

LSUHSC IRB Presents:
LUNCH
& **LEARN**

RELIANCE ON EXTERNAL IRBS
July 5, 2023

The logo features a fork, knife, and spoon on the left, and a pen on the right, flanking the text. The text 'LUNCH' is in purple and '& LEARN' is in yellow. A yellow triangle is in the bottom right corner of the slide.

1

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 Quali

LSU Health
NEW ORLEANS
Office of Research Services

2

2

Single IRB (sIRB)

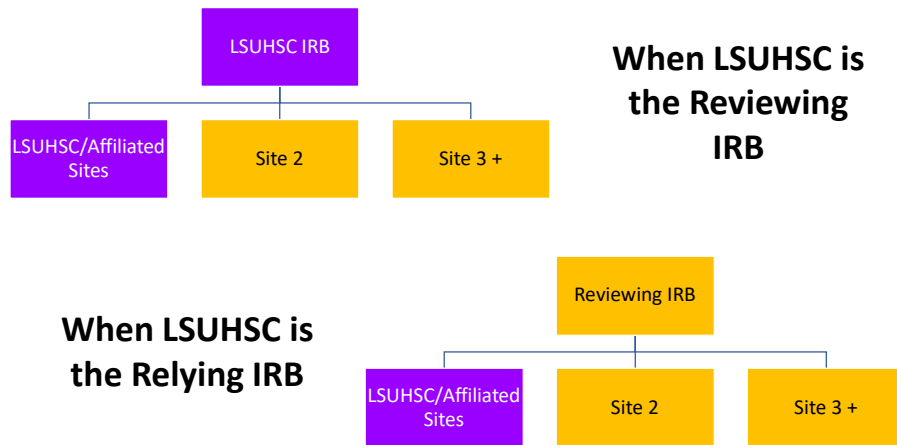
An arrangement entered into by two or more entities that allow the IRB of one institution/organization to serve as the Lead (Reviewing) IRB on behalf of the other institutions/organizations (Relying Institutions).

- 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*

3

3

What Does sIRB Look Like?



4

4

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*

5

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
- **IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA)**
 - Paper contract used on an as needed basis

