CLOSING A STUDY

March 6, 2024

Objectives

- Describe the three types of study closures that occur
- Discuss PI responsibilities after closure
- Walk through submitting a closure request

Types of Closures

There are three types of closures that can occur for IRB Protocols:

1. Study closures that are requested by the PI when study conduct is complete
2. Administrative closures by the IRB due to lapse in approval
3. Termination of IRB approval by the IRB due to non-compliance or misconduct

Study Closure by PI

A PI may request that a study be closed when:

- All research participants have completed all study-related activities (i.e., interventions, procedures, follow-up); and/or the research team has collected all PHI/specimen from participants and their charts; **AND**,
- The research team has completed analysis of all identifiable data and specimens as described in the protocol.

Note: De-identified data analysis can continue even after the IRB is closed.

Administrative Closures

A lapsed study that has not obtained Renewal approval by the Expiration Date will be administratively and permanently closed.

Expiration date = 60 calendar days after Continuing Review Date

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Termination of IRB Approval

The IRB may terminate IRB approval at any time in any of the following circumstances:

- Serious Non-Compliance that cannot be resolved
- Continuing Non-Compliance that has not been resolved
- Concerns for the safety/welfare of subjects
- Any other serious or continuing misconduct

Note: Except in the case where there is an imminent threat to subject safety/welfare, the IRB will usually first suspend the study to conduct an investigation into non-compliance or misconduct. The IRB will try to work with the study team to resolve any issues.

PI Responsibilities After Closure

Record Retention

- After study closure, the PI and the study team are required to keep all research-related files, with the exception of PHI, for ten years
- The files can be kept on campus or sent to storage (i.e., Vital Records or Iron Mountain)

Data Security

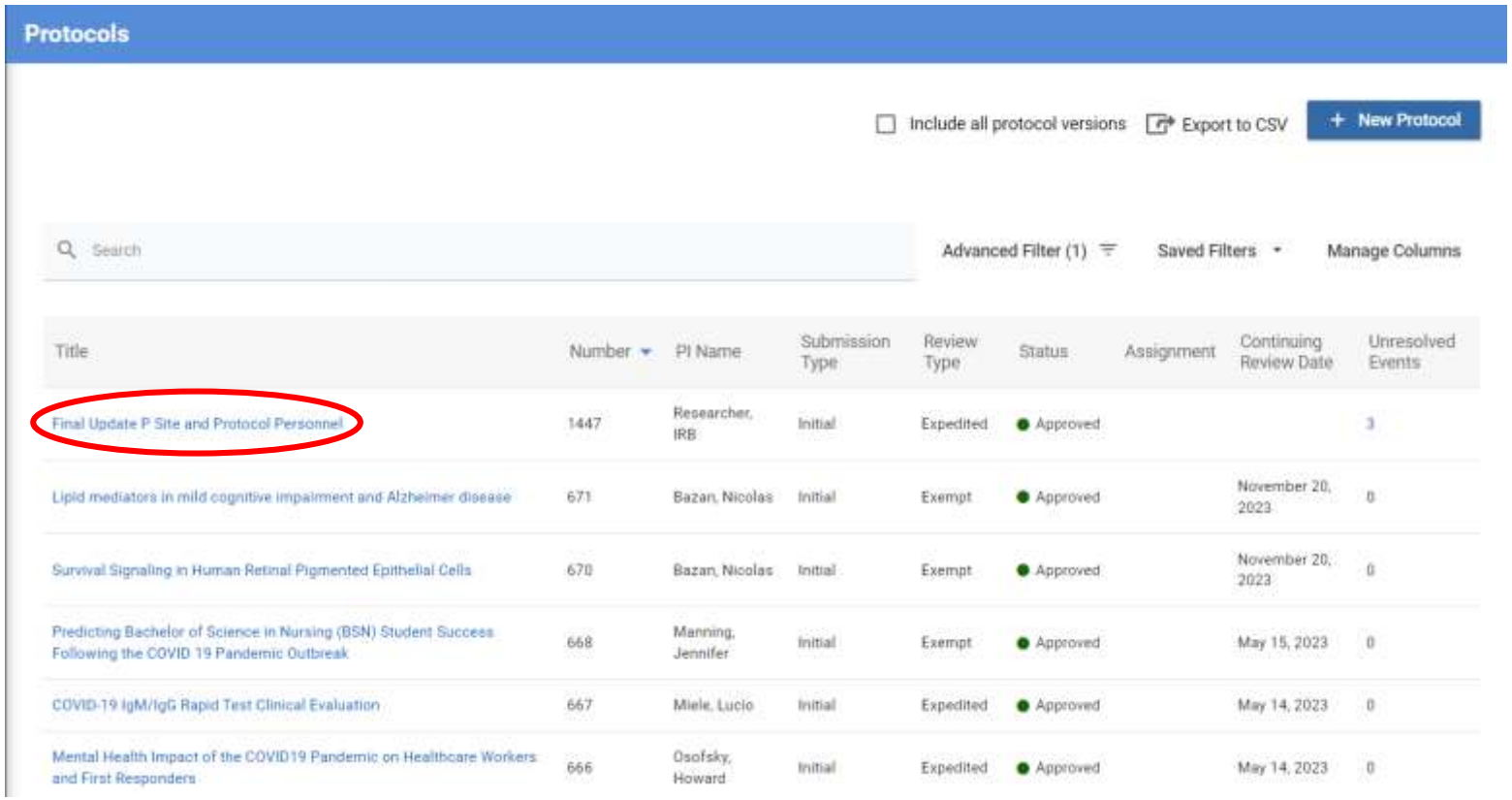
- If the study was approved for the collection and storage of PHI, the PI must ensure the PHI is only maintained for the specified time period approved by the IRB.
- After that point, the PI must destroy the PHI

