LSUHSC IRB Presents:

LUNCH & LEARN

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

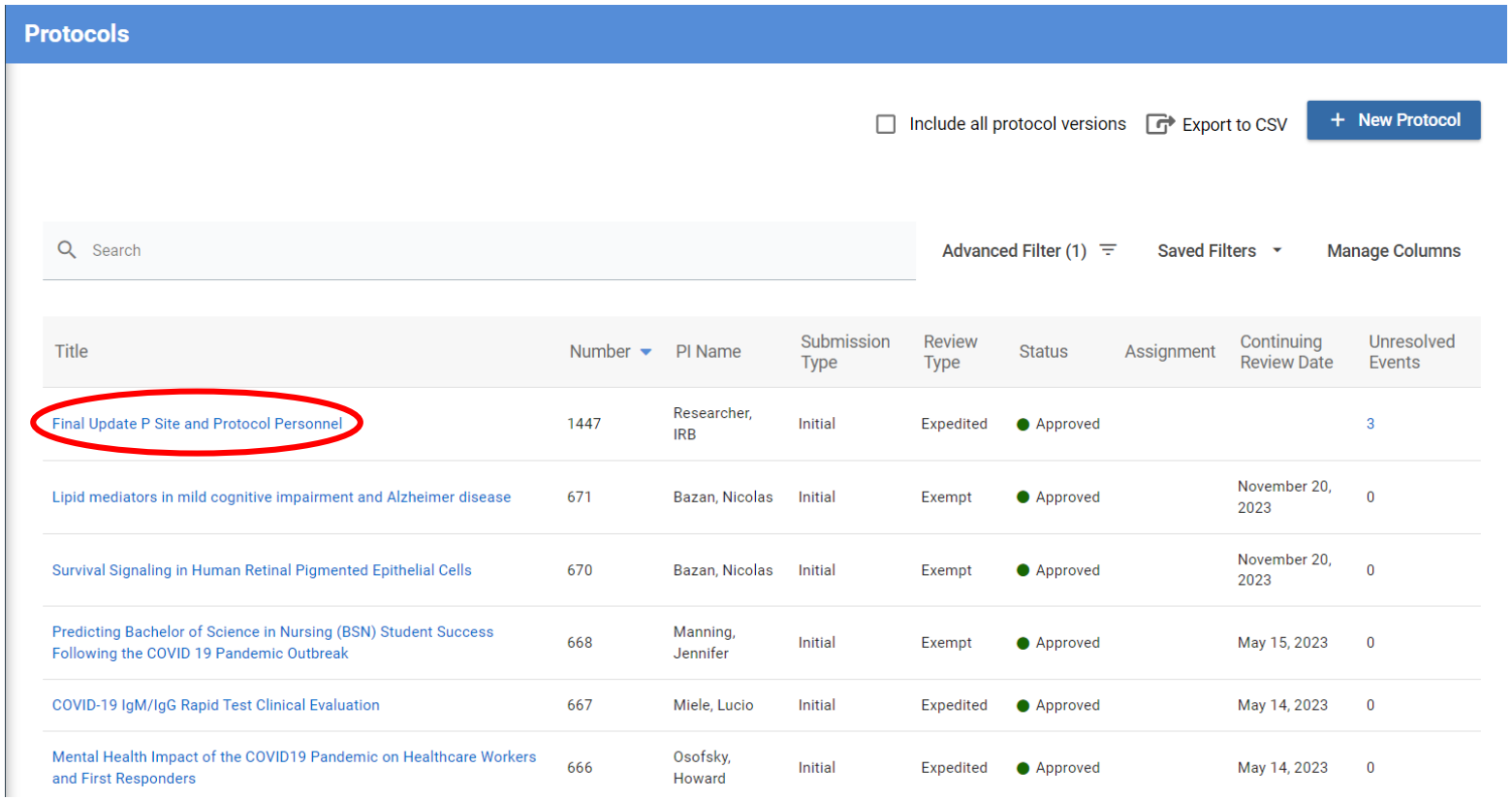
- Changes to study personnel
- Addition or alteration of research activities
- Addition or alteration of recruitment materials
- Addition or alteration of data collection forms
- Increase or decrease in proposed human research subject enrollment supported by a statistical justification
- Revising the 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)

