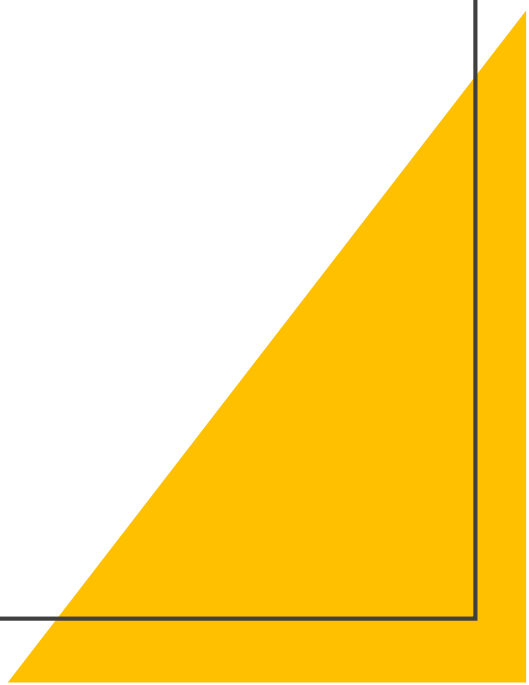


AMENDMENTS TO APPROVED RESEARCH

February 7, 2024



Objectives

- Define Amendments and provide examples
- Discuss tips for submitting an amendment to the IRB
- Walk through the submission and review process of an amendment

Amendments to Approved Research

Investigators are responsible for obtaining prior approval from the IRB before implementing any changes to previously approved research.

The only exceptions to this requirement are:

- A change that is necessary to eliminate an immediate hazard to one or more of the participants;
- A change that is limited to updating contact information on approved flyers or letters; or,
- A change correcting typographical errors that do not alter the original meaning of the text.

Tip: Amendments or changes to the protocol are sometimes referred to as “modifications.”

Examples of Common Amendments

- Changes to study personnel
- Addition or alteration of research activities
- Addition or alteration of recruitment materials
- Addition or alteration of data collection forms
- Increase or decrease in proposed human research subject enrollment supported by a statistical justification
- Revising the inclusion or exclusion criteria
- Alterations in the dosage or route of administration of an administered drug
- Changing the type, volume or frequency of biological sample collections
- Changing the length or number of study visits
- Alterations in human research subject compensation
- Addition or deletion of study sites
- Addition of serious unexpected adverse events or other significant risks


Tips for Submitting an Amendment

- For additions of new personnel, make sure training is up to date
- When revising already approved study documents, make sure to provide a tracked-changes copy of the document in word format and a clean copy in PDF format
- Check all study documents to ensure that the change is made consistently throughout the documents (i.e., a change in PI will require modifications to the IRB application, protocol, consent form, HIPAA authorization, and recruitment materials)

Submission of Amendments

1. Initiate an Amendment by first selecting the study you want to amend.

Protocols

Include all protocol versions  Export to CSV [+ New Protocol](#)

Search **Advanced Filter (1)** Saved Filters Manage Columns

Title	Number	PI Name	Submission Type	Review Type	Status	Assignment	Continuing Review Date	Unresolved Events
Final Update P Site and Protocol Personnel	1447	Researcher, IRB	Initial	Expedited	● Approved			3
Lipid mediators in mild cognitive impairment and Alzheimer disease	671	Bazan, Nicolas	Initial	Exempt	● Approved		November 20, 2023	0
Survival Signaling in Human Retinal Pigmented Epithelial Cells	670	Bazan, Nicolas	Initial	Exempt	● Approved		November 20, 2023	0
Predicting Bachelor of Science in Nursing (BSN) Student Success Following the COVID 19 Pandemic Outbreak	668	Manning, Jennifer	Initial	Exempt	● Approved		May 15, 2023	0
COVID-19 IgM/IgG Rapid Test Clinical Evaluation	667	Miele, Lucio	Initial	Expedited	● Approved		May 14, 2023	0
Mental Health Impact of the COVID19 Pandemic on Healthcare Workers and First Responders	666	Osofsky, Howard	Initial	Expedited	● Approved		May 14, 2023	0

Submission of Amendments

2. Select the Amend option in the right-hand menu












Protocol Reportable Events Activity Log **Ancillary Review** Permissions

IRB: #1447 Final Update P Site and Protocol Personnel

Selected Version:
1 | Initial | Approved

Protocol Information Show Less ^

Review Type Expedited	Status Approved	Approval Date Sep 09, 2022	Continuing Review Date --
Expiration Date --	Initial Approval Date Sep 09, 2022	Initial Review Type Expedited	

-  Amend
-  Renew
-  Renew & Amend
-  Action Items Summary
-  Admin Notes & Files
-  Review Assignments
-  Approval Update
-  Suspend
-  Close
-  Request Close
-  Print

Submission of Amendments

3. Complete the information in the Amend application.

Questions	Options	Tips
Under what Protocol Type was this study approved?	<ul style="list-style-type: none"> • Reliance Request • Full Board • Expedited • Exempt • Humanitarian Use Device • Expanded Access 	This should match the original application type you submitted (i.e., if the initial application was a Full Board, then select Full Board)
Is the study being amended a Legacy Study?	<ul style="list-style-type: none"> • Yes • No 	Protocol #1 - #1166 = Yes Protocol #1167 or higher = No
What is the current status of the study?	<ul style="list-style-type: none"> • Research not yet started • Open to enrollment • Closed to enrollment • Suspended or on hold • Other 	
Is the proposed modification being requested by the Sponsor of the study?	<ul style="list-style-type: none"> • Yes • No 	
Which modification(s) are applicable to this proposed amendment?	<ul style="list-style-type: none"> • Principal Investigator • Research Personnel • Study Title • Study Population • Funding/Sponsor Information • Performance Site • Other 	Select all that apply.

