LSUHSC IRB Presents:

LUNCH & LEARN

RELIANCE ON EXTERNAL IRBS

July 5, 2023

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 Kuali

2

LSU Health NEW ORLEANS
Office of Research Services

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).

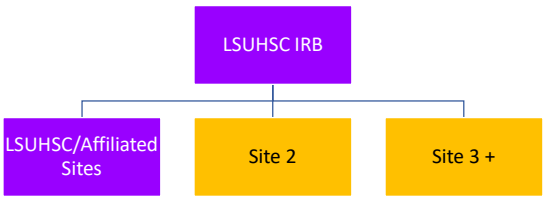
- Relying Institutions still carry out certain responsibilities, which are outlined in the reliance agreement/arrangement with the Reviewing IRB (i.e., training verification)
- *LSUHSC uses the term "Reliance" most frequently when we are a relying site, though it can be used when we are the lead as well*

3

LSU Health NEW ORLEANS
Office of Research Services

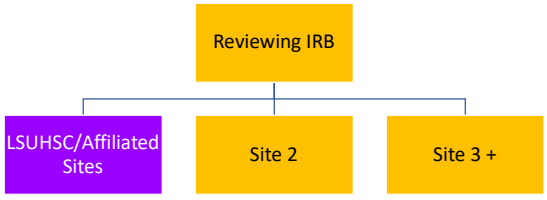
3

What Does sIRB Look Like?



When LSUHSC is the Reviewing IRB

When LSUHSC is the Relying IRB



4

LSU Health NEW ORLEANS
Office of Research Services

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*

LSU Health NEW ORLEANS
Office of Research Services

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

LSU Health NEW ORLEANS
Office of Research Services

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

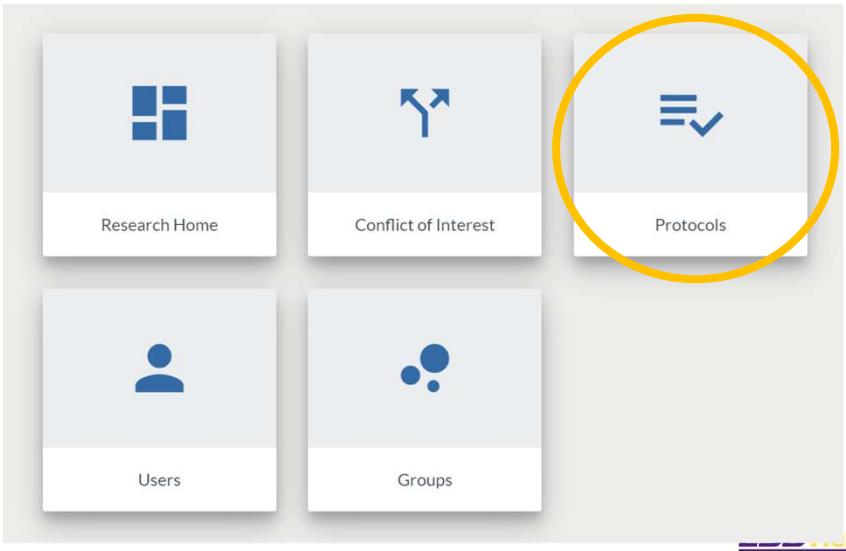
LSU Health NEW ORLEANS
Office of Research Services

