LSUHSC IRB Presents:

LUNCH & LEARN

EXPEDITED REVIEW

November 1, 2023

Objectives

- Remind study teams what does require review by the IRB
- Describe the levels of IRB review
- Define the categories of Expedited Review
- Outline the IRB review process for Expedited research

REFRESHER: 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*)

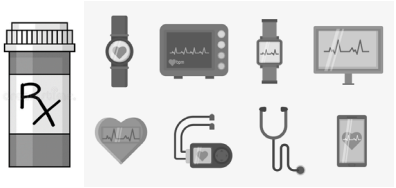
Levels of IRB Review

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

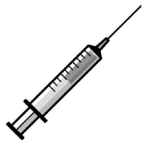
Exempt	Expedited	Full Board
Exempt from the requirements of Common Rule but not exempt from ethical considerations	Research involving minimal risk*	Greater than minimal risk to subjects
Fits one or more of the 8 Exempt Review Categories	Fits one or more of the 9 Expedited Review Categories	Not covered 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

Expedited Categories: Initial Review



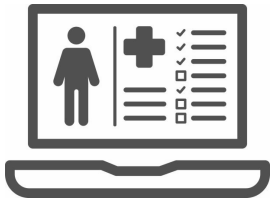
Category 1: Clinical studies of drugs and devices that do not require an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application.
Requires Consent/HIPAA



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).
Requires Consent/HIPAA

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

Category 4: Collection of data through non-invasive standard of care procedures.
Requires Consent/HIPAA



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

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

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

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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

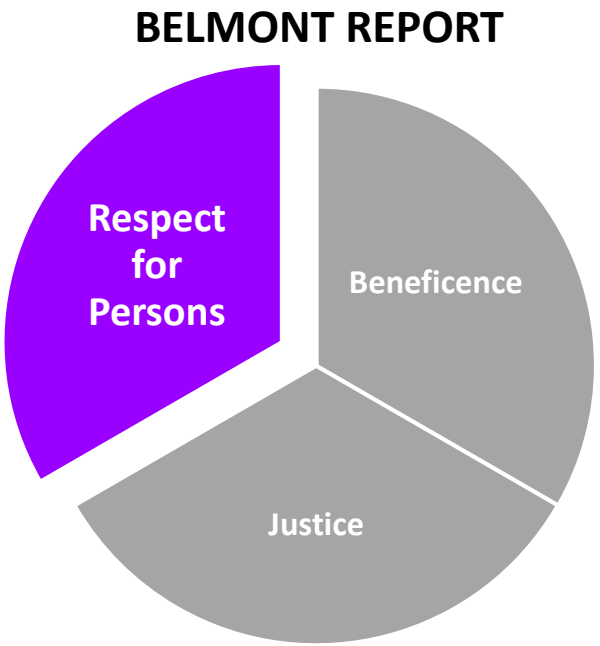
OR

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.

