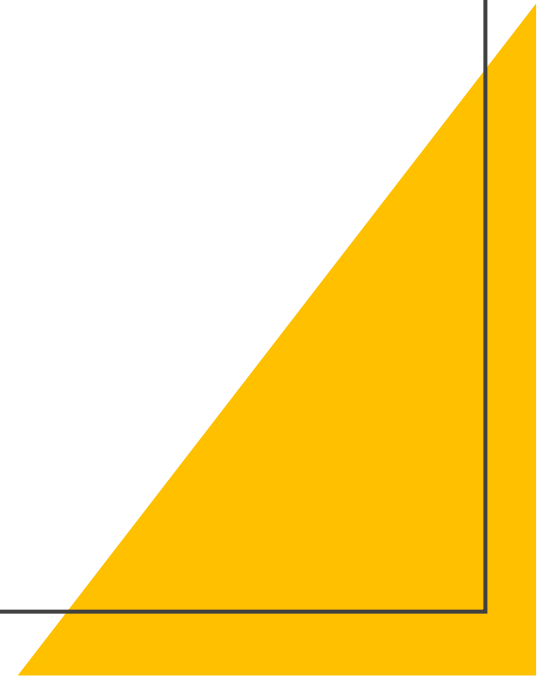


FULL BOARD REVIEW

December 6, 2023



Objectives

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

REFRESHER:

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?

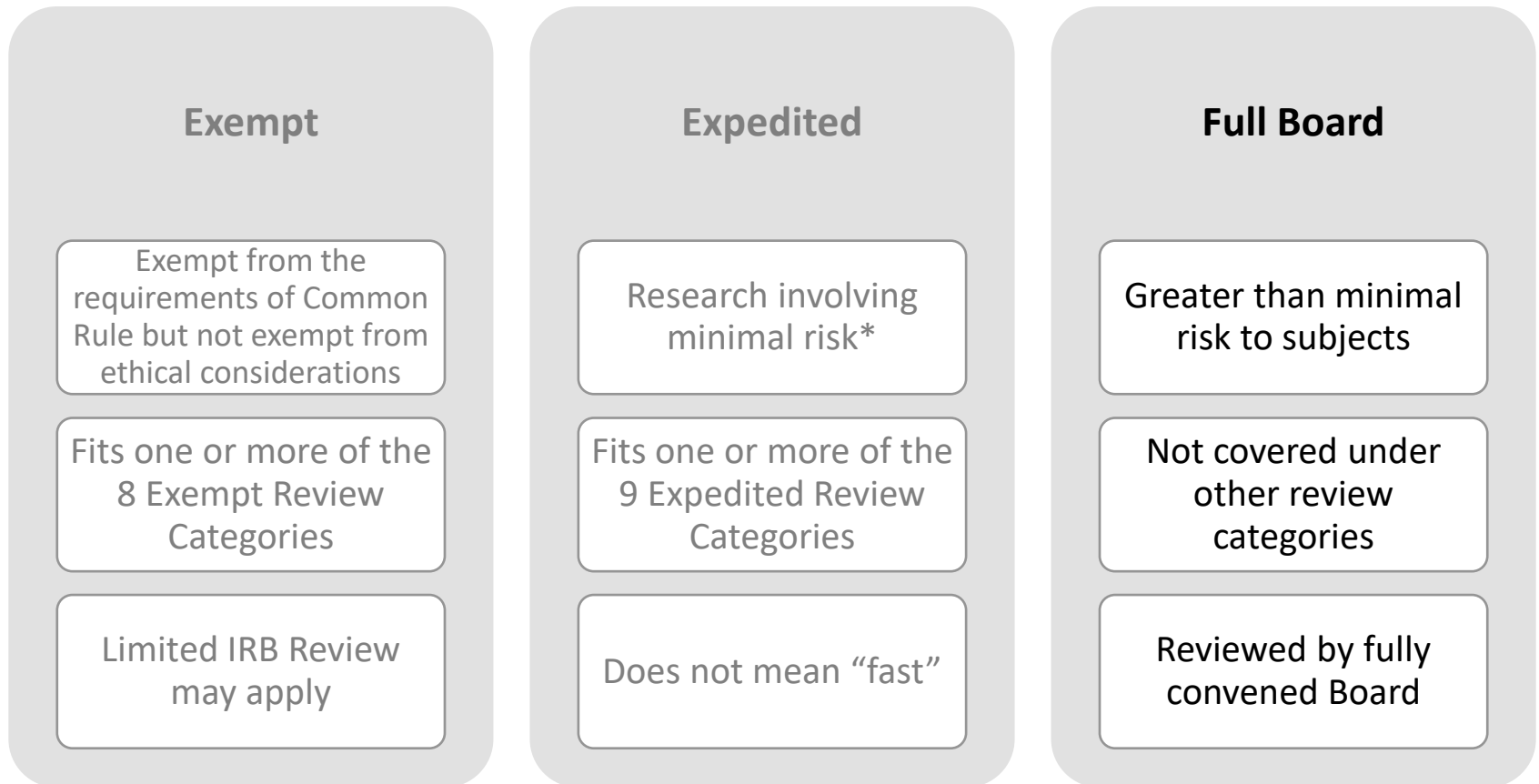
A living individual about whom an investigator conducting research:

