**Detailed Procedure When UTHealth PI is the Lead PI and UTHealth IRB is the Reviewing IRB**

First consult with the IRB office to ensure that UTHealth IRB is willing and able to be the Reviewing IRB for the proposed research study. If UTHealth IRB agrees to be the reviewing IRB for the proposed research, there are two options:

Option 1 – submit the application for UTHealth site as usual and add the other sites later as change requests. (Preferred option)

Option 2 – submit the application for UTHealth site and other sites at the time of initial submission.

**Initial Review:** UTHealth IRB requires evidence that the relying institution has granted permission for the institution to rely on UTHealth IRB. Each Site PI should follow their relying institution’s procedure for seeking permission to rely on another IRB within the UT System. In most institutions, this process is handled by the relying institution’s IRB office. Most institutions will require the Site PI to submit the following:

* Permission to rely on outside IRB (may be integrated into the electronic application)
* Site Specific Consent form (Site PI contact, local IRB contact)
* Protocol (if required by the relying institution)

The UTHealth lead PI must submit the following to the UTHealth IRB via iRIS, either as other study documents at initial submission or as a change request for each site:

* Written confirmation that the Relying Institution agrees to rely on UTHealth IRB (not necessary when SMART IRB platform is used)
* Completed Addition of Site form
* CV of the Site PI
* Site specific Consent Document (if applicable)

If UTHealth IRB accepts the request to rely, the application may be reviewed through expedited review or full board review. In addition to the regulatory criteria for approval for approval of research, UTHealth IRB will consider the following:

* Investigator Qualifications - The Site PI should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial.
* Study team - The Site PI should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely. Significant research -related duties may be delegated only to adequately qualified individuals.
* Recruitment plan and consent process – If the plan for recruitment and consent process is different from the strategy outlined by the lead PI, the Reviewing IRB should assess whether the Site PI’s plan is appropriate.

If UTHealth IRB requires more information or local context, then, UTHealth IRB may seek help from the relying institution’s IRB. Local context may be provided by a member or staff of the IRB from the relying institution. This individual may provide information as Consultant for UTHealth IRB and may participate in the UTHealth IRB meeting via teleconference. The Consultant does not have the right to vote at the UTHealth IRB meeting.

If the addition of site is approved, UTHealth IRB will send the approval letter and stamped consent document to the lead PI. The lead PI is responsible for distribution of documents to the site PIs.

**Continuing Review:** The UTHealth PI is responsible for submitting a renewal application to the UTHealth IRB via iRIS in a timely manner. Continuing review will occur at the same time for all the sites even if the sites were added after the original site had received approval earlier.

The UTHealth PI must gather information from all participating site under the UTHealth IRB oversight. The lead PI must consolidate information from all the sites into a single continuing review application. The lead PI must indicate the names of the sites whose information is included in the application. The lead PI may attach the individual forms from the Site PIs to the continuing review application.

When the continuing review application is approved, UTHealth IRB will issue an approval letter via iRIS. The approval letter will include the list of all the sites for which continuing approval has been granted. The lead PI is responsible for sending the approval letter to each Site PI.

If the continuing review is not approved before study expiry, research activity must stop at all the sites. If the investigators believe that stopping the study might be harmful for participants, the lead PI must submit a justification to UTHealth IRB to continue research activities. If one or more sites participating in the research study did not submit information to the lead PI for the continuing review application, UTHealth IRB will conduct continuing review for the sites that did submit their information. For the sites that did not submit information, the study will expire and all research activities must stop.

UTHealth IRB will communicate information to the relying institution when a study has expired at the relying institution. If any affiliated institutions are involved, it is the responsibility of the relying institution to communicate with them.

**Problem Reporting:** When a site becomes aware of a problem that needs to be reported to the IRB as per UTHealth problem reporting policy, the Site PI must submit the required information to the lead PI. The lead PI must submit the information to the Reviewing IRB in the relevant forms. Both the Site PI and lead PI must ensure that the problem reporting timelines are met. UTHealth IRB will review the report as per its policy on review or problem reports.

UTHealth IRB will communicate its findings and stipulations in writing to the lead PI. When UTHealth makes a determination of unanticipated problem involving risks to subjects or others or serious or continuing noncompliance, or issues a suspension or termination, UTHealth IRB staff communicate with the relying institution according to the IRB Authorization Agreement under which the research was reviewed.