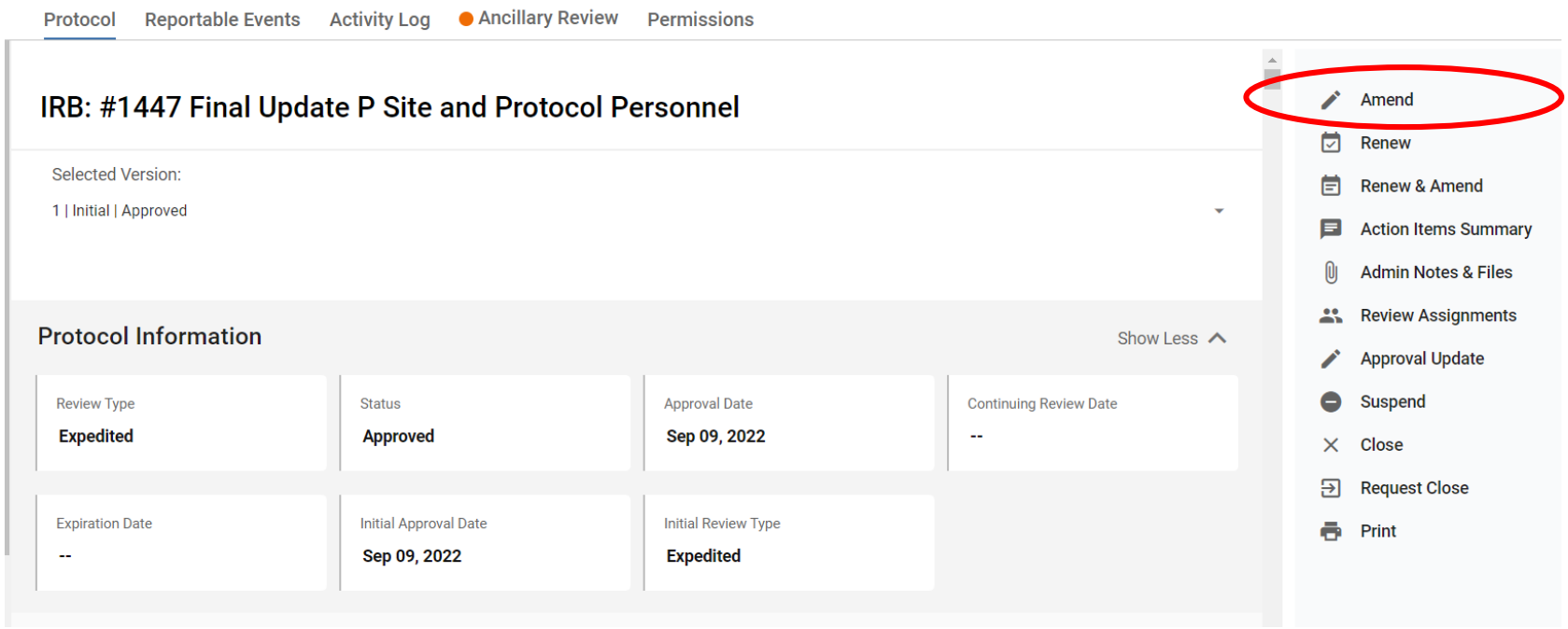
Submission of Amendments

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



Submission of Amendments

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



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Submission of Amendments

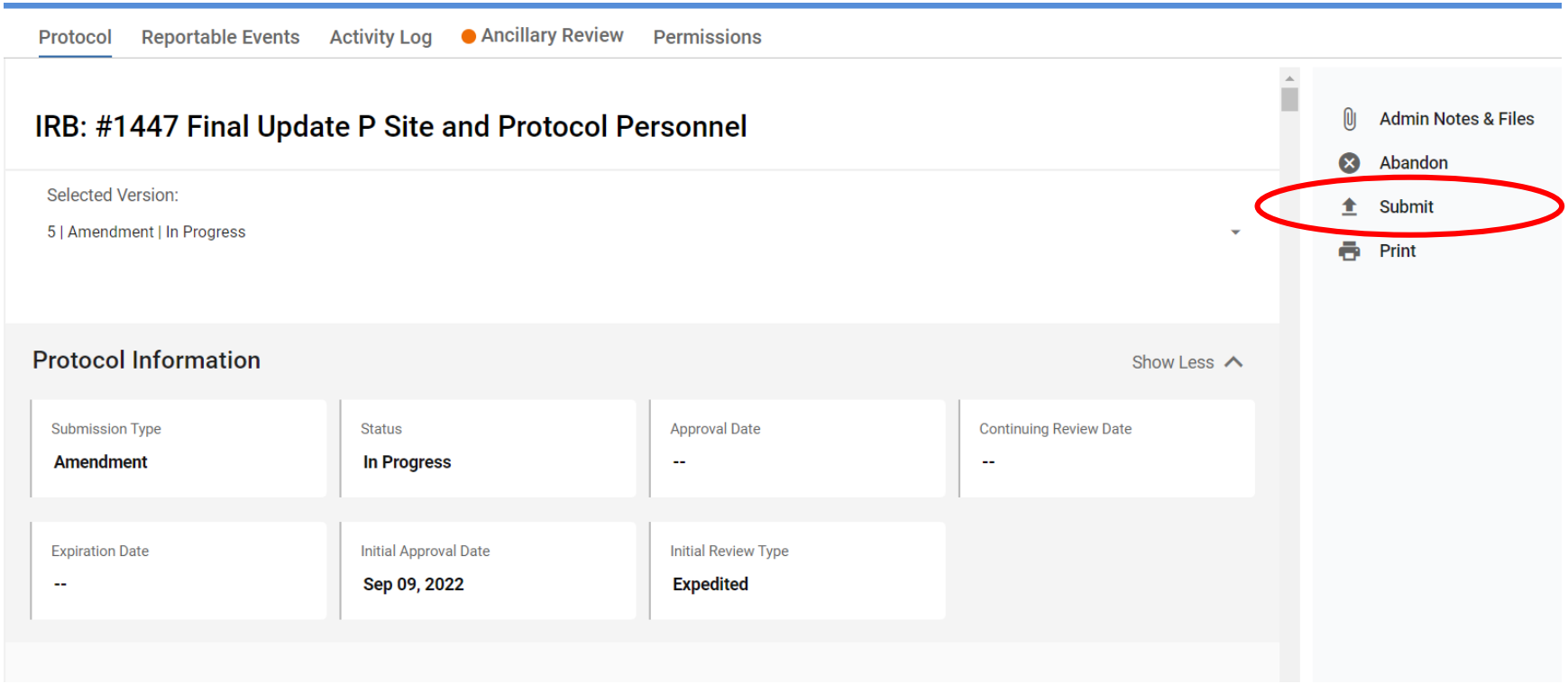
3. Complete the information in the Amend application.

Questions	Options	Tips
Under what Protocol Type was this study approved?	• 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?	• Yes • No	Protocol #1 - #1166 = Yes Protocol #1167 or higher = No
What is the current status of the study?	• 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?	• Yes • No	
Which modification(s) are applicable to this proposed amendment?	• Principal Investigator • Research Personnel • Study Title • Study Population • Funding/Sponsor Information • Performance Site • Other	Select all that apply.

Additional questions will follow that are specific to the types of modifications being made.