6

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

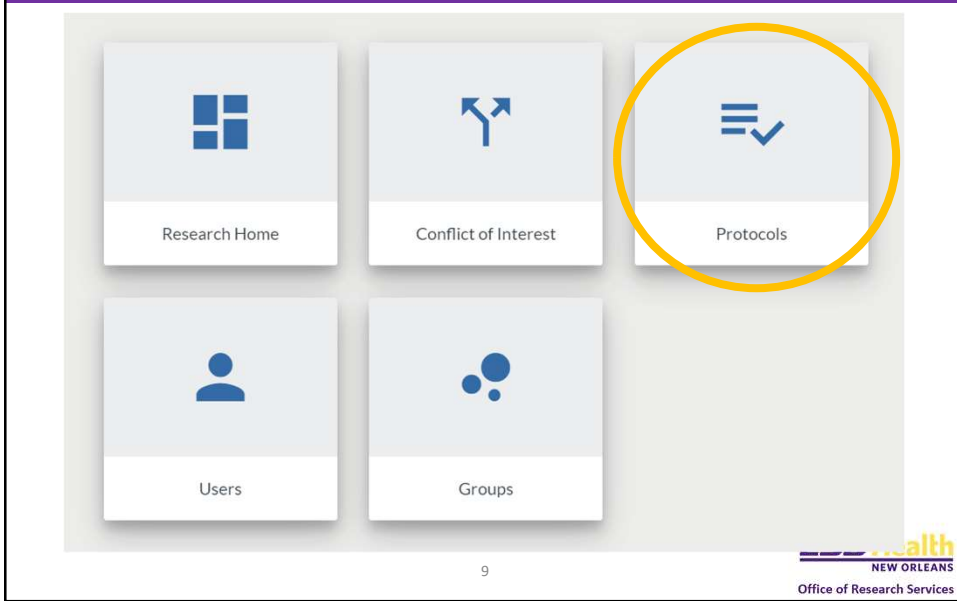
7

7

HOW TO SUBMIT A RELIANCE REQUEST

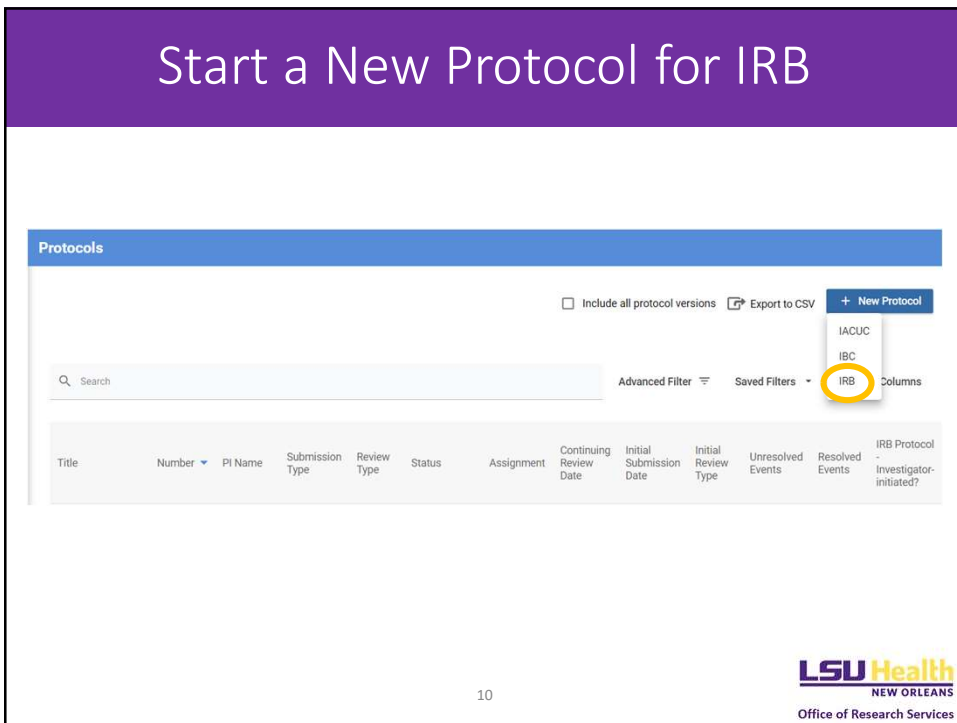
8

Log into Kuali and navigate to Protocols



9

Start a New Protocol for IRB



10

Complete the General Information and click Next

IRB - General Information

Title of Study:
Phase 1, randomized, clinical trial to test...

Principal Investigator:
Start typing the last name of the PI and the KR user profile will appear from which you can select the PI.
Dominguez, Gabriela

Department: Family Medicine

School: Medicine

Anticipated start date: August 1, 2023

Estimated completion date: August 1, 2025

National Clinical Trial (NCT) number (if applicable):
NCT00000000

Is this a new submission of a previously approved IRB protocol?
 Yes
 No

X Cancel
→ **Next**

11

11

Select Reliance Request as Protocol Type

← Back **Manage Protocols** → IRB: #1509 Phase 1, randomized, clinical trial to test....

Select the correct Protocol Type for this study:

Reliance Request

Is this reliance request limited to student or trainee researcher participation at another site?
LSUHSC defines trainee researcher as a resident, fellow, or other person undergoing training without a faculty or staff appointment.
 Yes
 No

→ Next

12

12

Student/Trainee Research Participation at Another Site Only

← Back Manage Protocols → IRB: #1509 Phase 1, randomized, clinical trial to test...

Select the correct Protocol Type for this study:

Reliance Request

→ Next

Is this reliance request limited to student or trainee researcher participation at another site?
LSUHSC defines trainee researcher as a resident, fellow, or other person undergoing training without a faculty or staff appointment.

Yes

No

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*

13

13

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*

14

14

Select the Proposed Reviewing IRB

RELIANCE REQUEST

Complete this form if your research is under the jurisdiction of the LSUHSC-NO IRB and you are requesting to use an external IRB to serve as the IRB of Record (Reviewing IRB). Instead, to confirm the protocol type for this study, review the "Protocol Type Selection" guidance document found [here](#).


Please visit the LSUHSC-NO [IRB website](#) for additional reliance study information and instructions.

Proposed Reviewing IRB:

NCI Central IRB

Options include:

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



15

When you select *Academic Institution* or *Other Non-Commercial...*

Reviewing IRB Information

Name of Reviewing IRB or institution:

Type name here

Explain why you are requesting reliance on this IRB:

Type answer here


Reviewing IRB contact name:	Contact email address:	Contact phone number:
<small>Type name here</small>	<small>Type email here</small>	<small>Type number here</small>

Is the Reviewing IRB accredited by AAHRPP?
AAHRPP accredited IRBs are listed [here](#).

Yes

No

Which reliance agreement, SOPs, and/or platform will the Reviewing IRB use for this study?



