

How To Guide: Submit a Study Closure in iMedRIS

1. Log into <https://irb.ihmc.us>. Select the protocol requiring a close out.
2. From the Submissions menu, select “Study Closure Form”.

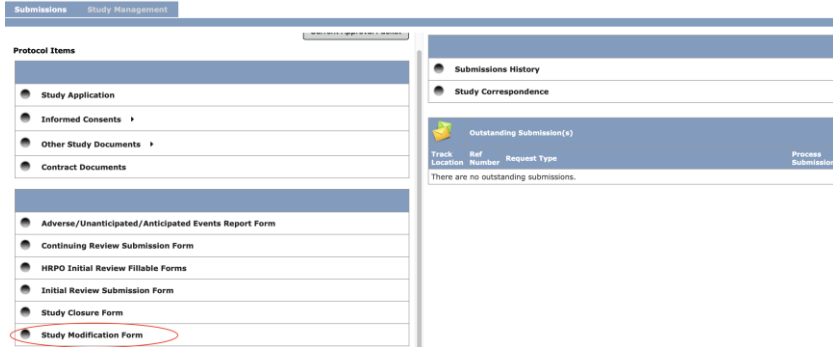


Figure 1: The Submissions menu of the selected study.

3. Select "Add a New Form”.

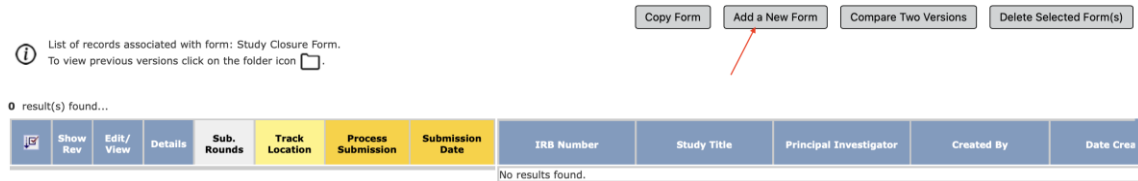


Figure 2: The Study Closure Form menu. All Study Closure Forms for the study appear here.

Section 1: Study Information

4. The *Study Information* tab populates, and the first three fields are filled automatically.
 - o Select the date of closure.
 - o Select the appropriate type of study closure:
 - Cancelled – Study will not be continued/completed as approved.
 - Completed – Study has concluded in its entirety.

The screenshot shows the 'Study Information' section of the 'Institutional Review Board: Study Closure Report' form. At the top, there are buttons for 'Print Friendly', 'Refresh Constant Fields', 'Save Section', and 'Save and Continue to Next Section'. The form has two tabs: 'Section view of the Form' and 'Entire view of the Form'. The 'Study Information' tab is selected. The form contains the following fields:

- IRB Number: IRB-2023-0061
- Study Title: Evaluating the Reliability and Efficacy of Voice-Based Reaction Time and Cognitive Testing Modality Compared to Traditional Touch-Based Methods
- Principal Investigator: Toshiya Miyatsu, Ph.D.
- Date of Closure: [Date Picker]

Below the fields, there is a section titled 'Select the appropriate type of study closure:' with two radio button options:

- Cancelled: Study will not be continued/completed as approved by the IRB.
- Completed: Participant(s) are off treatment and no active participation/intervention, no long-term follow-up, no data collection/analysis continues.

Figure 3: An example of the Study Closure Form Study Information section.

5. Select “Save and Continue to Next Section”.

Section 2: Study Summary

6. The *Study Summary Section* will populate. Complete all question fields. This includes:
 - Were participants enrolled in the study?
 - If yes, how many?
 - If yes, were any withdrawn?
 - Were there any unanticipated events that impacted participants?
 - Did the project include an IND or IDE?
 - Were there any deviations from the approved protocol?
 - If yes, elaborate in a free response section.
 - Were there records of participants or others reporting grievances or complaints?
 - If yes, elaborate in a free response section.
 7. Then, select “*Save and Continue to Next Section*”.
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Section 3: Adverse Events

