LSUHSC IRB Presents:

LUNCH & LEARN

EXEMPT DETERMINATIONS AND LIMITED IRB REVIEW

October 4, 2023

Objectives

- Remind study teams what does require review by the IRB
- Describe the levels of IRB review
- Define the categories of Exempt Determinations
- Outline the IRB review process and limited IRB review

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

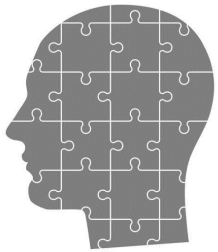
Exempt Categories

<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.

May require information sheet
**Cannot include any other procedures, such as collection of clinical data or biospecimens*

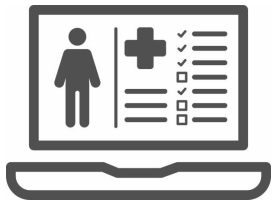
<u>Category 2</u>: Use of educational tests, surveys, interviews, or observations of public behavior

May require information sheet
**Limited IRB Review may be required.*
NO CHILDREN.



<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.)

May require information sheet
**Limited IRB Review may be required.*
NO CHILDREN.
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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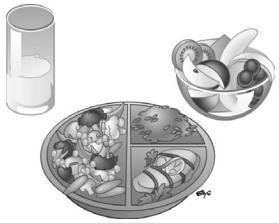
Exempt Categories

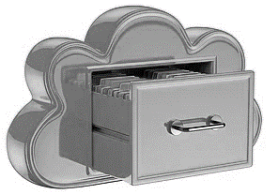
<u>Category 5</u>: Public service program research or demonstration projects

May require information sheet



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

May require information sheet
**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.

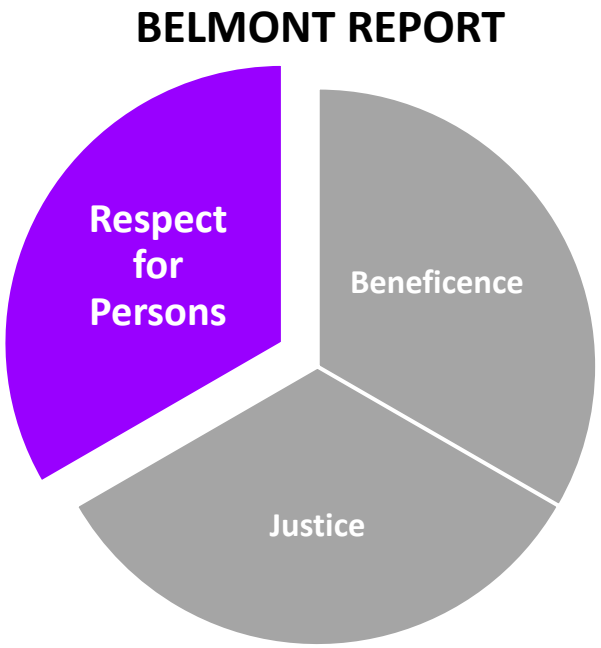
**Broad consent and limited IRB review required.*
***Most institutions do not use this category*

Informed Consent for Exempt Studies

- Voluntary informed consent should be obtained from participants for any exempt research where the investigator will be collecting data through interaction with participants.