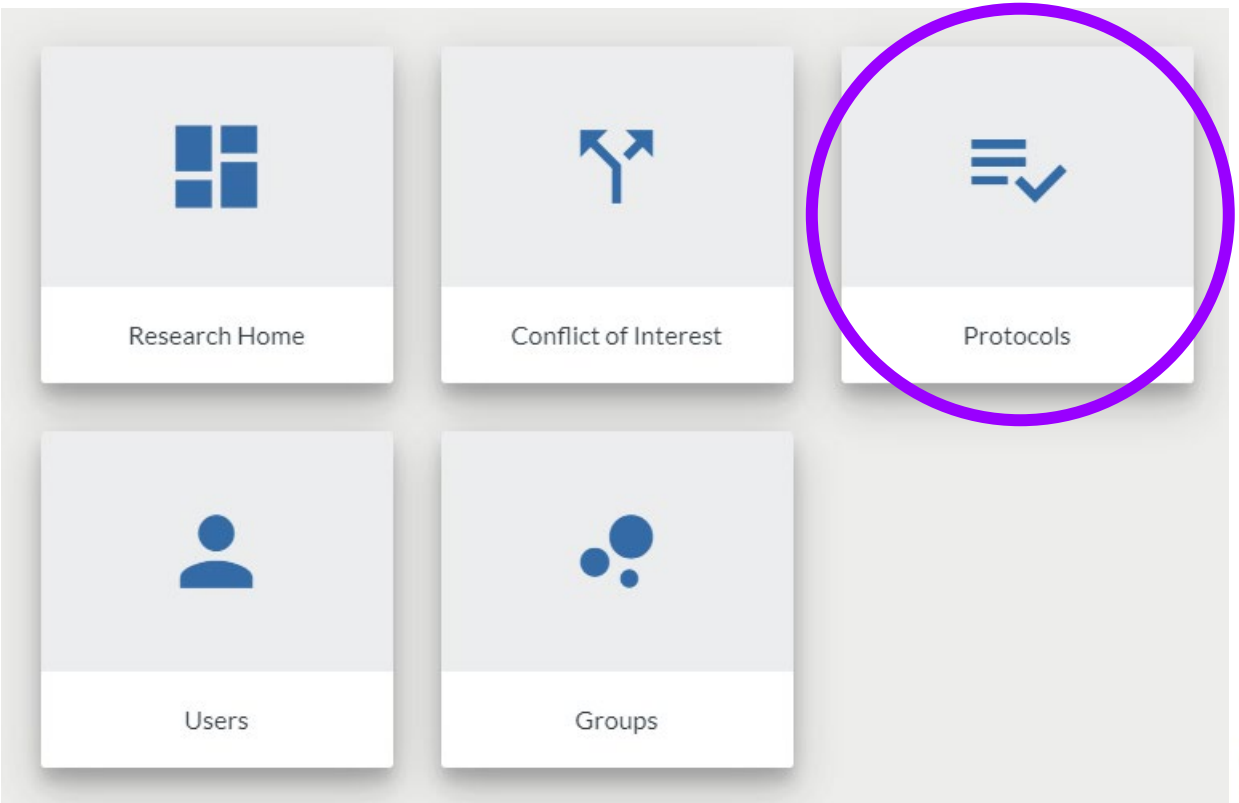
Informed Consent for Expedited Studies

- Voluntary informed consent should be obtained from participants for any exempt research where the investigator will be collecting data through interaction with participants.
- For Expedited research, the standard requirements for informed consent (or its waiver, alteration, or exception) apply.
- Templates for Consents can be found on the IRB website.



How to Submit for an Expedited Application

- Start a New Protocol in Kuali Protocols and select *Expedited* under “Protocol Type.”
- Additional instructions for submitting a study for exempt determination are available in the Kuali Quick Guides found on the IRB website.