Commitments to Participants

- If the PI made any commitments in the consent to participants (i.e., providing information about study results, payment, etc.), s/he must honor those commitments

Submitting a Closure Request

1. Initiate a closure by first selecting the study you want to close.



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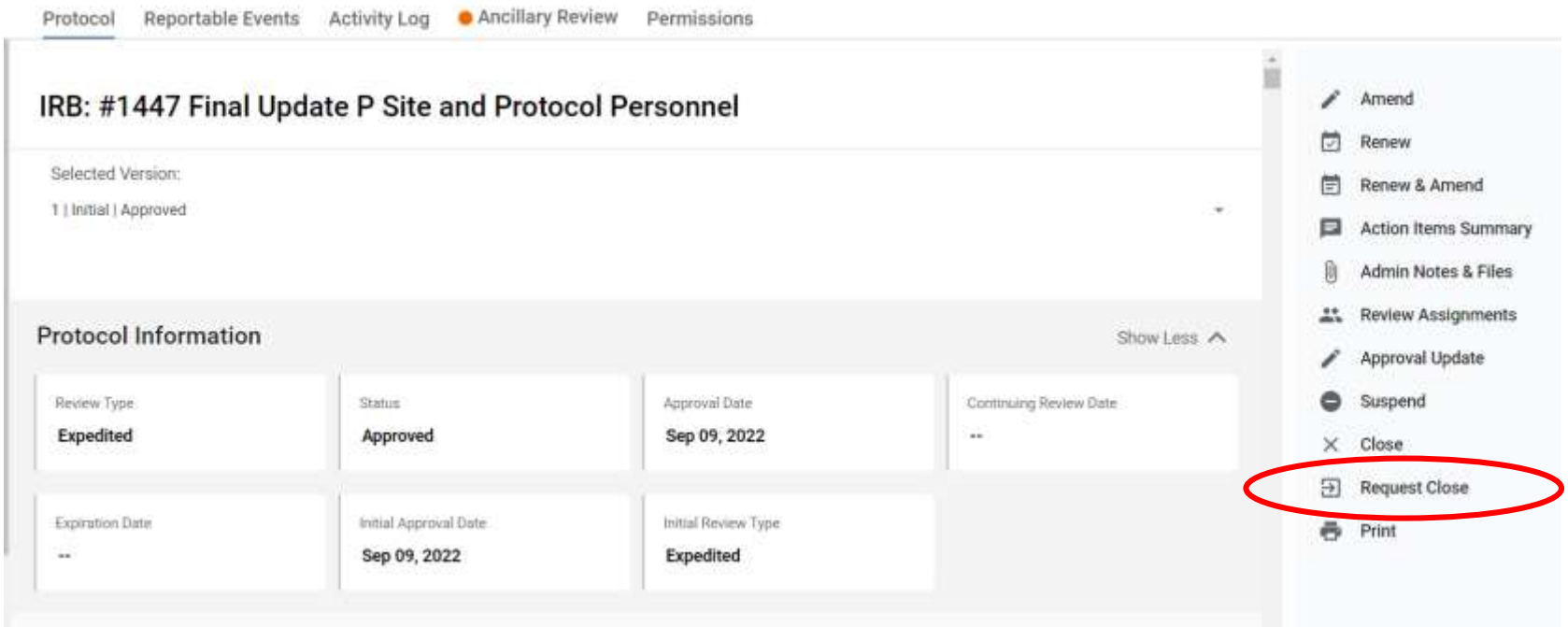
Submitting a Closure Request

