LSU HEALTH COORDINATOR COMPETENCIES

X

ADHERENCE TO ETHICAL STANDARDS

Institutional Review Board Overview

Objectives

- Describe the IRB's scope of oversight – what does and what does not require review by the IRB
- Describe the IRB review process
- Outline a basic overview of the system, including how to gain access to the system, how to use and navigate within the system, how to find out study status, and how to get help with the system
- Describe how to communicate with the IRB and make use of the many tools available on the IRB website

Goals of Institutional Review Board (IRB)

- To ensure protections for the rights and welfare of human participants involved in research activities being conducted under its authority
- To ensure compliance with all federal, state, and institutional regulations
- To ensure ethical conduct of research
- To balance the obligation to protect individuals from harm with the desire to maximize the benefits to society that research may bring

What Research Requires IRB Review?

Does the Study Require IRB Review?

If the study <u>meets both</u> of the following definitions, then it requires IRB review:

Is it Research?

A *systematic investigation*, including development, testing, and evaluation, designed to develop or contribute to *generalizable* knowledge (*HHS Common Rule*)

Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration (*FDA*)

Does it involve Human Subjects?

A living individual about whom an investigator conducting research:

A. Obtains information or biospecimens through *intervention* or *interaction* with the individual, AND uses, studies, or analyzes the information or biospecimens; *OR*
B. Obtains, uses, studies, analyzes, or generates *identifiable private information* or identifiable biospecimens (*HHS Common Rule*)

An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient (*FDA*)

Levels of IRB Review

There are three levels of IRB review for human participant research. Each category is different in the level of scrutiny and review procedures required.

Exempt	Expedited	Full Board
Exempt from the requirements of Common Rule but not exempt from ethical considerations	Research involving minimal risk*	Greater than minimal risk to subjects
Fits one or more of the 8 Exempt Review Categories	Fits one or more of the 9 Expedited Review Categories	Not covered under other review categories
Limited IRB Review may apply	Does not mean “fast”	Reviewed by fully convened Board

*Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

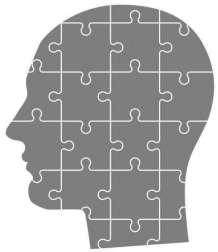
Exempt Categories

<u>Category 1</u>: Research conducted in established or commonly accepted educational settings, involving normal educational practices, so long as the research is not likely to adversely affect students' opportunity to learn the required educational content or the assessment of educators who provide instruction.

*****Cannot include any other procedures, such as collection of clinical data or biospecimens*

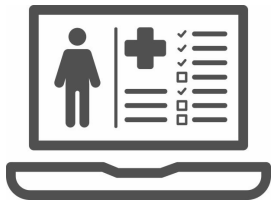
<u>Category 2</u>: Use of educational tests, surveys, interviews, or observations of public behavior

*****Limited IRB Review may be required.*
NO CHILDREN.
NO IDENTIFIERS.



<u>Category 3</u>: Research involving benign "behavioral" interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection (e.g., playing games, providing education to change behavior, puzzles, etc.)

*****Limited IRB Review may be required.*
NO CHILDREN.
NO LINKS.
NO DECEPTION.



<u>Category 4</u>: Secondary research using identifiable information or biospecimens if publicly available, or recorded such that subjects cannot be re-identified*

*****See §346.104(d)(4)(ii), (iii), and (iv) for all criteria*

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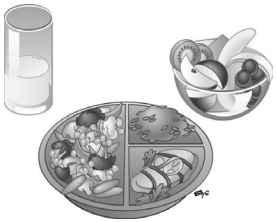
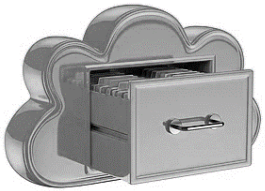
Exempt Categories

<u>Category 5</u>: Public service program research or demonstration projects



<u>Category 6</u>: Taste and food quality evaluations

**Only exempt category that FDA allows*



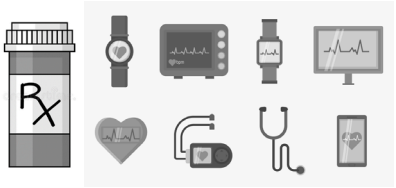
<u>Category 7</u>: Storage or maintenance of identifiable information or biospecimens for secondary use.

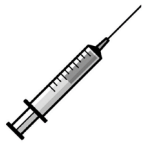
**Broad consent and limited IRB review required.*
***Most institutions do not use this category*

<u>Category 8</u>: Secondary research using identifiable information or biospecimens.

