Objectives

- To define Single IRB
- To educate on when Reliance is appropriate
- To educate on the different ways Reliance arrangements are documented
- To inform study teams on how to submit a Reliance Request application via Kuali
Single IRB (sIRB)

An arrangement entered into by two or more entities that allow the IRB of one institution/organization to serve as the Lead (Reviewing) IRB on behalf of the other institutions/organizations (Relying Institutions).

- Relying Institutions still carry out certain responsibilities, which are outlined in the reliance agreement/arrangement with the Reviewing IRB (i.e., training verification)
- LSUHSC uses the term “Reliance” most frequently when we are a relying site, though it can be used when we are the lead as well

What Does sIRB Look Like?

When LSUHSC is the Reviewing IRB

When LSUHSC is the Relying IRB
When is Reliance Appropriate?

Reliance may be appropriate in several situations, including:
- Requested or required by the sponsor/funding agency;
- Encouraged or mandated by an existing network or consortium;
- IRB expertise concerns (i.e., special subject population, atypical research design, sensitive topics);
- Efficiency considerations;
- Conflict of interest concerns; or,
- Proposed IRB has already reviewed the study.

*The LSUHSC IRB reserves the right to deny a Reliance Request*

Documenting Reliance Arrangements

- **NCI CIRB, PETAL cIRB, WCG IRB, ADVARRA IRB**
  - LSUHSC has master reliance agreements in place with these IRBs

- **SMART IRB or IREx**
  - Online portals for documenting reliance with sites that are a signatory to the SMART IRB reliance agreement

  - Paper contract used on an as needed basis
LSUHSC IRB Requirements of Study Team
When Relying

- Submission of a Reliance Request prior to project start-up
  - Required to document LSUHSC willingness to rely

- Submission of Reviewing IRB-approved amendments & continuing reviews
  - Required for acknowledgement
  - Note about continuing review dates

- Submission of Study Closure letter from Reviewing IRB

HOW TO SUBMIT A RELIANCE REQUEST
Log into Kuali and navigate to Protocols

Start a New Protocol for IRB
Complete the General Information and click Next

IRB General Information

- Title of Study: [Field]
- Principal Investigator: [Field]
- Department: [Field]
- School: [Field]
- Anticipated start date: [Field]
- Estimated completion date: [Field]
- National Clinical Trial (NCT) number (if applicable): [Field]
- Is this a new submission of a previously approved IRB protocol? [Yes/No]

Select Reliance Request as Protocol Type

- Select the correct Protocol Type for this study: Reliance Request
- Is this reliance request limited to student or trainee researcher participation at another site? [Yes/No]
Student/Trainee Research Participation at Another Site Only

Only answer “Yes” if only LSUHSC students/trainees are involved

- **LSUHSC defines trainee researcher as resident, fellow, or other person undergoing training without a faculty/staff appointment**

Complete the General Information

- Funding & Sponsor Information
- Performance Site(s)
  - list only local performance sites
- Study Population
- Enrollment
  - list only local enrollment goals
- Protocol Personnel
  - list only LSUHSC personnel involved
Select the Proposed Reviewing IRB

**Options include:**
- NCI Central IRB
- PETAL IRB
- Advarra IRB
- Western IRB (WIRB), now WCG IRB
- Academic Institution
- Other Commercial
- Other Non-commercial

When you select Academic Institution or Other Non-Commercial...
When you select Advarra, WCG, or Other Commercial...

Complete the Study Information

- Summarize Activities
- Reviewing IRB Review Category
- Local Considerations (i.e., consent processes, populations)
- Use/disclosure of identifiable protected health information (PHI)
- Plan for reporting reportable new information (i.e., unanticipated problems, non-compliance)
- Involvement of test products (i.e., drug, biologic, device)
- Involvement of biologic specimen or biohazards
Attach Supporting Documents

Supporting Documents

Attach all applicable supporting documents in the table below. The following documents are required under the conditions stated:
- Protocol
- Reference agreement (if the referencing IRB is any IRB other than LSUHSC, CHU, PMHS, or any non-US IRB or NCI institutional review boards)
- Local Consent (if requested by the referencing IRB)
- Consent form or documentation of waiver of consent from the referencing IRB (if consent is applicable to the study)
- LSUHSC IRB approval letter (if consent is applicable to the study)
- HIPAA form or documentation of waiver of HIPAA authorization from the referencing IRB (if HIPAA authorization is applicable to the study)

Click the ‘Add Info’ button to upload a Supporting Document. Be sure to name the document appropriately and select the correct document type as you can easily identify it in the future. Repeat this process until all documents have been uploaded.

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<thead>
<tr>
<th>DOCUMENT TYPE</th>
<th>APPR/REVIEW</th>
<th>FILE UPLOAD</th>
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**Must include:**
- Protocol
- Consent Form or Waiver
- LSUHSC HIPAA Authorization or Waiver
- LSUHSC Cover Letter, if using non-HSC consent template
- Patient-facing documents to be used locally

Save the Date!

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<th>Date</th>
<th>Time</th>
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