- 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*)

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.



*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

Examples of Full Board Research

Common examples include research involving greater than minimal risk procedures such as:

- Clinical Trials involving investigational drugs, biologics, and devices
- Studies involving disclosure of information that could require mandatory legal reporting (e.g., child/elder abuse, etc.)
- Studies involving deception
- Studies involving vulnerable populations, per federal regulation
 - Children
 - Prisoners
 - Pregnant women and neonates
- Research taking place internationally

What is an Investigational New Drug?

- An Investigational New Drug (IND) is a drug or biological drug that has not been approved for general use by the FDA. It is used in a clinical trial to investigate its safety and efficacy.
- The term also includes biological products that are used in vitro for diagnostic purposes.
- An IND application is a request for authorization from the FDA to administer an investigational drug or biological product to humans.

Three Types of INDs



Research IND: study of an unapproved drug, an approved product for a new indication, or an approved product on a new patient population



Emergency Use IND: allows for use of an unapproved drug in an emergency situation that does not allow time for submission of an IND or when a patient does not meet inclusion criteria for an approved research IND



Treatment IND: submitted for experimental drugs that show promise in clinical testing for serious or immediately life-threatening conditions (*usually approved towards the end of a clinical trial*)

What is an Investigational Device & an Investigational Device Exemption?

- An **investigational device** is a device that has not been cleared for marketing by the FDA. It is used in clinical studies in order to collect safety and effectiveness data.
- An **Investigational Device Exemption (IDE)** application permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act (FD&C Act) that would apply to devices in commercial distribution.

IDE Types

IDE

- Involves an Investigational Device; **and,**
- Used in clinical research investigation; **and,**
- Intended to design, cure, mitigate, treat, or prevent disease; **and,**
- Intended to affect the structure or function of the body; **and,**
- Device is deemed significant risk (SR)

Abbreviated IDE

- Involves an Investigational Device; **and,**
- Used in clinical research investigation; **and,**
- Intended to design, cure, mitigate, treat, or prevent disease; **and,**
- Intended to affect the structure or function of the body; **and,**
- Device is deemed non-significant risk (NSR)

IDE Exempt

- Involves a legally marketed device used in accordance with labeling; **or,**
- Diagnostic device that meets the requirements of §809.10(c); **or,**
- A device undergoing additional testing; **or,**
- A device intended solely for animal use

Classifications of Devices

Significant Risk (SR):

- Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- For a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.



Non-Significant Risk (NSR):

- One that does not meet the definition of a significant risk device.



