	GUIDANCE			
LSU Health	NON-HSC RESEARCH PERSONNEL TRAINING AND DOCUMENTATION REQUIREMENTS			
Human Research Protection Program	NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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Purpose

The purpose of this document is to provide guidance on training and documents required for Non-LSUHSC (HSC) affiliated individuals when listed as research personnel for exempt, expedited, and full board studies. Requirements are contingent on who will serve as their IRB of Record for the study as described below.

Home Institution IRB or Designee Serves as the IRB of Record

Training/COI Requirements: Non-HSC affiliated researchers must comply with their home institution's training and COI disclosure requirements.

Required Documents: IRB approval of the study from the non-HSC's IRB of record (home institution).

HSC IRB Serves as the IRB of Record

Agreement Requirement: An appropriate, fully executed agreement, as described <u>here</u>, must be in place for HSC to serve as the IRB of Record for Non-HSC personnel. Use this <u>decision tree</u> to determine which agreement (IAA or IIA) is most appropriate for your research study.

<u>Exception</u>: If this is a multi-center, single IRB study, an IRB Authorization Agreement (IAA) is not needed if you prefer to establish reliance via SMART IRB or IRB Reliance Exchange (IREx). To do this, respond "Yes" to the RELIANCE ARRANGEMENT question found in the initial protocol and list the information for the institution(s)/IRB(s) that will be relying on the LSUHSC-NO IRB in the Participating Sites tab.
This is not an option for exempt studies except where indicated.

Training/COI Requirements: Individual must complete HRPP-required training as described <u>here</u>.

Required Documents:

- A fully executed, appropriate agreement for the study.
 - Note: Once an executed Master IAA is on file with the HSC IRB, you do not need to attach it. Master IAA processes post-implementation are site specific and will follow the established procedure with each institution (e.g., attaching a signed attestation page for new non-HSC research personnel or not further action required).
- Documentation of required training/disclosure if not completed through the preferred provider listed in the training table found <u>here</u>.
- CV for any non-HSC affiliated research personnel listed as a sub-investigator.

Actions to take in Kuali Research

- List all non-HSC affiliated research personnel in the Protocol Personnel Table, indicating who will serve as their IRB of Record;
- Follow the instructions that appear based on your response; and
- Attach the required documents in the Non-HSC Research Personnel Documents Table.

Please note: The submission will not be approved until all required attachments are provided for each non-HSC affiliated research personnel, as applicable.