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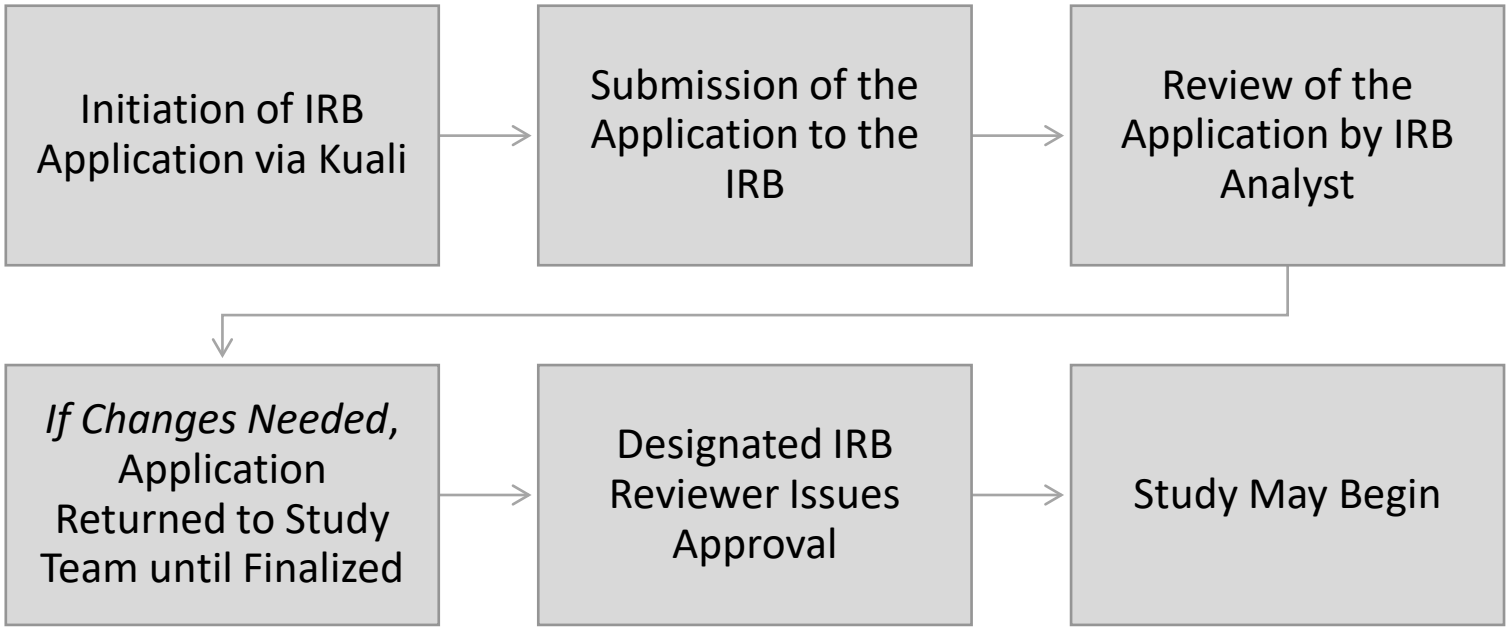
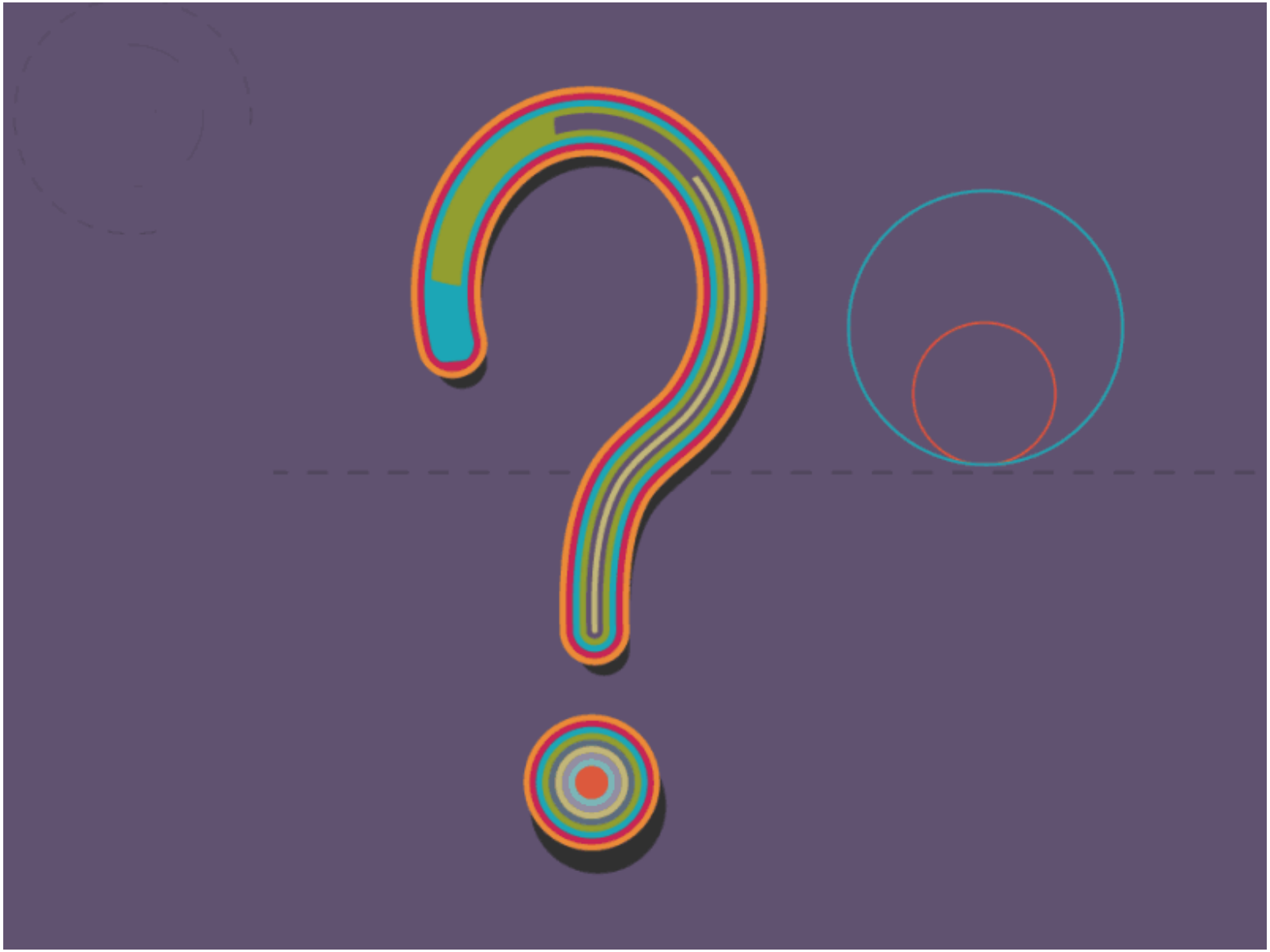
IRB Review Process





Save the Date!

December Lunch & Learn

Date: December 6, 2023
Time: 12:00 PM
Topic: Full Board Review