**Broad consent and limited IRB review required.*
***Most institutions do not use this category*

Expedited Categories: Initial Review



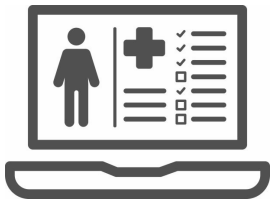


Category 1: Clinical studies of drugs and devices that do not require an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application.

Category 2: Research that collects blood samples by finger stick, heel stick, ear stick or venipuncture from healthy, non-pregnant adults and sometimes children (limited amount of blood).

Category 3: Prospective non-invasive collection of biological specimens for research purposes only.

Category 4: Collection of data through non-invasive standard of care procedures.



Category 5: Review of data, documents, records, specimens that have been or will be collected solely for non-research purposes.

Category 6: Collection of data from voice, video, digital or image recordings made for research purposes.

Category 7: Research performed on individual or group characteristics or behaviors or involves employing surveys, interviews, oral histories, focus groups, etc.

Expedited Categories: Continuing Review

<u>Category 8</u>: Continuing review of research previously approved by the convened IRB as follows:

Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants;

OR

Where no participants have been enrolled and no additional risks have been identified

OR

Where the remaining research activities are limited to data analysis.

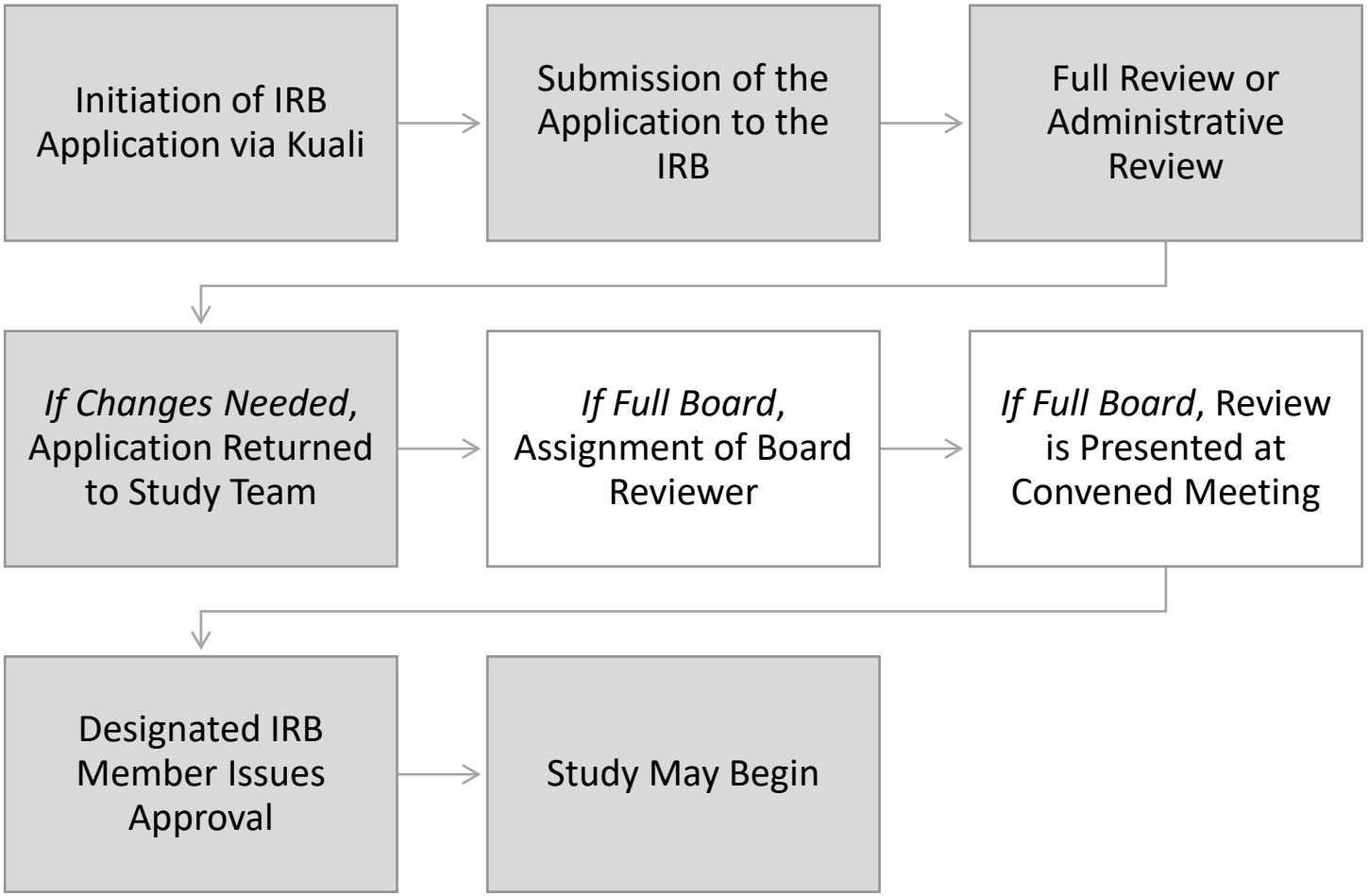
<u>Category 9</u>: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Other IRB Reviews

