

**APPLICATION: Final Report**

Use this Final Report application to formally close an IRB- approved study when:

- All research activities are complete;
- The study was never initiated; or
- The study was terminated early.

IRB approval of this Final Report will permanently close the study in the IRB system. Once closed, no further interaction with participants may occur, and no identifiable data may be analyzed or used.

**GENERAL STUDY INFORMATION**

1. IRB Project #:

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2. Project Title:

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3. Sponsor / Funding Source:

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4. Principal Investigator:

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5. Department/Affiliation:

*Select a department from the drop-down menu. If not listed, select "Other" and enter the department name.*

6. PI Email Address:

**CLOSURE JUSTIFICATION**

*Select ONE option below that best describes the study status at closure:*

Study Completed as Planned: *All research activities involving human subjects (including intervention, interaction, and data collection) have been completed.*

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Enrollment Closed with No Participants Enrolled: *Enrollment was permanently closed. No participants were enrolled and no data were collected.*

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Study Never Initiated: *The study did not begin, and no study-related activities (including recruitment or data collection) were initiated.*

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Sponsor-Initiated Early Closure: *The sponsor requested early termination of the study. If known, specify the reason (e.g., safety concerns, feasibility issues, or business decisions):*

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Principal Investigator-Initiated Closure: *The PI closed the study early due to recruitment failure, resource limitations, feasibility concerns, or other operational issues.*

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Other Reason for Closure: *Describe any reason not listed above:*

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**Date of Study Closure:**

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## ENROLLMENT SUMMARY

Report cumulative totals for the entire study. Numbers must be consistent with prior IRB submissions. If no participants, records, or specimens were enrolled or accessed, enter "0" for all fields.

1. Total Number Approved by the IRB: *Provide the total number of participants, records, and/or specimens approved for this study.*

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2. Total Number Enrolled or Collected: *Total number of participants enrolled or records/specimens collected over the life of the study.*

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3. Enrollment Since Last Continuing Review (if applicable): *Number enrolled, or collected, since the most recent continuing review. Enter "0" if none.*

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4. Withdrawals or Loss to Follow-Up: *Total number of participants withdrawn, terminated early, or lost to follow-up.*

## STUDY OUTCOMES

Complete items below to confirm that the study has closed with no outstanding safety or compliance issues.

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|---|-----|----|-----|
| 1. Are there any protocol deviations associated with this study that have not yet been reported to the IRB? | YES | NO | N/A |
|---|-----|----|-----|

If YES, provide details for each deviation, including:

- Description of the deviation
- When and how it occurred
- Whether participants were affected
- Corrective and/or preventive actions taken or planned

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|---|-----|----|-----|
| 2. Are there any adverse events or unanticipated problems involving risks to subjects or others (UPIRTSO) that have not yet been reported to the IRB? | YES | NO | N/A |
|---|-----|----|-----|

If YES, describe:

- Nature of the event or problem
- Severity and relationship to the study
- Actions taken and outcomes
- Plans for reporting or follow-up

3. Provide a **non-identifiable** summary of study findings or outcomes. Include, as applicable:
  - Whether study objectives were met or partially met
  - General description of results or trends (no individual-level data)
  - Whether outcomes were consistent with expectations
  - Whether findings revealed any new or increased risks to participants

## DATA AND RECORDS

Each statement below **must be reviewed and confirmed** prior to permanent study closure.

**Important:** Once a study is closed, **no further analysis of identifiable data is permitted after closure.**

Any data shared externally must be secured, locked, and no longer accessible for analysis.

If any item below cannot be attested to, do not submit this Final Report. Contact the IRB for guidance.

I attest that no identifiable data is currently being analyzed.

I attest that external entities are not analyzing shared study data.

I attest that identifiable data shared externally are locked and inaccessible for analysis.

For applicable studies, I attest that long-term follow-up/survival data collection has ended.

## DEVICE / DRUG / BIOLOGIC DISPOSITION

N/A

Required for studies involving investigational products. Describe how investigational product(s) were returned to the sponsor, destroyed, or retained upon study closure, in accordance with the approved protocol and applicable requirements.

## FINAL DOCUMENTATION

The following documents are recommended to support study closure. Not all document types apply to every study. Attach only documents that apply to your study.

Final Study Report or Summary	Publications or Abstracts (Optional)
Final Consent Form(s)	Patient Disclosure Form – HUD or Emergency Use Only
Data Sharing or Data Use Agreements	Sponsor Communications – applicable to the closure

## PRINCIPAL INVESTIGATOR SIGNATURE

By signing below, the Principal Investigator attest that:

- All study activities are complete or terminated.
- All reports required have been submitted to the IRB of Record.
- Identifiable data and/or biological specimens from this study will only be used in future research if participants have provided consent for such use and new IRB approval is obtained.
- No further participant contact or data collection will occur.
- All data retention and disposition plans comply with institutional and regulatory requirements.

Signature of New  
Principal Investigator:

Date of  
Signature:

**Note: Before signing, ensure the form is complete and accurate. Once signed, the document will lock and no further changes can be made.**

Submit completed form and applicable documents to [aasjrbsubmissions@trinity-health.org](mailto:aasjrbsubmissions@trinity-health.org)