

STUDIES WITH LSUHSC

LSUHSC-NO and Ochsner Clinic Foundation (OCF) have agreed to use a single IRB mechanism for regulatory review of human subjects research studies involving both institutions. This could include situations where the study team includes personnel from both institutions or when investigators from one institution are using resources or facilities of the other institution. The lead IRB for such studies, and the process for IRB review, is determined by the primary affiliation of the Principal Investigator (PI).

If the PI is a member of the OCF faculty or staff...

- The Ochsner IRB will serve as the Lead IRB and IRB of record.
- The LSUHSC IRB will serve as the relying IRB.
- The PI submits a study application to the Ochsner IRB using the eIRB electronic submission system.
 - When applicable, the submission must include a consent document prepared using the Ochsner Informed Consent template, the joint HIPAA Authorization Form and the LSUHSC-NO ICF Cover Letter.*
 - Ochsner IRB reviews the study.
 - If approved, Ochsner IRB Office registers the study in the IRB Reliance Exchange (IREx) system and uploads study documents and approval letter.
- The lead LSUHSC investigator submits an abbreviated application, the External IRB Reliance Application, to the LSUHSC IRB Office at CIRB@lsuhsc.edu.
 - The LSUHSC External IRB Relations Specialist reviews application for local requirements including training compliance and conflict of interest disclosure for LSUHSC personnel.
 - Once all local requirements are verified, Specialist issues a Facilitated Review Assurance Document to the lead LSUHSC investigator for signature and accepts reliance in IREx.
- Study may be initiated **ONLY** after Lead IRB issues study approval AND Relying IRB issues facilitated review acknowledgement and accepts reliance in the IREx system.

If the PI is a member of the LSUHSC faculty or staff...

- The LSUHSC IRB will serve as the Lead IRB and IRB of record.

- The Ochsner IRB will serve as the relying IRB.
- The PI submits a study application to the LSUHSC IRB using the appropriate procedure as described here.
 - When applicable, the submission must include a consent document prepared using the LSUHSC Informed Consent template, the joint HIPAA Authorization Form and the Ochsner ICF Cover Letter.*
 - LSUHSC IRB reviews the study.
 - If approved, LSUHSC IRB Office registers the study in IRB Exchange (IREx) and uploads study documents and approval letter.
- The lead Ochsner investigator submits an abbreviated application in eIRB.
 - On the Basic Information page, select YES to the following question: Are you requesting the use of a non-Ochsner IRB as the IRB of Record? LSUHSC must be checked as the IRB of Record
 - Ochsner IRB staff reviews application for local requirements including training compliance and conflict of interest disclosure for Ochsner personnel.
 - Once all local requirements are verified, staff issues an external IRB acknowledgement letter.
 - IRB staff will complete reliance documentation in IREx.
- Study may be initiated ONLY after Lead IRB issues study approval AND Relying IRB issues external IRB acknowledgement and accepts reliance in the IREx system.

**When the Ochsner IRB serves as the IRB of Record, use the Ochsner ICF template to prepare the consent document for the study. LSUHSC researchers consenting LSUHSC-affiliated participants must attach the LSUHSC ICF Cover Letter to the IRB-approved consent document and also use the separate joint HIPAA authorization form. When the LSUHSC IRB serves as the IRB of Record, use the LSUHSC ICF template to prepare the consent document for the study. Ochsner researchers consenting Ochsner-affiliated participants must attach the Ochsner ICF Cover Letter to the IRB-approved consent document and also use the separate joint HIPAA authorization form.*