- Continuing Review/Renewal
- Amendments
- Reportable New Information
- Closure Requests
- Non-Human Subjects Research Determinations
- Reliance Requests

What is the IRB Review Process?

IRB Review Process



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Limited IRB Review

What is it?

- Ensures that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of the data

When does it apply?

- For exempt studies where there is still a requirement to address privacy and confidentiality, such as Category 2(iii) and 3(i)(c)

Who conducts it?

- IRB Chair or experienced reviewer designated by the Chair from among IRB members

The .111 Criteria

1. Risks to subjects are minimized
2. Risks are reasonable in relation to anticipated benefits
3. Selection of subjects is equitable
4. Informed consent will be sought from each subject or their LAR
5. Informed consent will be appropriately documented or waived
6. Plan for adequate provisions for monitoring data collection for safety, when appropriate
7. Adequate provisions to protect privacy and maintain confidentiality of the subject, when appropriate
8. Additional safeguards are included when some or all of the subjects are likely to be vulnerable

As required by the Common Rule (45 CFR 46.111) and FDA Regulations (21 CFR 56.111)


What is Kuali
Protocols?

Kuali

Initial or post-approval research applications requiring IRB review are submitted through the Kuali Research (KR) electronic submission system.

- All LSUHSC Faculty and Staff are able to log into Kuali using your LSUHSC Single Sign-On Credentials
- Non-LSUHSC study team members can reach out to the IRB Office to request an External User Account be created for them.

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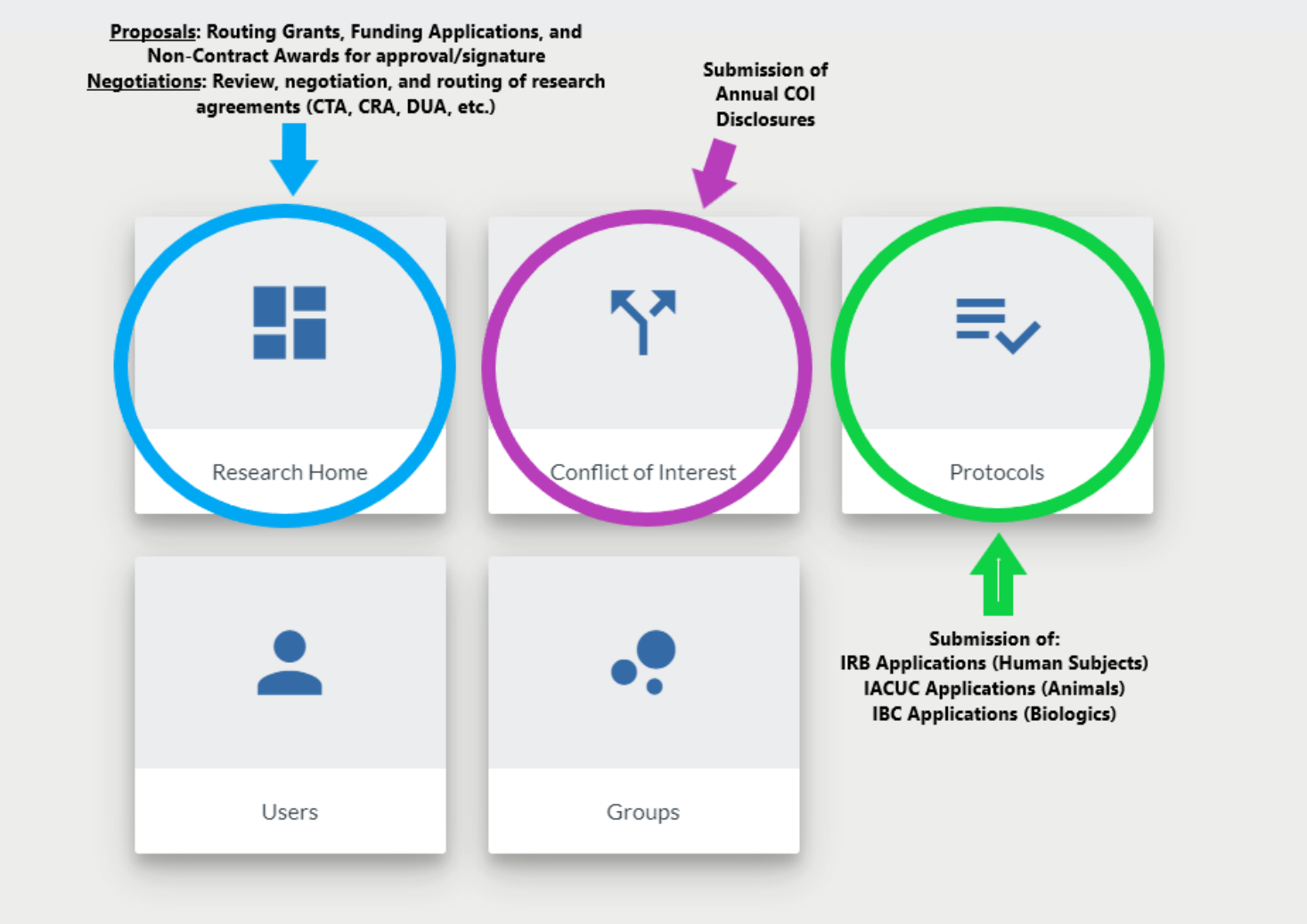
Kuali Modules