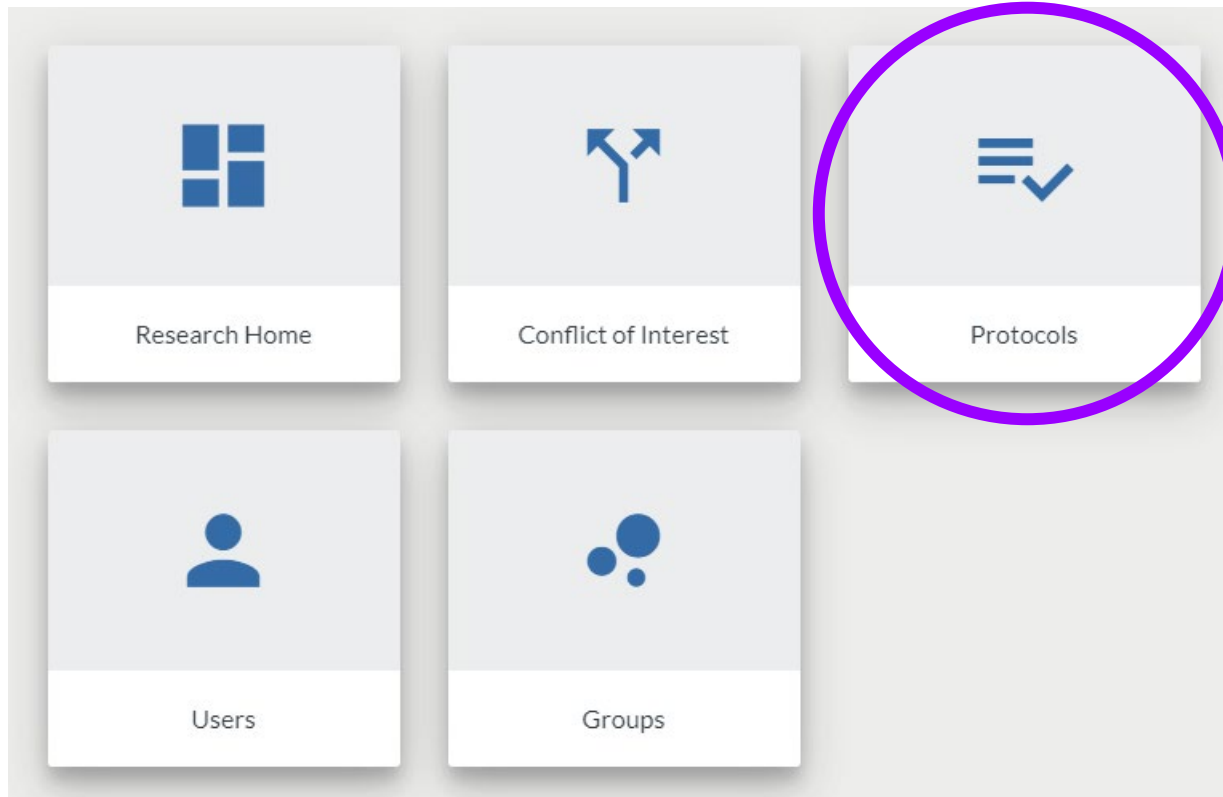
Informed Consent for Full Board Studies

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

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



When to Submit a Full Board Application

- Committee meetings are typically held on the 3rd Wednesday of each month.
- IRB applications for full committee review must be received by the last working Wednesday of the month prior to the meeting date.
- In general, researchers should allow sufficient time for the pre-review process to ensure that submission materials are adequate for IRB review. Only complete and consistent submission materials will be assigned to a meeting agenda for review.

DECEMBER 2023

SUN	MON	TUE	WED	THU	FRI	SAT
26	27	28	29	30	1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31	1	2	3	4	5	6

