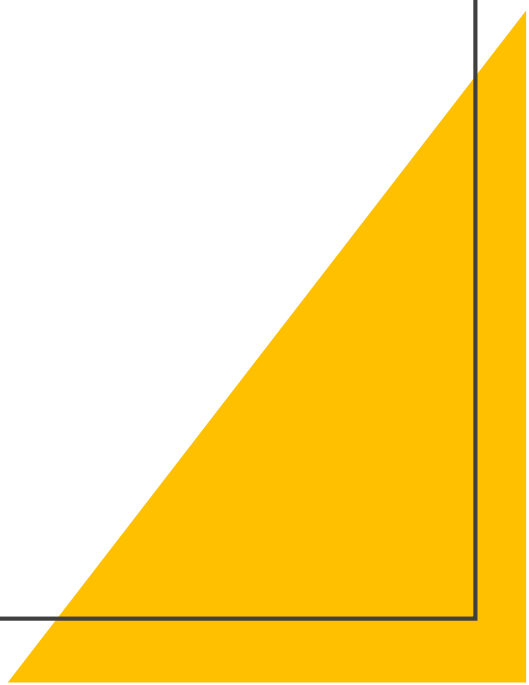




## CLOSING A STUDY

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**

## 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			

continuing review date


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## FEBRUARY 2024

SUN	MON	TUE	WED	THU	FRI	SAT
28	29	30	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	1	2

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## MARCH 2024

SUN	MON	TUE	WED	THU	FRI	SAT
25	26	27	28	29	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

Admin closure date if CR not approved

# 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.

Protocols

Include all protocol versions

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



# Submitting a Closure Request

## 2. Select the Request Close 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 <b>Expedited</b>	Status <b>Approved</b>	Approval Date <b>Sep 09, 2022</b>	Continuing Review Date --
Expiration Date --	Initial Approval Date <b>Sep 09, 2022</b>	Initial Review Type <b>Expedited</b>	

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

# Submitting a Closure Request

## 3. Complete the information in the Closure Request application.

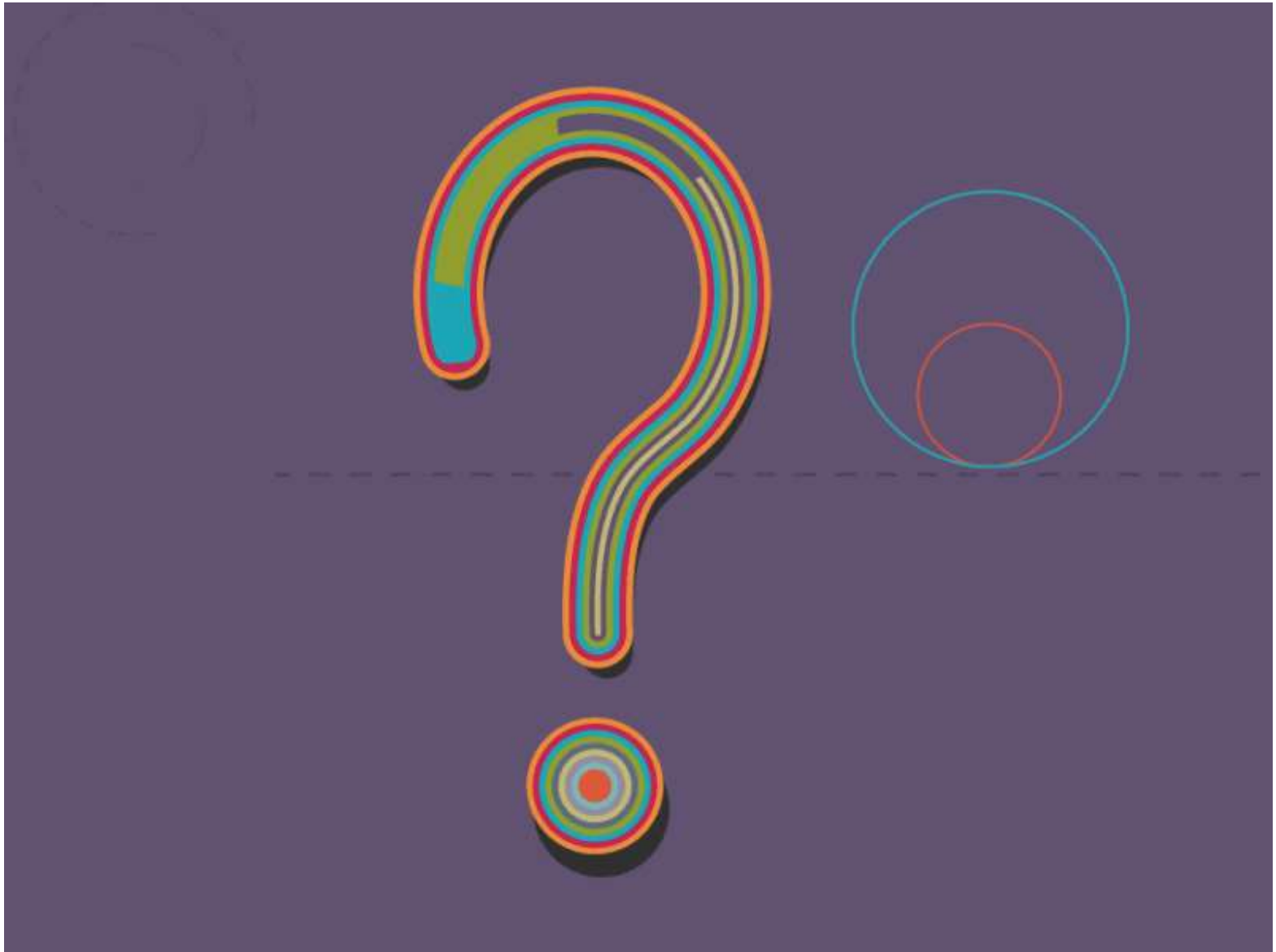
Questions include:

- 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.

The screenshot displays the IRB submission interface for IRB #1447. The main title is "IRB: #1447 Final Update P Site and Protocol Personnel". Below the title, it shows "Selected Version: 2 | Close Request | In Progress". The "Protocol Information" section includes "Submission Type: Close Request" and "Status: In Progress". At the bottom, there is a "CLOSURE REQUEST FORM" section with a "Save complete" button. On the right-hand side, a vertical menu contains four options: "Admin Notes & Files", "Abandon", "Submit", and "Print". The "Submit" option is highlighted with a red circle.



# Save the Date!

## April Lunch & Learn

**Date:** April 3, 2024

**Time:** 12:00 PM

**Topic:** Overview of the Office of Research Services