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Contacting the IRB & Accessing Our Resources

Who Can I Contact in the LSU Health IRB?

The IRB Office is located on the 2nd Floor of the LSUHSC-NO Library, Administration, and Resources Center (RCB 206).

433 Bolivar Street, Room 206, New Orleans, LA 70112
(504) 568-4970 *Main Telephone and Voicemail*

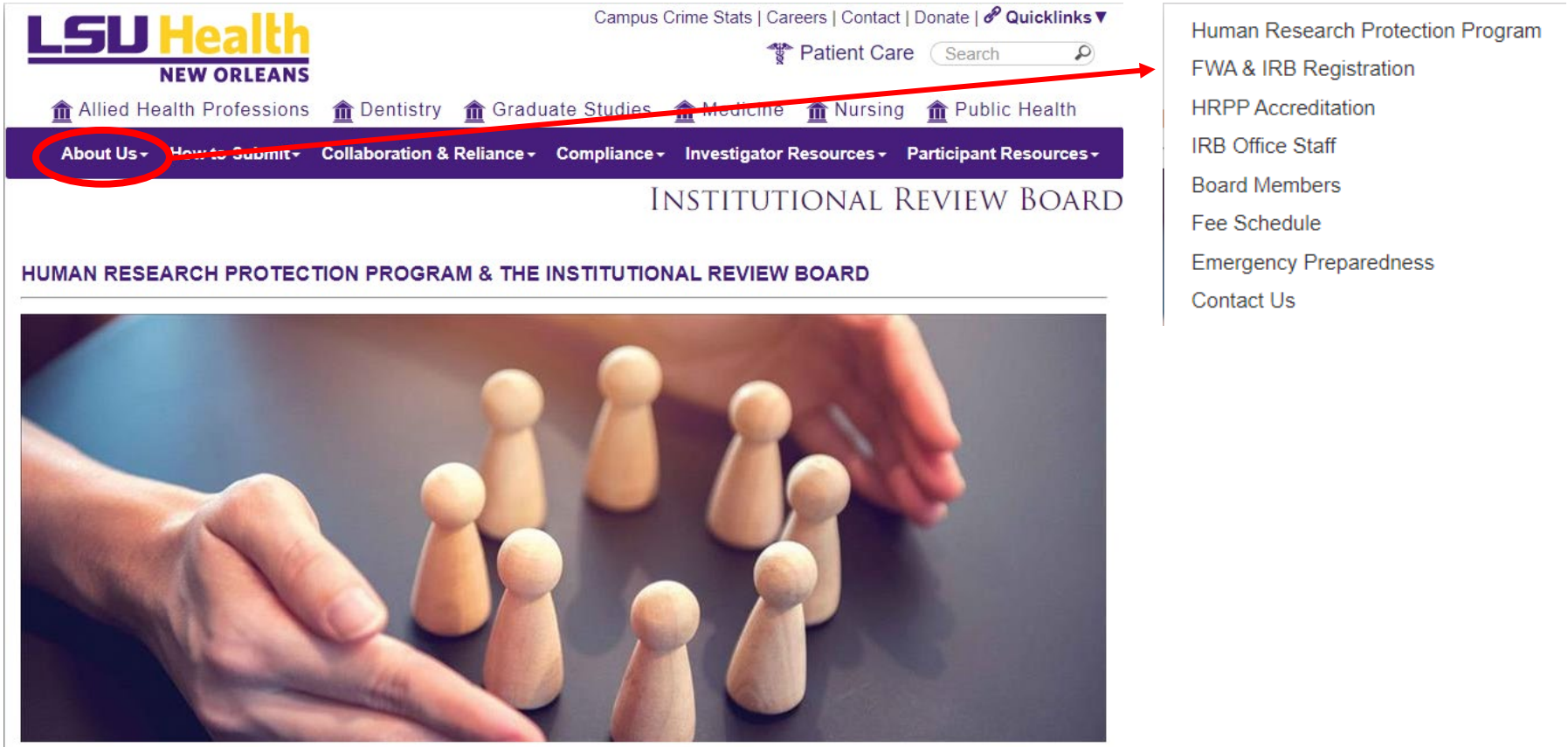
Staff Member	Position	Email	Phone
General Inbox		IRBOffice@lsuhsc.edu	
Reliance Inbox		CIRB@lsuhsc.edu	
Lynn Arnold, BS, MBA	Manager	larnol@lsuhsc.edu	(504) 568-3779
Noel Cal, MA	IRB Analyst II	ncal@lsuhsc.edu	(504) 568-2491
Mya Sherman, MS, MA	IRB Analyst II	msherm@lsuhsc.edu	(504) 568-1668
Mark James, PhD	IRB Analyst I	mjam20@lsuhsc.edu	(504) 568-1285