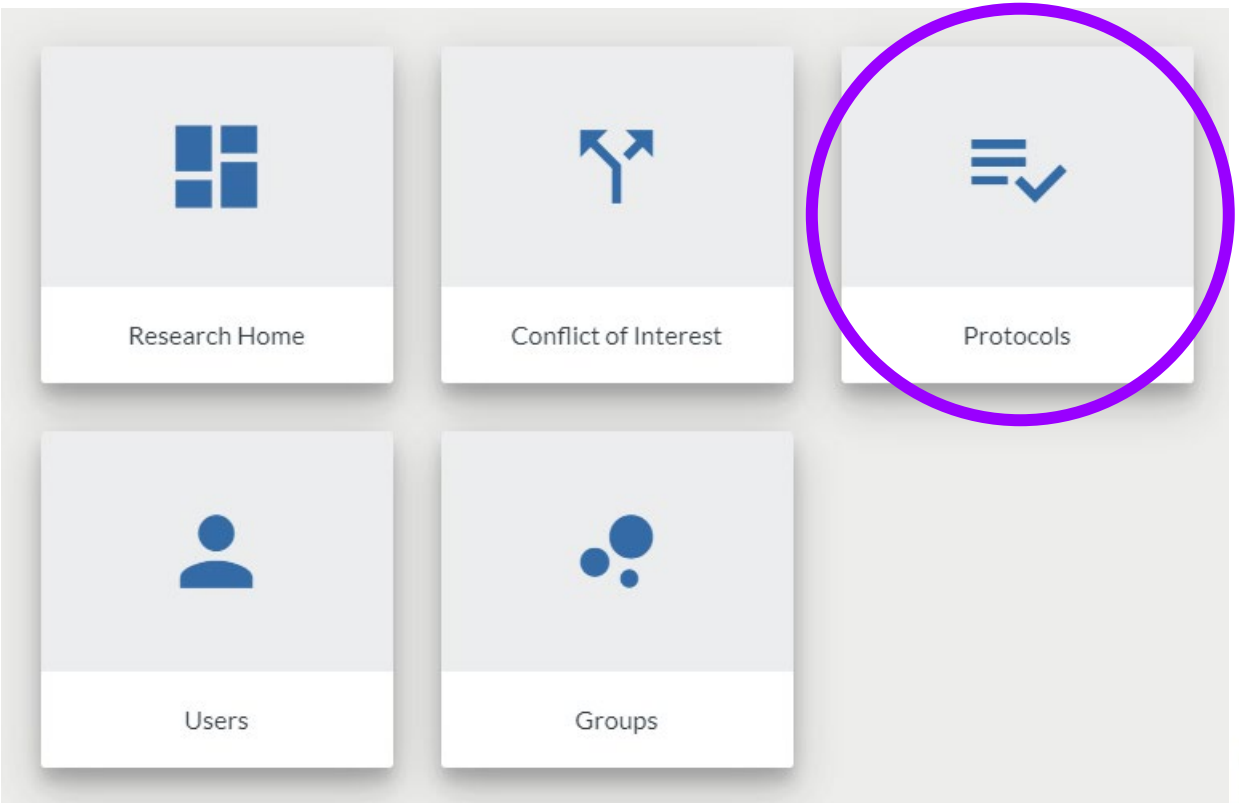
- For Exempt research, LSUHSC requires investigators to provide an Information Sheet to participants or read from an oral script.

- The information sheet or script should:
  - ✓ Provide a brief description of the research
  - ✓ Include the basic elements of informed consent
  - ✓ Not contain a signature block



How to Submit for an Exempt Determination

- Start a New Protocol in Kuali Protocols and select *Exempt Research* 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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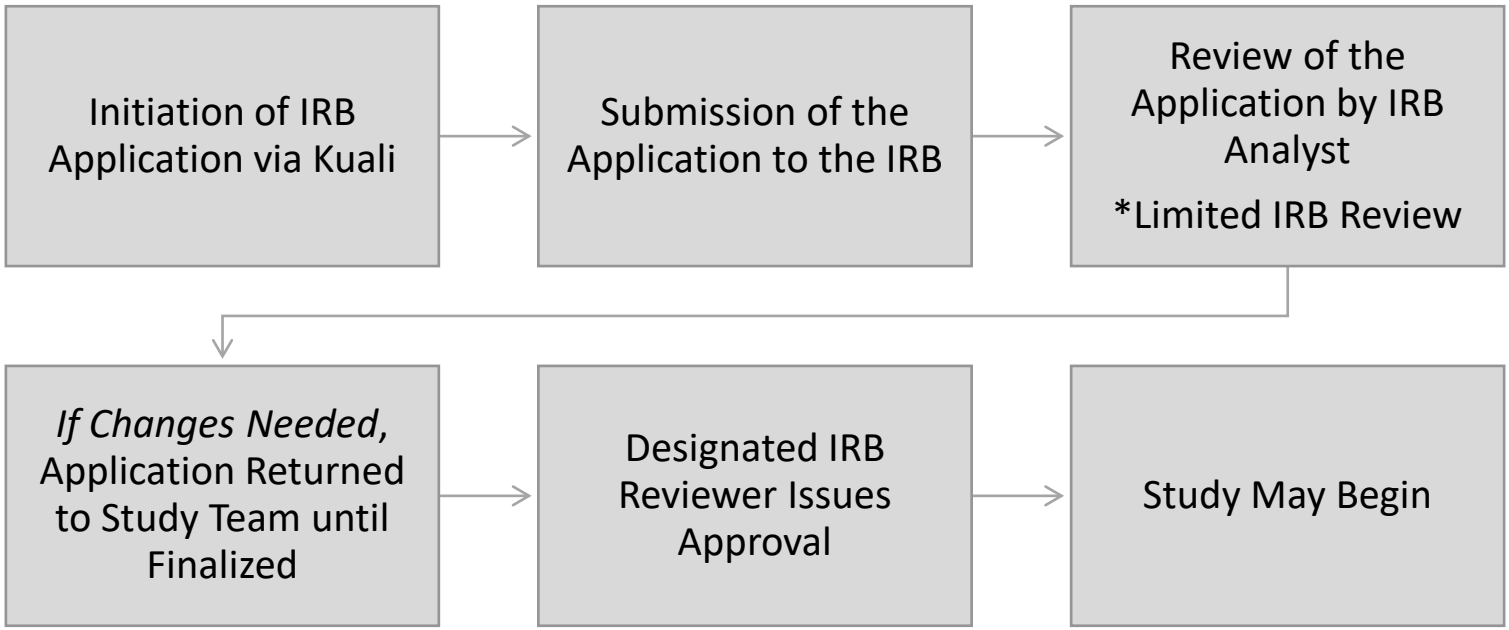
IRB Review Process



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Limited IRB Review

What is it?