7

HOW TO SUBMIT A RELIANCE REQUEST

8

Log into Kuali and navigate to Protocols

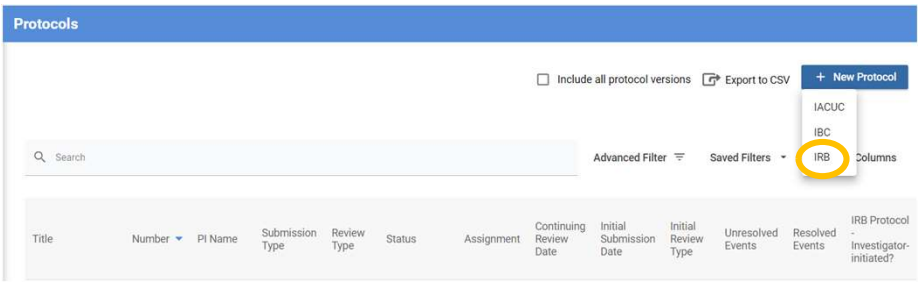


9

LSU Health NEW ORLEANS
Office of Research Services

9

Start a New Protocol for IRB

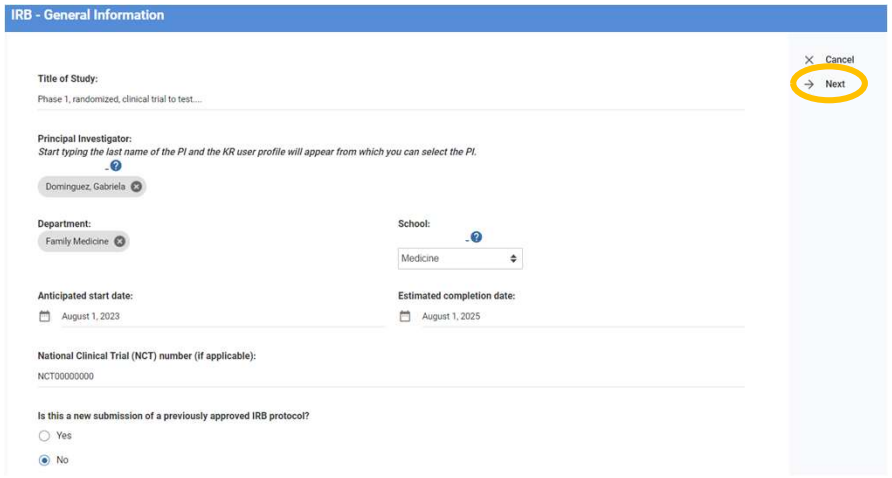


10

LSU Health NEW ORLEANS
Office of Research Services

10

Complete the General Information and click Next



11

LSU Health NEW ORLEANS
Office of Research Services

11

Select Reliance Request as Protocol Type

12

LSU Health NEW ORLEANS
Office of Research Services

12

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*

13

LSU Health NEW ORLEANS
Office of Research Services

13

Complete the General Information

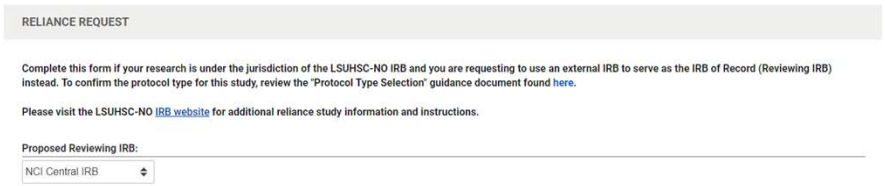
- Funding & Sponsor Information
- Performance Site(s)
  - *list only local performance sites*
- Study Population
- Enrollment
  - *list only local enrollment goals*
- Protocol Personnel
  - *list only LSUHSC personnel involved*

14

LSU Health NEW ORLEANS
Office of Research Services

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:

