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
Why Do Human Research Subjects Need Protection?

What Research Requires IRB Review?
Does the Study Require IRB Review?

If the study meets both 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*)
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**
- Exempt from the requirements of Common Rule but not exempt from ethical considerations
- Fits one or more of the 8 Exempt Review Categories
- Limited IRB Review may apply

**Expedited**
- Research involving minimal risk*
- Fits one or more of the 9 Expedited Review Categories
- Does not mean “fast”

**Full Board**
- Greater than minimal risk to subjects
- Not covered under other review categories
- Reviewed by fully convened Board

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*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

**Category 1**: 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*

**Category 2**: Use of educational tests, surveys, interviews, or observations of public behavior

*Limited IRB Review may be required.*

NO CHILDREN.

NO IDENTIFIERS.

**Category 3**: 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.

**Category 4**: 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*
Exempt Categories

Category 5: Public service program research or demonstration projects

Category 6: Taste and food quality evaluations
*Only exempt category that FDA allows

Category 7: 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

Category 8: 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.

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LSU Health
New Orleans
Office of Research Services
Category 8: 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.

Category 9: 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

1. Initiation of IRB Application via Kuali
2. Submission of the Application to the IRB
3. Full Review or Administrative Review
   - If Changes Needed, Application Returned to Study Team
   - If Full Board, Assignment of Board Reviewer
     - If Full Board, Review is Presented at Convened Meeting
   - Designated IRB Member Issues Approval
4. Study May Begin
   - Study May Begin

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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?
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.
Kuali Modules

- **Proposals**: Routing Grants, Funding Applications, and Non-Contract Awards for approval/signature
- **Negotiations**: Review, negotiation, and routing of research agreements (CTA, CRA, DUA, etc.)

**Submission of Annual COI Disclosures**

- **Research Home**
- **Conflict of Interest**
- **Protocols**

**Users**

**Groups**

**Submission of**
- IRB Applications (Human Subjects)
- IACUC Applications (Animals)
- IBC Applications (Biologics)

LSU Health
NEW ORLEANS
Office of Research Services
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

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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.
LSUHSC-NO’s Human Subjects Research Protection Program (HRPP) and Institutional Review Board (IRB) are responsible for reviewing all research activities or investigations involving human beings, with the purpose of protecting the rights and welfare of individuals participating in such research. It is the policy of LSUHSC-NO that all activities involving human beings and/or information or specimens collected from human beings must be presented to the HRPP for a determination as to whether:

- the activity is human subjects research (HSR),
- the HSR activity can be given Exempt status under federal regulations, or
- the HSR activity must have IRB review, approval, and continued oversight.
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Institutional Review Board (IRB) Website: How to Submit
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HUMAN RESEARCH PROTECTION PROGRAM & THE INSTITUTIONAL REVIEW BOARD

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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