REPORTING OF RELIANCE STUDY UPDATES

GENERAL INFORMATION

What is a “Reliance” Study?
When one or more institutions choose to rely on another IRB (commercial or institutional) for review and oversight for a research project.

For context of this document, a “reliance study” is research for which LSUHSC-NO (HSC-NO) is relying on an External IRB (e.g., NCI CIRB, PETAL cIRB, WIRB, Institutional IRBs) for oversight. Click here for detailed IRB Reliance information.

Post Approval Information:

Once a reliance request is granted and the External (Reviewing) IRB has approved the research, the HSC-NO PI and study team are responsible for understanding the Reviewing IRB’s policies and procedures, the IRB-approved documents and conditions of approval, any applicable laws and regulations, and conducting the research accordingly. Additionally, post-approval updates must be submitted to the HSC-NO IRB as described below.

Please note: post-approval updates must be submitted to the HSC-NO IRB using the Reliance Study Reporting xForm, as detailed below, with the exception of study closures. To close a study, use the standard closure procedure and form found on our website.

What is an Applicable, Post-Approval Update?

After reliance study approval, the local study team is still required to submit some items to the HSC-NO IRB for acknowledgment and verification of training requirements. Only eligible (reliance) studies can use the Reliance Study Reporting xForm in IRBManager to submit the following applicable, post-approval updates:

- Principal Investigator (PI) and Personnel Changes (for personnel associated with the LSUHSC component of the multi-center study ONLY). Do not submit changes in study personnel at the Lead or other participating sites.
- Documentation from the Reviewing IRB of Acknowledgment/Determination for Modifications, Changes in PI, Continuing Review, and/or Reportable New Information (e.g., unanticipated problems, adverse events, unresolved participant complaints etc.)
- Updated/New, Reviewing-IRB Approved study documents associated with an approved modification/change in PI, as applicable (e.g., consents, protocol, and/or recruitment materials).
- Additional documents from the Reviewing IRB (e.g., documents related to RNI), as applicable.

Please note all materials must be reviewed and approved/acknowledged by the Reviewing IRB prior to local acknowledgement.
GENERAL xForm TIPS

Entering Contacts: If you receive a “no results found” message when entering a person in the xForm, this means that the individual is not a contact in the IRBManager System. There will be a link provided at the top of the form for you to click to add the contact to the system as needed. Once the contact is added to the system, you may then re-enter the name to continue the submission process.

Show Help: On certain sections, you will see a “Show Help” tool that you can click on for additional guidance related to that section.

Add Note: Certain sections have the “Add Note” (green arrow) option. This option is available for you to provide additional clarification, if necessary, but does not substitute for listing the information in the fields.

INSTRUCTIONS - STARTING RELIANCE STUDY REPORTING xForm

Step 1: Log into IRB manager: https://lsuhsc-no.my.irbmanager.com/

a. Follow login instructions as listed in the quick start guide found here.

Step 2: Find the Reliance Study of interest by selecting the #Active studies to locate it or directly selecting the study under “my studies” column as shown below.

Step 3: Once in the reliance study, click on Start xForm on the left side of your screen under "Actions."
Step 4: Select the Reliance Study Reporting xForm by clicking on the form’s title:

RELIENCE STUDY REPORTING xForm CONTENT

Once you are brought to the Reliance Study Reporting xForm, a screen similar to the image below will appear, and the questions that appear will depend on the study status and the responses of the submitter.

Step 1: Indicate what reliance study updates you are submitting. Please note that this question will ONLY appear for studies with the status of “External IRB Approved Studies.”

If the form was started from an ineligible study (not a reliance study/inactive study) the following instructions will appear, guiding the submitter to press “next” and “submit” for the form to be removed from the system.

Please click "Next" and then "Submit" for the xForm to be completed and removed from the IRBManager System. Thank you!
Step 2: Answer all remaining question and provide requested attachments, as applicable.

Please note: All updates require approval/acknowledgment letters from the Reviewing IRB, with the exception of change in personnel associated with the LSUHSC component of the multi-center site ONLY. If the questions appears and you select “No,” you will not be able to move forward with the xForm.

Do you have a Decision/Acknowledgment Letter(s) from the Reviewing IRB for the applicable update?  
Yes/No

CHANGE IN PI; LSUHSC NO Component ONLY

ATTACH - Letter of Approval.

CONTINUING REVIEW

Provide the attachment(s) and updated approval period. List accurate dates to avoid errors in communication between the study and system, as the information is directly important into the study.

ATTACH - Letter of Approval

Indicate the Type of Updated Approval Period:

- Approving  
- Non-approving

Modification

Attach the Letter of Approval and any Updated/New Study Documents

Reportable New Information (RNI)

Attach the Letter of Approval or Acknowledgement and any additional documents associated with the RNI

Additional Notes - Particular Submission Types

Continuing Review:

The dates you enter will be directly imported into IRBManager. Ensure that they are correct and match the Reviewing IRB’s updated approval period.

PI/Personnel Changes:

Only personnel/PI changes associated with the LSUHSC component of the multi-center study may be submitted. Personnel changes at the reviewing (lead) site or other participating sites will not be accepted. Additional information and any revised consent/study documents related to these changes will be collected later in the form. For specific quick guides on personnel/PI changes in IRBmanager, visit our IRBManager Guidance Page.

Helpful tip: Submit the xForm even if you are unsure if all training requirements have been fulfilled in order to avoid delays in processing. IRB staff reviews the training when the application is submitted and informs the study team of any deficiencies.
Attachments:

- Click “Add Attachment
- Name the document
- Select the document type
- Add attachment by clicking “Attach”

Repeat this process for as many attachments as you are submitting.

Submitting the Form

After you have responded to all of the required questions, press “Next” one more time and then click “Submit” for the form to be processed.

Once you submit the form you will get the following message:

IRB Stage – Personnel/PI Changes

After the xForm has been submitted, you can check the status of it by visiting your dashboard and referencing the “xForm” section. It will be listed under the # “xForms being processed at a later stage.”
Upon clicking on the "xForms being process at a later stage," the "Stage" column will provide the current status of the xForm.

If it is with the IRB, it will say "Training Verification Personnel/PI Changes".

### ACKNOWLEDGMENT AND XFORM

If your update included personnel/PI changes, you will receive all training verification notifications (as applicable) through IRBManager generated e-mails. You can also check the status of the xForm by visiting your dashboard as shown above.

Once the reliance study updates have been processed and acknowledged by the HSC-NO IRB, you will receive an e-mail generated through the IRBManager system similar to the one below that will include a link to the xForm you submitted. This is your HSC-NO IRB Acknowledgment of the Reliance Study Update.

The Email provides instruction on how to access the completed xForm as well as all attachments associated with the reliance study update within the Event in IRBManager. Visit our IRBManger Guidance page for a detailed quick guide on how to Navigate your study and event details page.

To access the xForm associated with this acknowledgment, you can either:

**OPTION 1**: Click on the link in the e-mail to be brought to the xForm OR

**OPTION 2**: From your dashboard, Click on #xForms, a screen will appear similar to the one below, which shows all xForms associated with you as a user (submitter), including completed forms.
Option 2 continued:

Viewing and Saving a Copy of the xForm

Upon opening the completed xForm, scroll to the bottom xForm to download a pdf as needed.

If you have any questions about IRBManager please visit our website or contact the LSUHSC-NO Office of Research Services by e-mail:

IRBOffice@lsuhsc.edu