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Human Research Protection Program

Institutional Review Board (IRB) Researcher Education Series

OVERVIEW OF THE INSTITUTIONAL REVIEW BOARD (IRB)

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History of IRBs

1947: Nuremberg Code

A result of the Nazi Doctors' trial that formed the basis for the Declaration of Helsinki and the Belmont Report

1964: Declaration of Helsinki

International statement of ethical principles to guide medical professionals conducting research, including guidelines for consent

1974: National Research Act

*Established a commission that produced recommendations regarding review of research by IRBs and resulted in the creation of **45 CFR 46** or **The Common Rule (1978)***

The Common Rule was the first set of federal regulations to detail specific requirements and procedures for organizational assurances, IRB Review, informed consent , and ethical conduct of research. It was intended to ensure compliance with the principles of the Belmont Report. Additional protection added in following years (Subparts, B, C and D)

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History of IRBs

1979: Belmont Report

Defined three fundamental ethical principles for human subjects research:

1. *Respect for Persons - protect autonomy, require informed consent*
2. *Beneficence - maximize benefits, minimize risks*
3. *Justice - fair recruitment, fair distribution of risks and benefits*

2000: HIPAA Privacy Rule

The rule addresses uses and disclosures of private health information for research purposes

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Function of an IRB

Ethics & Regulations

IRBs plays an integral role in protecting the rights and welfare of human subjects by approving only the research proposals that meet rigorous ethical and regulatory standards. The Federal regulations governing human research grant IRBs a narrow charge.

Education

Post-Approval Monitoring

Evolution of HRPP Programs

- The 1999 death of Jesse Gelsinger in a clinical trial led to increased precautions around investigator and institutional conflict of interest and led to a re-conceptualization of the IRB as just one part of a broader human subjects protection program
- The 2013 discovery that cells from Henrietta lacks had been used for years without her consent informed the process of revising the Common Rule and, the shape of the Final Rule.

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The Common Rule (45 CFR 46)

The “Common Rule” is the set of regulations which were developed to ensure compliance with the principles of the Belmont Report. The regulations fall under the Department of Health and Human Services. These regulations have been adopted by many other federal departments which regulate human research.

There are many other regulations with which LSUHSC-NO IRB is required to comply, such as the Food and Drug Administration, but these are all in addition to the “Common Rule”.

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What is "Research"?

A **systematic investigation**, including development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**.

Systematic Investigation: activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question or hypothesis

Generalizable knowledge: knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population

- Contributes to theoretical framework for an established body of knowledge
- Benefits other researchers, scholars, and practitioners in the field
- Dissemination of results is intended to inform the field of study
- Results can be applied to a population beyond the site of data collection
- Results are intended to be replicated in other settings

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What is "Minimal Risk"?

Minimal Risk for the General Public

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

As defined by 45 CFR 46.102(i)

Minimal Risk for Prisoners

The probability and magnitude of physical or psychological harm is that normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of a healthy person

As defined by 45 CFR 46.303(d)

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IRB Review Categories

Review Categories Based on "Risk"

Exempt Research - research involving no or very minimal risk that is "exempt" from regulatory requirements

- 8 Categories
- Minimizes unnecessary oversight

Expedited Research - no greater than minimal risk research not requiring review by a convened board

- 9 Categories

Full Board Research - greater than minimal risk research requiring review by a **convened board**. The most rigorous level of review

Unsure if your study needs IRB review? Submit a Non-Human Subjects Research Determination

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.111 Criteria for Approval

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

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

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Privacy vs. Confidentiality

Privacy: subject's control over the extent, timing, and circumstances of sharing themselves and their information

- About people
- Controlling access that others have to themselves
- A human right
- Defined by the subject, not the IRB

Confidentiality: pertains to the treatment of information that the subject has agreed to disclose for the purpose of research

- About identifiable data
- Extension of privacy
- Agreement about maintenance and access to data
- Protects subject from inappropriate PHI disclosure as it relates to HIPAA

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Kuali Research

kuali

In June 2020, LSUHSC transitioned to the Kuali Research system for all IRB submissions

Non-Human Subjects Research Determinations
Initial Applications (Exempt, Expedited, Full Board, Reliance)
Amendments
Renewals
Reportable New Information
Emergency Use of Test Articles
Humanitarian Use Devices
Closures

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Kuali Research Review Process

The IRB Review Process:

1. PI or study team member creates an application in Kuali
2. PI submits the application to the IRB
3. The assigned IRB staff reviewer completes a full review for exempt, expedited or reliance applications; or an administrative review for full board studies.
4. For full board studies, the application is assigned to a reviewer and brought to the meeting for presentation and vote from the full board
5. If changes are needed, the IRB staff reviewer will return the application to the study team member until issues are resolved.
6. Once all issues are resolved, the IRB will approve the study
7. The study team will receive an email from the Kuali System with the IRB determination

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Tips for Successful Submission

- Make sure training is completed by all members of the study before submission
  - Feel free to reach out to the staff to verify it is complete
- Do not ask for a determination of application type over email; it is easier for the staff to make a determination using information provided in the application
- It is good clinical practice to include a protocol, or at least an abstract
  - LSUHSC pays for Protocol Builder
- Permission letters are required for research conducted at most external sites -obtain them in advance
- Use an excel spreadsheet for data collection
- Download applications and forms from our website to ensure you have the latest version.
- Place version dates on your documents at initial submission and only chage them when updating the document.