Submission of Amendments

4. Select the Submit option in the right-hand menu once ready for IRB review.

Protocol Reportable Events Activity Log **Ancillary Review** Permissions

IRB: #1447 Final Update P Site and Protocol Personnel

Selected Version:
5 | Amendment | In Progress

Protocol Information Show Less ^

Submission Type Amendment	Status In Progress	Approval Date --	Continuing Review Date --
Expiration Date --	Initial Approval Date Sep 09, 2022	Initial Review Type Expedited	

- Admin Notes & Files
- Abandon
- Submit**
- Print

Review of Amendments

Exempt/Expedited

- Administrative & scientific review by IRB Analyst
- Application returned for changes, if needed
- IRB approval issued

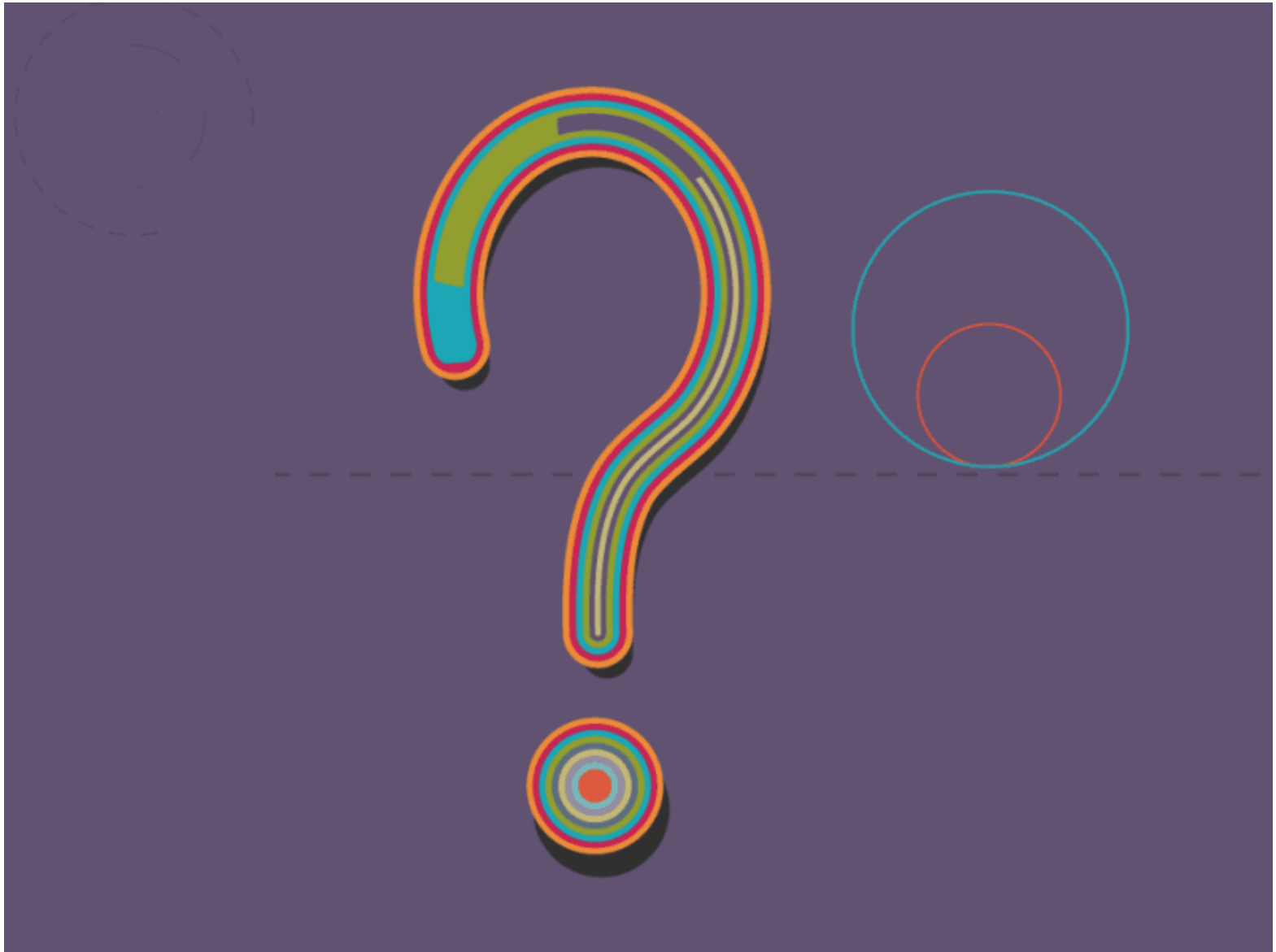
Full Board

- Administrative review
- Application returned for changes, if needed
- Assignment to Full Board Reviewer and meeting
- Review presented at meeting
- IRB approval issued

Reliance

- Administrative review
- Application returned for changes, if needed
- IRB acknowledgment provided

Note: Significant changes that increase the risk or new activities may result in a change of review type. Accordingly, IRB review of modifications also focuses on verifying that the project continues to be eligible for its current review status.



Save the Date!

March Lunch & Learn

Date: March 6, 2024
Time: 12:00 PM
Topic: Closing a Study