8. The *Adverse Events Section* will populate. Complete all question fields. This includes:
 - Number of Adverse events
 - Were any adverse events serious adverse events?
 - If yes, specify how many.
 - Did any deaths occur.
 - If yes, specify how many, regardless of cause.
 - Were the above adverse events reported to the IRB according to the procedure?
 - If not, and Questions 2 or 3 were yes, elaborate.
 9. Then, select “*Save and Continue to Next Section*”.
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Section 4: IND Safety Information

10. The *IND Safety Information Section* will populate. Complete all question fields. This includes:
 - Were all IND Safety Report information received from the sponsor submitted to the IRB in accordance with procedures?
 - If not, elaborate.
 11. Then, select “*Save and Continue to Next Section*”.
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Section 5: Final Report

12. The *IND Safety Information Section* will populate. Complete all fields.

13. First, either provide a written summary of the project outcome, or attach a copy of the manuscript sponsor's report.

- To provide a written summary, type in the text response field. A brief summary is recommended even if you attach a final report.

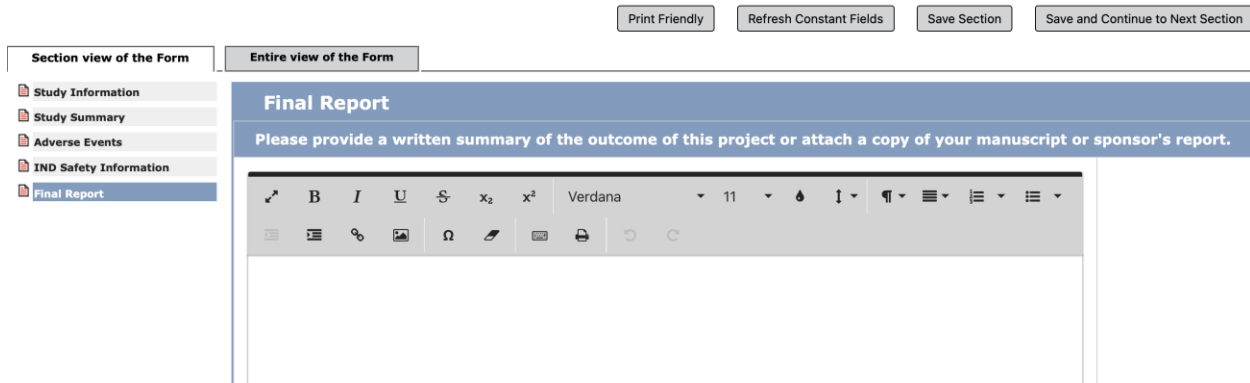


Figure 4: The text response field for a written project summary.

- To attach a copy of the manuscript or sponsor report, select the attachment option that best fits your needs.
 - Select or Revise Existing – To edit already attached documents.
 - Add a New Document – To attach a new document.
 - Add Multiple Documents – To attach several (up to 5) documents.
- If you plan on having a report or manuscript but it is not yet ready for submission, select the “*Pending Report*” option below the attachments section.

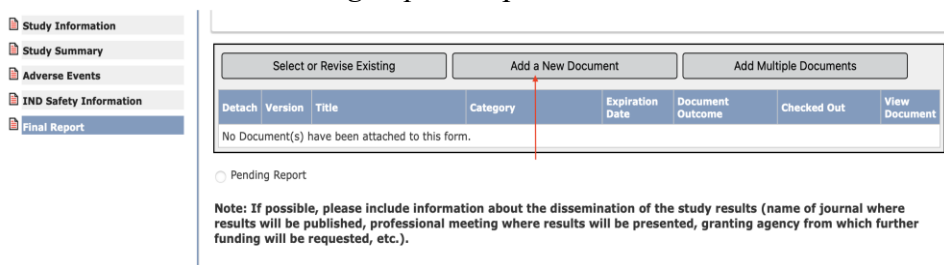


Figure 5: The common selection is *Add a New Document*. Note the “*Pending Report*” option below the attachments.

14. Complete the remaining fields:

- Have all sponsor monitoring reports been submitted?
 - If not, attach them using the self-populating *Document Attachment* pane.
- Do you have a final close-out letter from the sponsor?
 - If yes, attach it using the self-populating *Document Attachment* pane.

15. Then, select “*Save and Continue to Next Section*”.

16. The screen will display “*Form has been Completed*”.

- Non-PIs will select “*Notify PI to Sign & Submit*”, then exit the form.
- PIs will select “*Signoff and Submit*”.