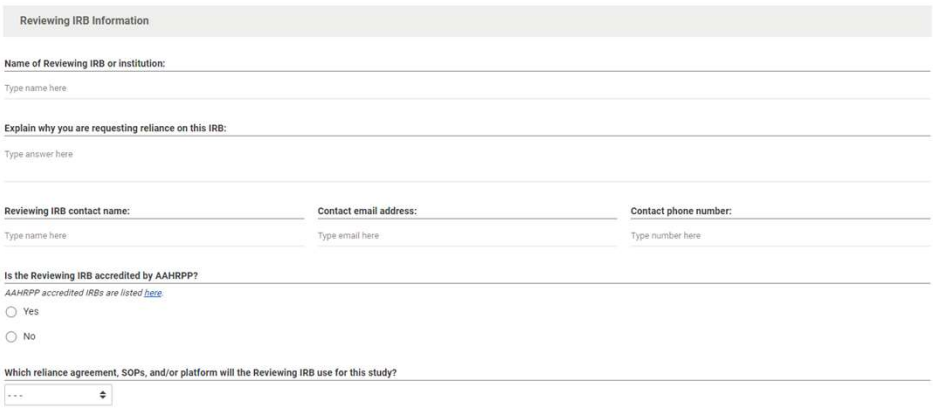
- NCI Central IRB
- PETAL IRB
- Advarra IRB
- Western IRB (WIRB), *now WCG IRB*
- Academic Institution
- Other Commercial
- Other Non-commercial

15

LSU Health NEW ORLEANS
Office of Research Services

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: Type name here

Contact email address: Type email here

Contact phone number: Type number here

Is the Reviewing IRB accredited by AAHRPP?

AAHRPP accredited IRBs are listed here

Yes

No

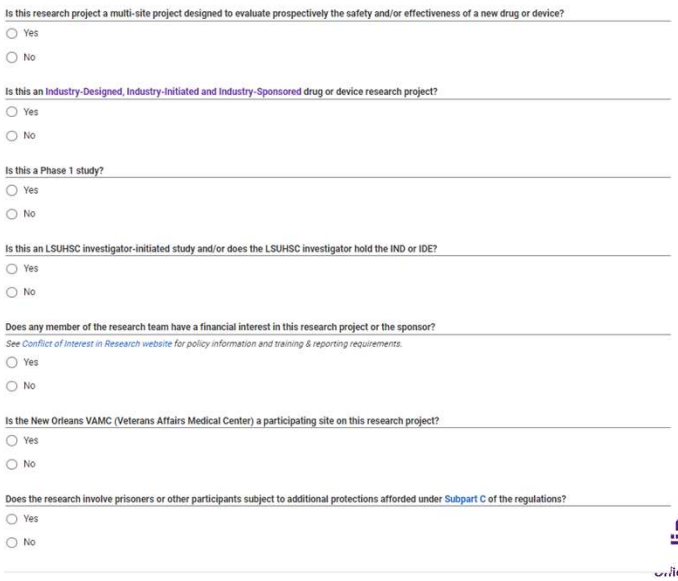
Which reliance agreement, SOPs, and/or platform will the Reviewing IRB use for this study?

16

LSU Health NEW ORLEANS
Office of Research Services

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

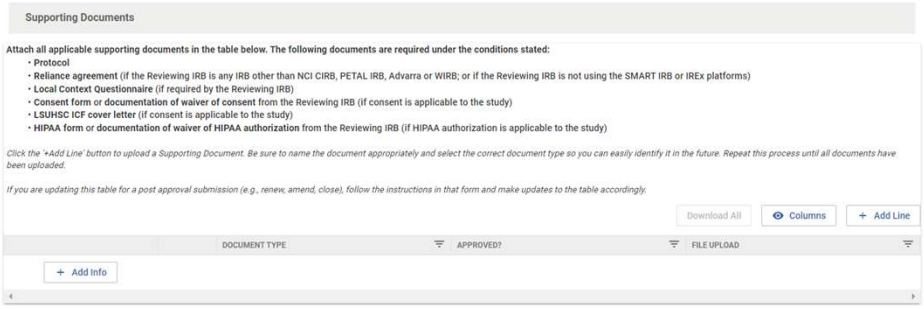
Complete the Study Information

- 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

LSU Health NEW ORLEANS
Office of Research Services

18

Attach Supporting Documents



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

LSU Health NEW ORLEANS
Office of Research Services

19

Save the Date!

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

20

LSU Health NEW ORLEANS
Office of Research Services

20

LSU Health NEW ORLEANS
Office of Research Services

21