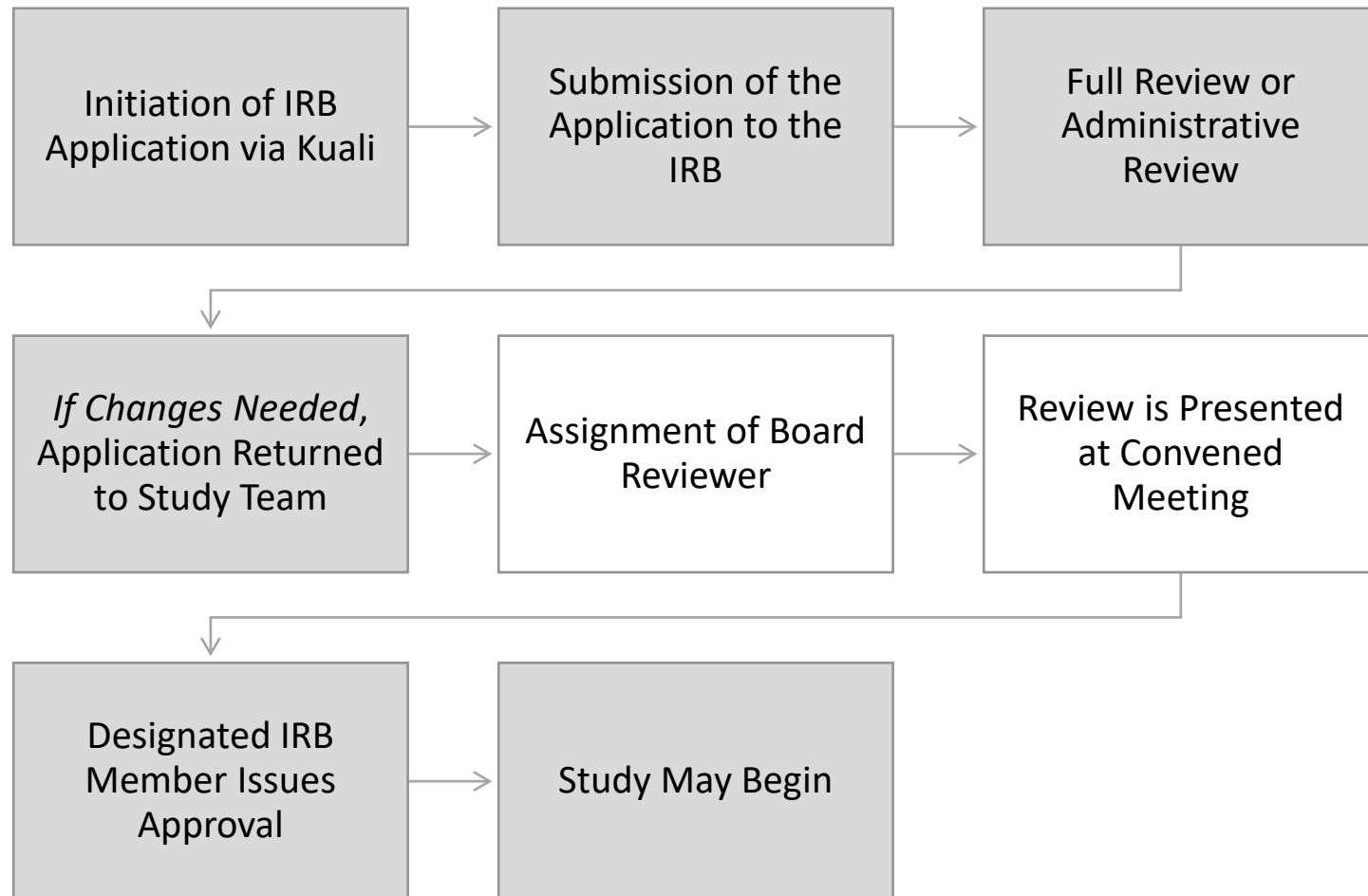
www.GrabCalendar.com

JANUARY 2024

SUN	MON	TUE	WED	THU	FRI	SAT
31	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31	1	2	3