Submission of Amendments

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



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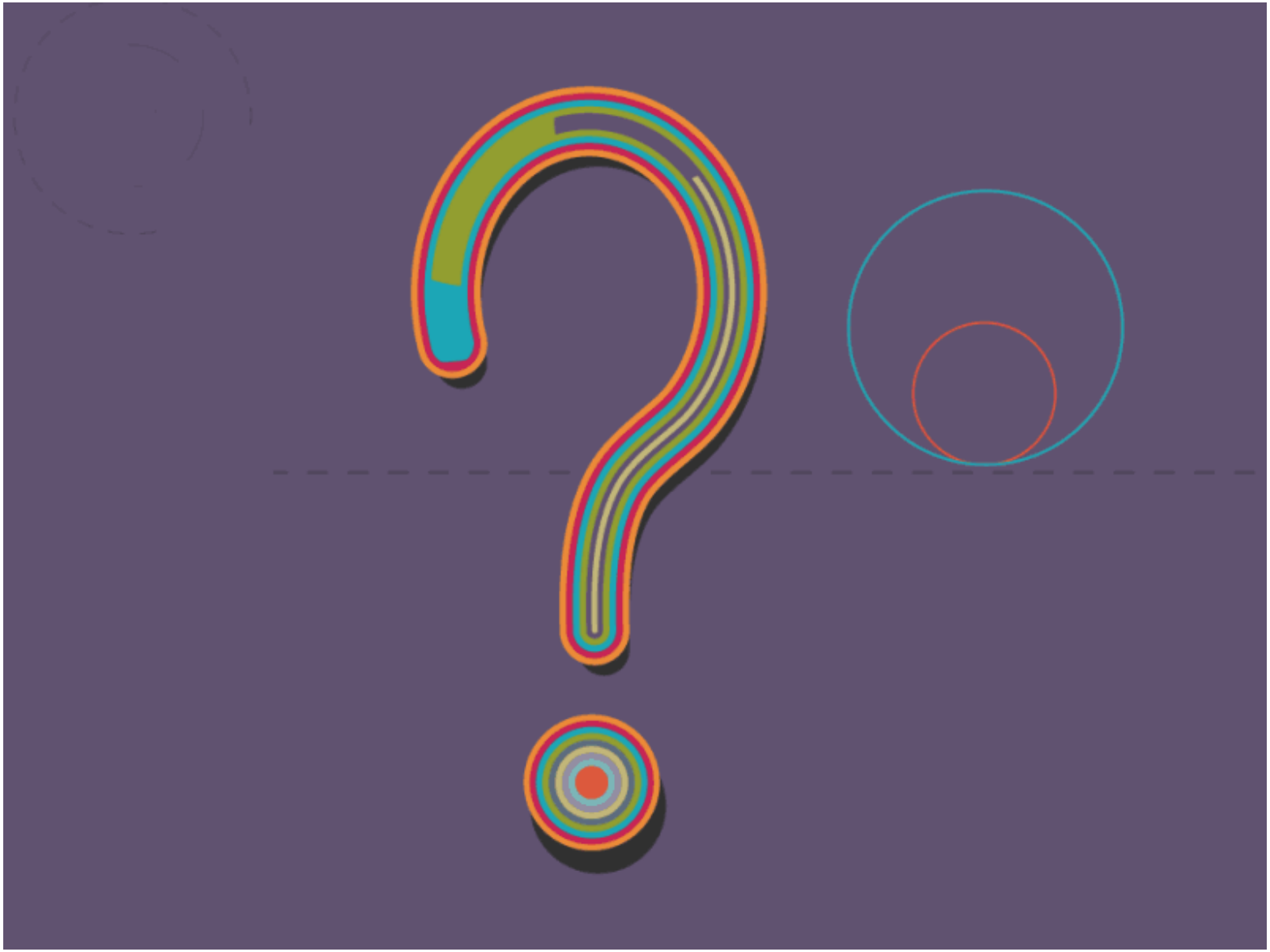
Review of Amendments

Exempt/Expedited	Full Board	Reliance
• Administrative & scientific review by IRB Analyst • Application returned for changes, if needed • IRB approval issued	• Administrative review • Application returned for changes, if needed • Assignment to Full Board Reviewer and meeting • Review presented at meeting • IRB approval issued	• 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