

CTSI IRB Protocol Submission and Review Procedures

1. Collaborating investigators outline each institution's involvement in the protocol. The Lead PI should review the *Decision Tree* to determine which institution's IRB may serve as the **Reviewing IRB**.
2. Each participating investigator completes the *CTSI Protocol Registration (CPR) Notice* to document research activities specific to each site. This form is used by each investigator to consult with his/her home IRB regarding which site may serve as the **Reviewing IRB**.
3. The designated CTSI IRB administrator will consult with the collaborating IRBs to finalize which will serve as the **Reviewing IRB**, and notifies the Lead PI of the outcome.
4. The investigator whose home institution is the **Reviewing IRB** will serve as the Lead PI. The Lead PI is responsible for submitting the IRB application to the **Reviewing IRB**, using their application form(s) and following the relative requirements. The submission should identify all "Relying" sites and include the CPR Notice for each site.
5. The **Reviewing IRB** completes its review and issues approval with a contingency that the Relying IRB accepts the submission as approved. The **Reviewing IRB** reviews consent forms for each collaborating site and works with the Relying IRBs to address local site requirements.
6. Site investigators are responsible for following his/her home IRB requirements related to the reliance process. For example, Cedars-Sinai Medical Center (CSMC) requires their investigators to submit an abbreviated application to the CSMC IRB in order to accept the **Reviewing IRBs** review and approval. Note: All local IRBs can accept or decline the **Reviewing IRBs** approval and can require a separate review by the local IRB.
7. The **Reviewing IRB** issues approval to the Lead PI and notifies the Relying IRBs of approval. If applicable, the **Reviewing IRB** will release consent forms to the Lead PI to begin enrollment at the Reviewing institution. The other sites must follow local IRB requirements related to the reliance process prior to enrolling subjects.
8. The IRB reliance process does NOT include ancillary oversight committees (e.g., Cancer Center Protocol Review Committee, Institutional Biosafety Committee, Radiation Safety Committee, Human Stem Cells Oversight Committee, Conflict of Interest Committees, Privacy Board, and others). If the protocol requires ancillary committee approvals at Relying Institutions, enrollment may not be initiated at these sites until all relevant approvals have been granted.
9. The Relying IRB issues an Acknowledgement Letter to document acceptance of the IRB approval issued by the **Reviewing IRB**. At this time, once all required ancillary approvals have been received, the Relying IRB will release the consent forms approved by the **Reviewing IRB** in order for enrollment to begin at the relying site.