksheet About Local Context;

8. In the local consent form:
   a. incorporate NCI CIRB-approved boilerplate language into the NCI CIRB-approved model consent form.
   b. make no language changes to the consent form with the exception of NCI CIRB-approved boilerplate language;
   c. obtain NCI CIRB approval of changes to the boilerplate language prior to implementation; and
   d. obtain NCI CIRB approval of translations of the consent form prior to implementation;

9. Maintain a regulatory file for each study under NCI CIRB purview as per University and sponsor policy; and

10. Conduct full board review of any study enrolling prisoners, since the NCI CIRB is not constituted to review studies enrolling prisoners.

4. APPLICABLE REGULATIONS AND GUIDELINES
   45 CFR 46.114
   21 CFR 21.114

5. REFERENCES TO OTHER APPLICABLE SOPS

   SOP 1001, HIPAA
   NIC CIRB SOPs: www.NCICIRB.org
6. ATTACHMENTS

STUDY-SPECIFIC WORKSHEET ABOUT LOCAL CONTEXT (PI)

ANNUAL SIGNATORY WORKSHEET ABOUT LOCAL CONTEXT (INCLUDING BOILERPLATE LANGUAGE TO THE MODEL CONSENT FORM) (HSC HRPP)

ANNUAL PRINCIPAL INVESTIGATOR WORKSHEET ABOUT LOCAL CONTEXT (PI)

7. PROCESS OVERVIEW

A. Submission Procedures for Initial Review

1. Investigators who wish to open a CIRB-approved research project at HSC shall submit the following documents to the HRPP via the IRB electronic information system:
   a. CIRB-approved protocol
   b. CIRB approval letter
   c. Documentation of approval and any other University-required committee reviews (i.e., IBC)
   d. Proposed HSC HIPAA Authorization form

2. The submission is received in the IRB Office. HRPP staff shall review the submission to confirm that HSC investigator(s) and KSP have met all HSC IRB education requirements.

3. The Administrator shall conduct a pre-review of the submission and verify all necessary documents have been submitted.

4. The Administrator shall assign the submission to the IRB Chair to review on behalf of the Privacy Board.

5. The IRB Chair reviews the submission to confirm accuracy of the HIPAA Authorization form and for any other issues that might require HSC IRB review.

6. The Administrator shall update the outcome of the HSC IRB Chair review, communicate the outcome and any stipulations to the Investigator, and report the HSC IRB Chair review to the next appropriate HSC IRB agenda. The Administrator stamps the HSC IRB Approval stamp to the HIPAA Authorization form.

7. The Investigator shall upload the appropriate documents to CIRB, following CIRB procedures. CIRB becomes IRB of record at that time.

B. Closing the Study

1. The Investigator shall submit a final closure request to the HSC IRB electronic information system to inform the University of the closure of the research project at the HSC component or affiliate sites.

C. Submission of CIRB Required Worksheets

1. CIRB required worksheets shall be completed and submitted to CIRB as follows:
   a. Annual Institution Worksheet About Local Context (including University approved boilerplate language to the model consent form): HSC HRPP office
   b. Annual Investigator Worksheet About Local Context: HSC Investigator with copy to HSC HRPP office
   c. Study-Specific Worksheet About Local Context: HSC Investigator
   d. Other CIRB worksheets/forms required by the NCI CIRB for participation: to be determined by the HSC HRPP office as needed.