Subscribe to the IRB LISTSERV for News and Updates related to Human Subjects Research

Tips for Communicating with the IRB

- Exempt from IRB does not mean you don't have to submit anything to the IRB. Exempt Determination is an IRB review procedure
- Expedited review does not mean that we will hasten our review. Expedited review is an IRB review procedure
- Please be kind. We are not here to make your life more difficult; we are here to not only protect human subjects, but we are also protecting you as the researcher and the institution as a research site.
- Email IRBOffice@lsuhsc.edu with any questions or concerns

IRB Website: About Us



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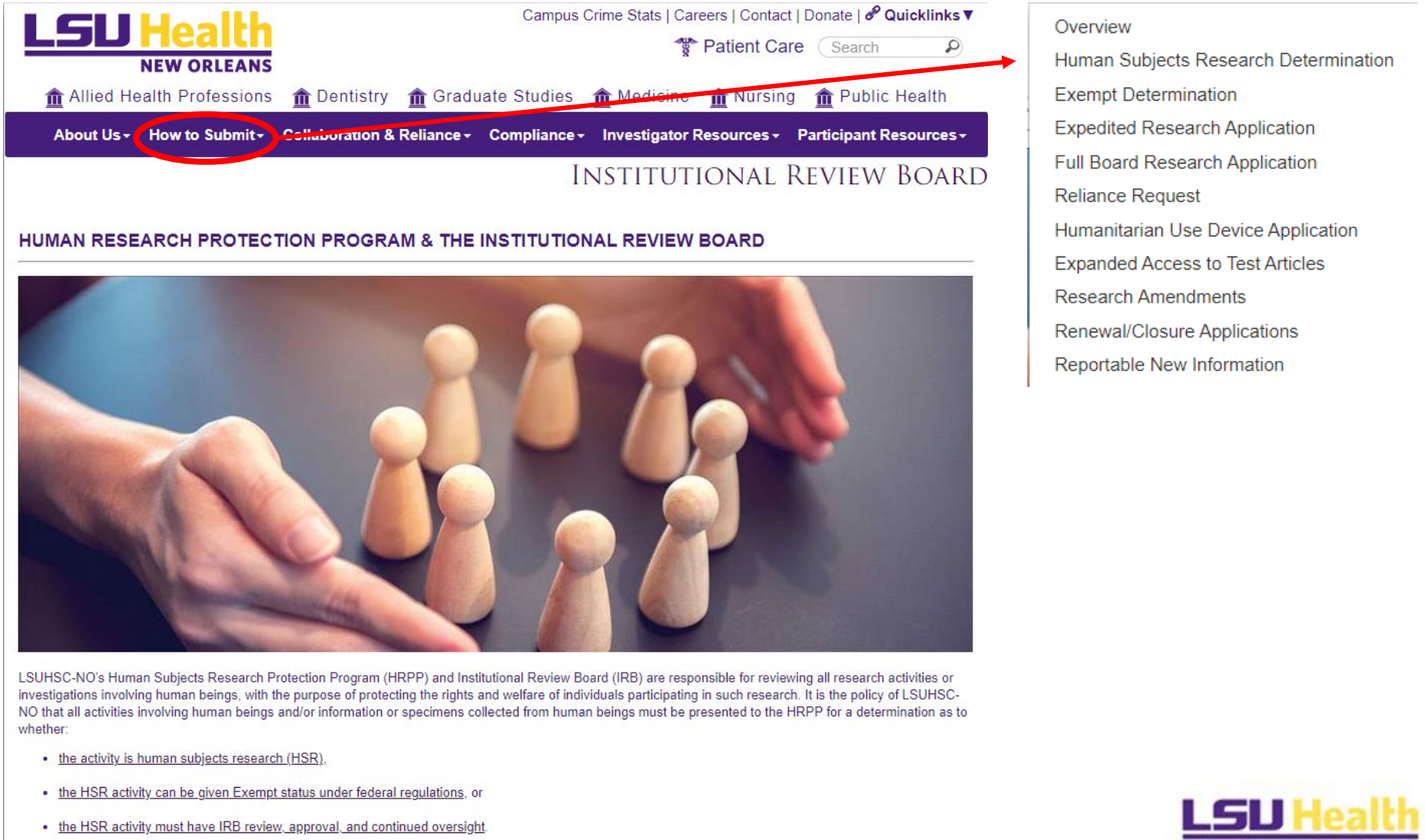
IRB Website: How to Submit