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Tips for Communicating with the IRB

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

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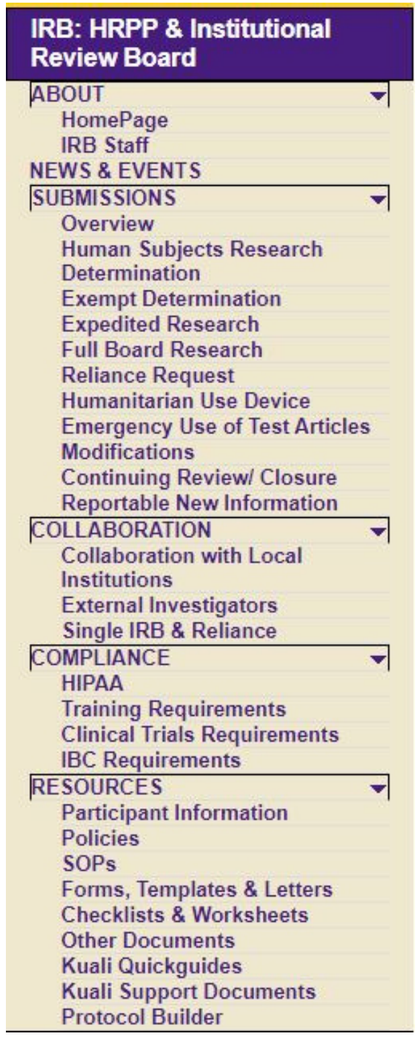
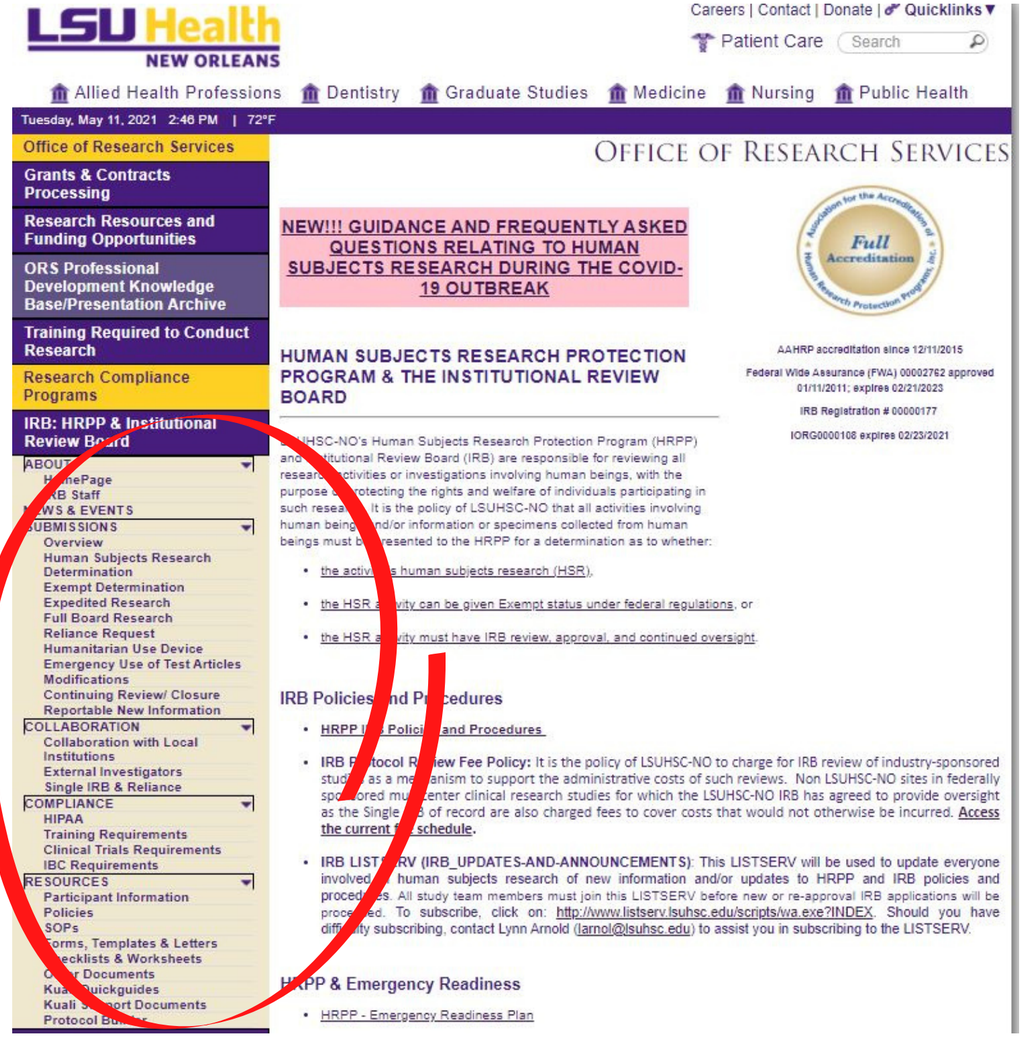
IRB Webpage





Visit our website at https://www.lsuhsc.edu/administration/academic/ors/irb.aspx for:

- Details on the different application types
- Information for collaborating with other institutions
- Training requirements
- Kuali Quickguides
- Document Templates

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Institutional Review Board (IRB) Student Education Series

QUESTIONS?