2. Select the Request Close option in the right-hand menu



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Submitting a Closure Request

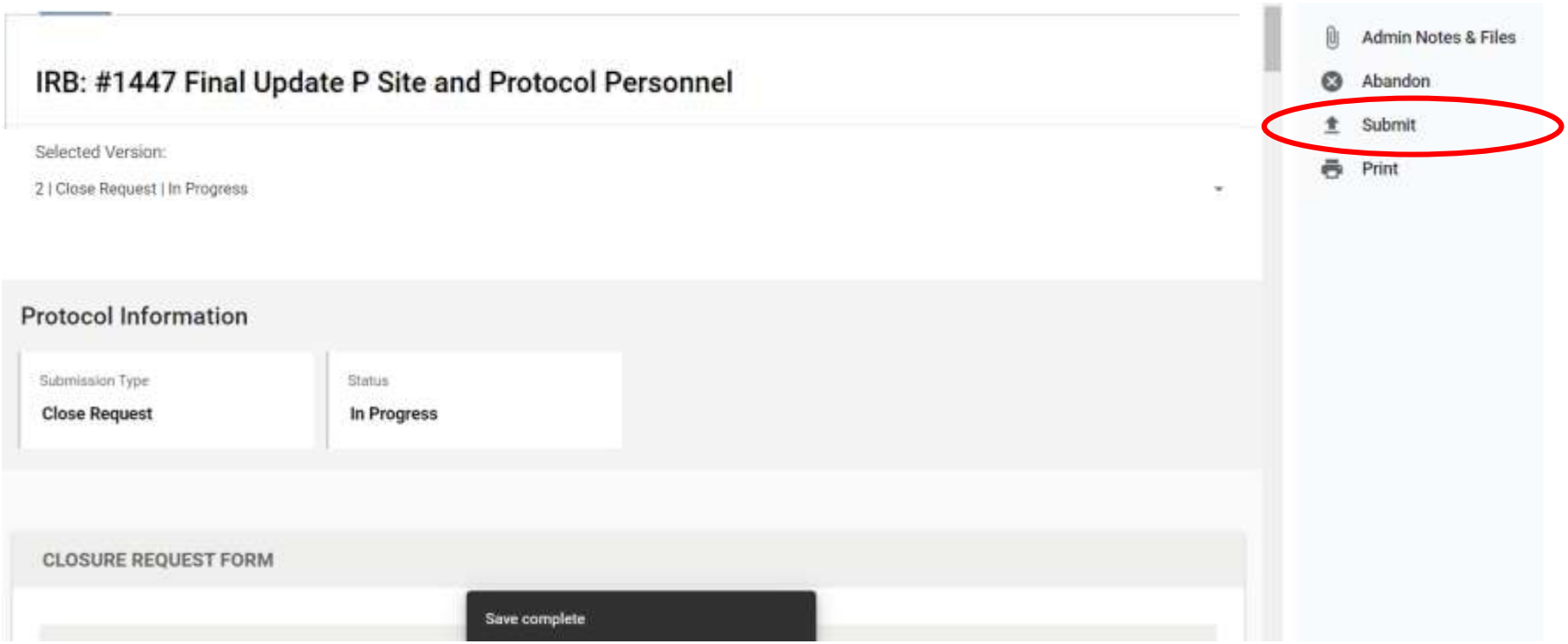
3. Complete the information in the Closure Request application.