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IRB Review Process



Possible Outcomes of a Full Board Review

Approve

- When all criteria for approval are met

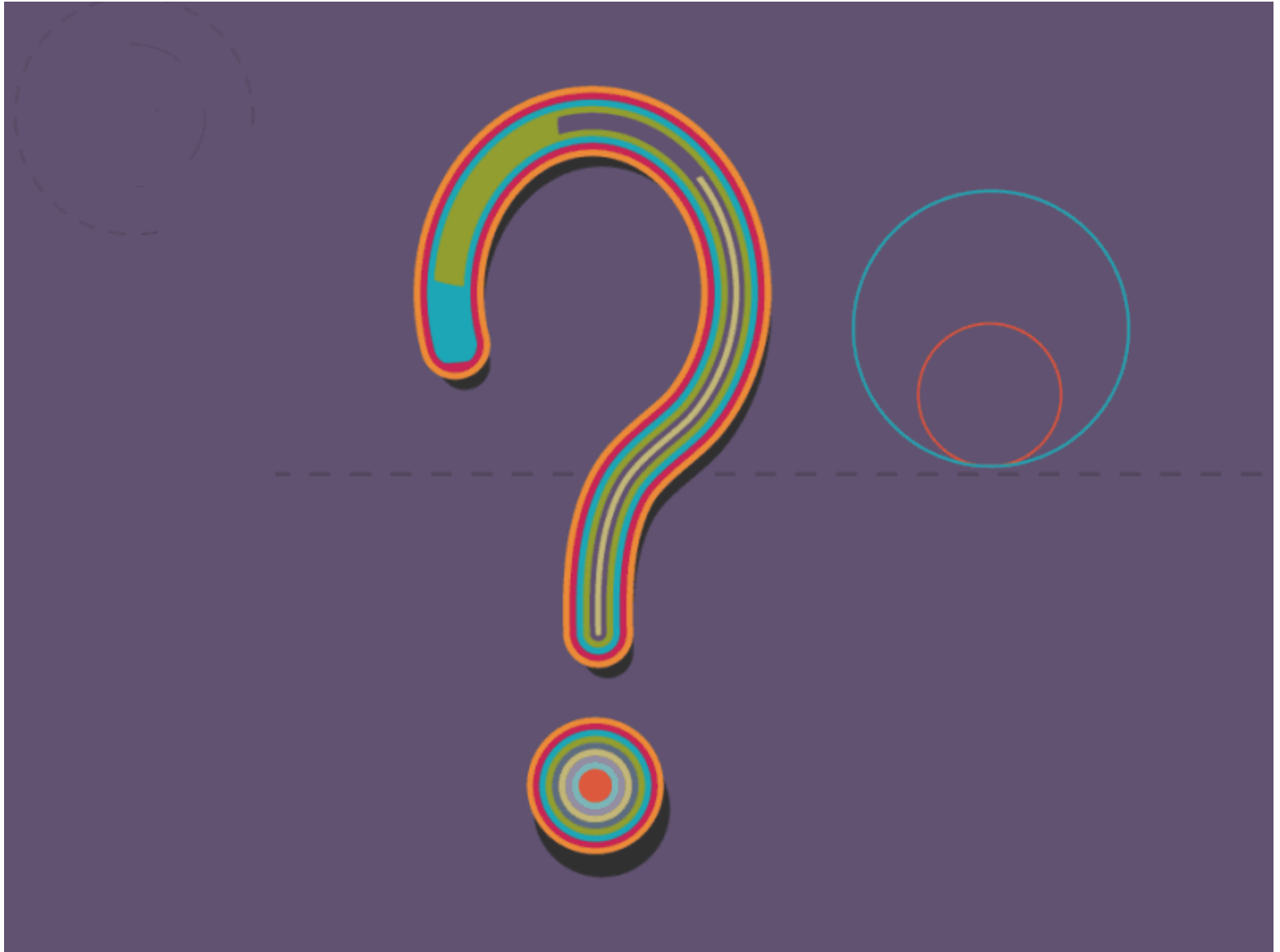
Modifications Required to Secure Approval

- Minor modifications required prior to approval
- The Chair or designated reviewer can review changes

Defer

- Significant modifications required prior to approval
- The convened Board will have to review all modifications

Disapprove



Save the Date!

January Lunch & Learn

Date: January 10, 2024
Time: 12:00 PM
Topic: Informed Consents