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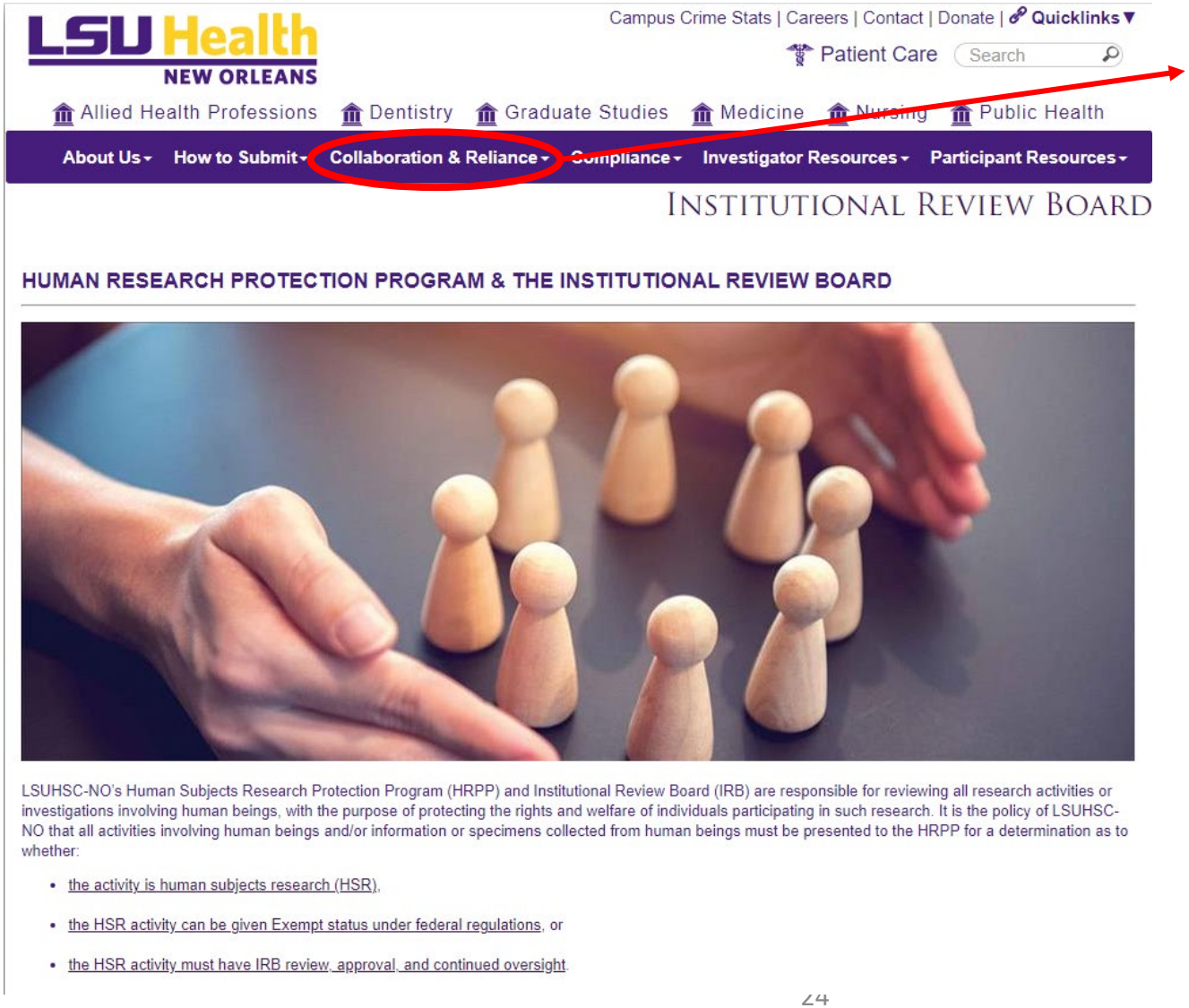
IRB Website: Collaboration & Reliance