Questions include:

- Reason for requesting closure
- Collection/storage of PHI
- Summary of progress
- Enrollment numbers
- Reportable New Information updates
- Clinical Trial Requirements

Submitting a Closure Request

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



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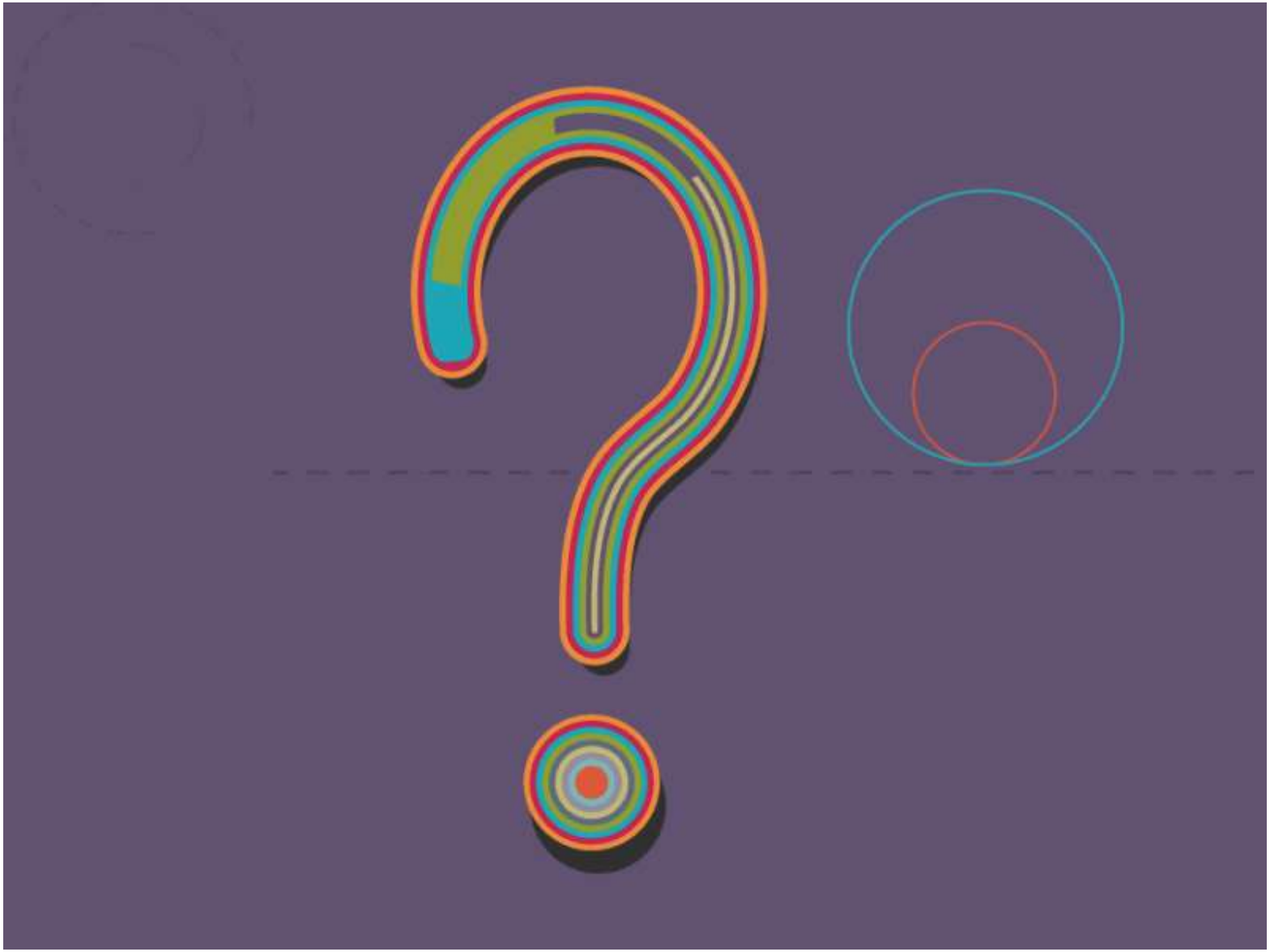

Save the Date!

April Lunch & Learn

Date: April 3, 2024
Time: 12:00 PM
Topic: Overview of the Office of Research Services