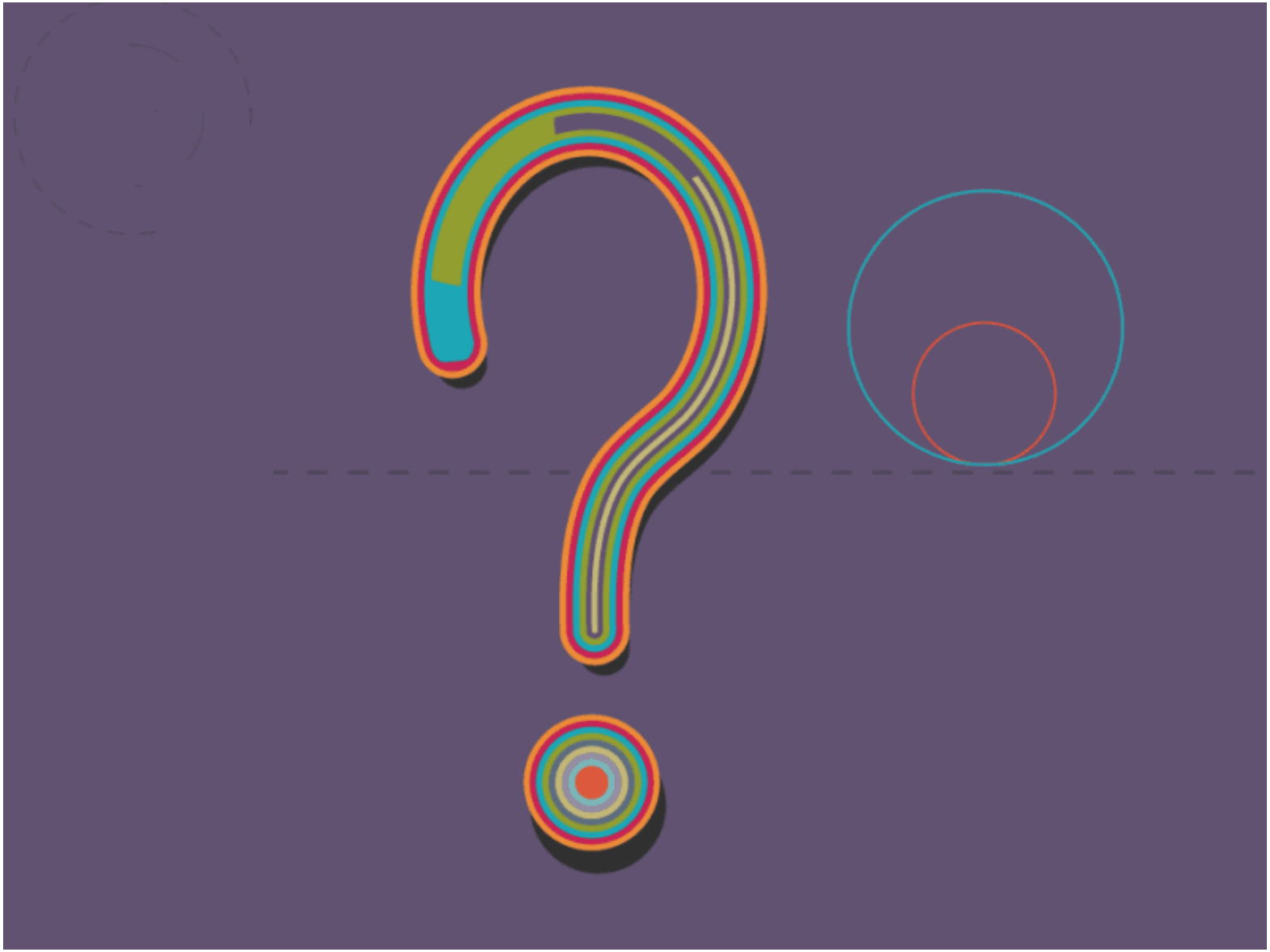
- Ensures that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of the data

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



Save the Date!

November Lunch & Learn

Date: November 1, 2023
Time: 12:00 PM
Topic: Expedited Review