Single IRB & Reliance

Working with Local Institutions

Working with External Investigators

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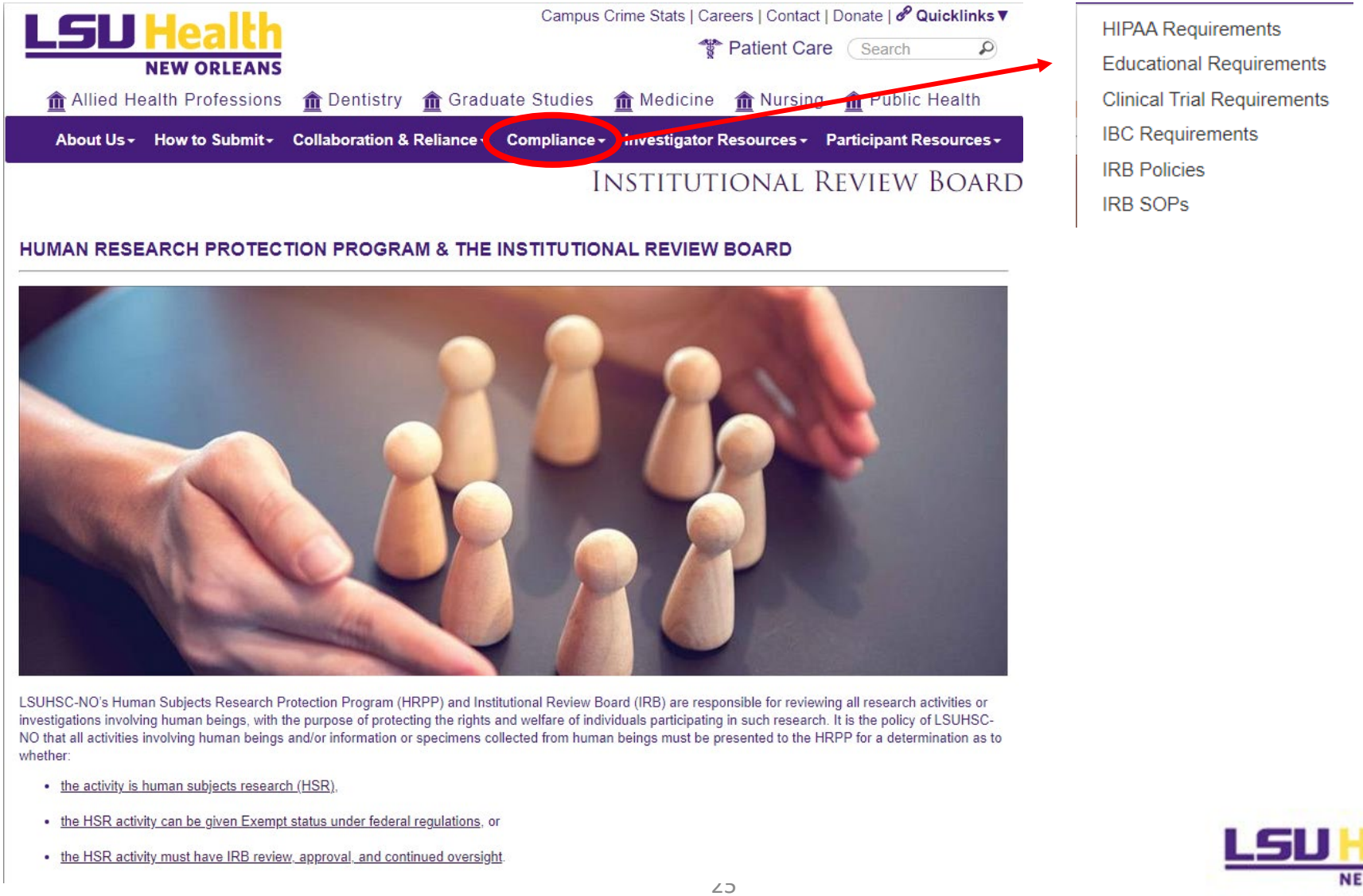
IRB Website: Compliance