16

When you select *Advarra, WCG, or Other Commercial...*

Is this research project a multi-site project designed to evaluate prospectively the safety and/or effectiveness of a new drug or device? _____

- Yes
 No

Is this an Industry-Designed, Industry-Initiated and Industry-Sponsored drug or device research project? _____

- Yes
 No

Is this a Phase 1 study? _____

- Yes
 No

Is this an LSUHSC investigator-initiated study and/or does the LSUHSC investigator hold the IND or IDE? _____

- Yes
 No

Does any member of the research team have a financial interest in this research project or the sponsor? _____

See Conflict of Interest in Research website for policy information and training & reporting requirements.

- Yes
 No

Is the New Orleans VAMC (Veterans Affairs Medical Center) a participating site on this research project? _____

- Yes
 No

Does the research involve prisoners or other participants subject to additional protections afforded under [Subpart C](#) of the regulations? _____

- Yes
 No

LSU Health
NEW ORLEANS

Office of Research Services

17

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

18

LSU Health
NEW ORLEANS

Office of Research Services

18

Attach Supporting Documents

Supporting Documents

Attach all applicable supporting documents in the table below. The following documents are required under the conditions stated:

- Protocol
- Reliance agreement (if the Reviewing IRB is any IRB other than NCI CIRB, PETAL IRB, Advarra or WIRB; or if the Reviewing IRB is not using the SMART IRB or IREx platforms)
- Local Context Questionnaire (if required by the Reviewing IRB)
- Consent form or documentation of waiver of consent from the Reviewing IRB (if consent is applicable to the study)
- LSUHSC ICF cover letter (if consent is applicable to the study)
- HIPAA form or documentation of waiver of HIPAA authorization from the Reviewing IRB (if HIPAA authorization is applicable to the study)

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


If you are updating this table for a post approval submission (e.g., renew, amend, close), follow the instructions in that form and make updates to the table accordingly.

Download All Columns + Add Line

DOCUMENT TYPE	APPROVED?	FILE UPLOAD
+ Add info		

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



19

19

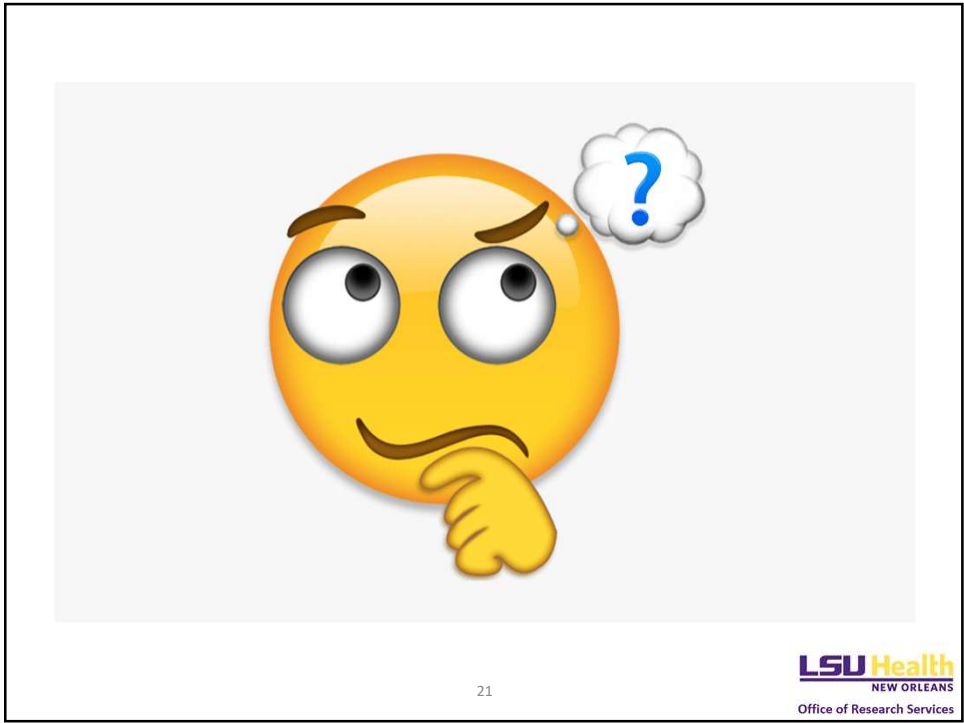
Save the Date!

Date	Time	Topic
08/02/2023	12:00PM	Study Team Regulatory Responsibilities



20

20



21