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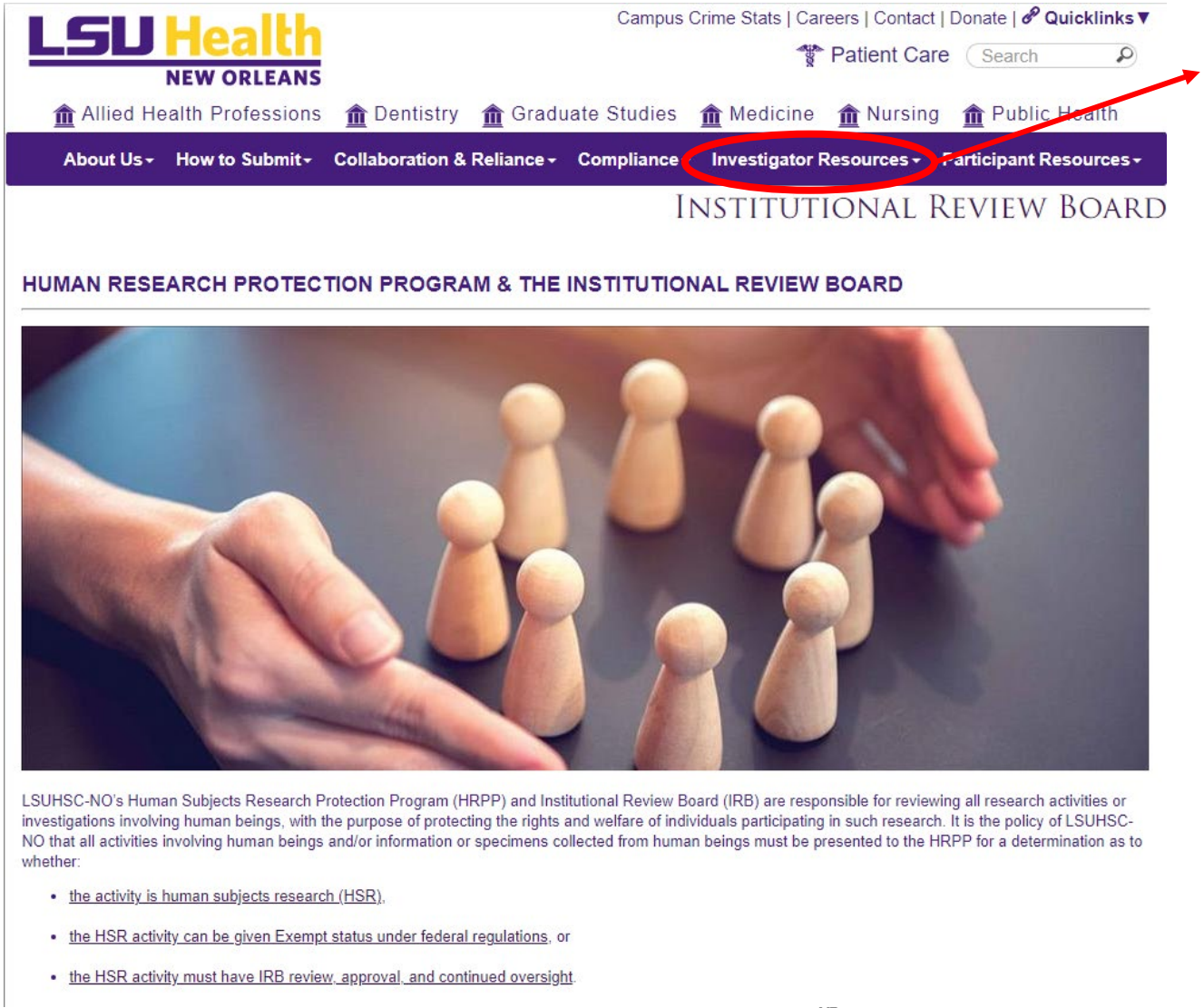
IRB Website: Investigator Resources



- Agreement Templates
- Consent Templates
- HIPAA Forms
- Checklists & Worksheets
- Kuali Quickguides
- Kuali Support Documents
- Other Documents
- Protocol Builder
- Research Staff Education

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IRB Website: Participant Resources

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LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ❑ Protocol Compliance
- ❑ Informed Consent
- ❑ Patient Recruitment & Retention
- ❑ Management of Patients
- ❑ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development