Study Closure Request Form

Complete this form to request an IRB protocol to be closed. By completing and submitting this form, IRB staff will assess whether closing your protocol is appropriate at this time and subsequently close the protocol or provide you with necessary information.

Your protocol is eligible to be closed if all research activities are completed. This means that the contractual obligations related to the protocol are completed (if applicable) and that no research activities continue to occur.

Do not complete this form if you will continue any of the below research activities:

- You are continuing to recruit or enroll participants in your study.
- You are conducting any research-related interventions and interactions with participants are ongoing.
- You are or you may follow-up with participants, including reporting back results.
- You are collecting or analyzing individually identifiable, private data.
- Your study accessed "secondary data" and you haven't met the requirements set by the data providers.
- Your study is funded, and you haven't met the requirements set by your sponsors.

How to Submit This Form

1. Download and complete this form.
2. Add an **amendment** request on eIRB and indicate you are requesting to close your protocol.
3. Add "Closure Request" to the beginning of your protocol's title on the eIRB's "Title" tab.
4. Upload this completed form to the eIRB's protocol's "Supporting Documents".
5. Submit the amendment request for the IRB to review.

IRB staff will contact you if they have any questions about your request. If your request is approved, you will receive an automatic notification from the IRB system and/or a notification from IRB staff that the study has been closed.

Please contact irb-coordinator-post@ncsu.edu if you have any questions about completing this form or whether your protocol is eligible for closure.

Protocol Number: Click or tap here to enter text.
Protocol Title: Click or tap here to enter text.
Faculty Point of Contact: Click or tap here to enter text.
Email Address: Click or tap here to enter text.
Principal Investigator (if different): Click or tap here to enter text.
Email Address: Click or tap here to enter text.
Funding Source(s): Click or tap here to enter text.

1. **Please identify your relationship to the research team:**
   - ☐ I am the Faculty Point of Contact and the Principal Investigator
   - ☐ I am the Faculty Point of Contact and Faculty Advisor
   - ☐ I am the Principal Investigator
   - ☐ I am a Student Investigator
   - ☐ I am a research staff member: Click or tap here to enter text.
     Email Address: Click or tap here to enter text.

2. **Is there anyone else on the research team we should contact if we have any questions about this closure request?**
   - ☐ No
   - ☐ Yes: Click or tap here to enter text.
     Email Address: Click or tap here to enter text.

3. **Does this protocol involve a reliance agreement?**
   - ☐ Yes, the NC State University IRB is the reviewing IRB.
   - ☐ Yes, the NC State University IRB is relying on another institution's IRB for review.
   - ☐ Yes, the NC State University IRB has issued one or more individual investigator agreement(s).
   - ☐ No.

4. **Please indicate why this protocol is being closed:**
   - ☐ All data collection methods, interventions, and analysis of identifiable data have been completed.
   - ☐ The PI is leaving NC State University, and no other NC State University researcher will continue to be engaged with the research.
   - ☐ The research is not complete but will no longer be continuing.

5. **Please indicate what research activities remain (check all that apply):**
   - ☐ None, all research activities have been completed or will no longer be continuing.
   - ☐ Data analysis of *de-identified* information or biospecimens, as described in the approved protocol.
   - ☐ Manuscript or publication writing, using *de-identified* information or biospecimens.
   - ☐ **Other**: Click or tap here to enter text.

6. **Have you handled all data, including video/audio recordings and images, as described in the approved protocol?** *This includes data collection or transfer, data storage, data sharing (if appropriate), destruction or removal of identifiers (if appropriate), deletion of data (if appropriate), etc.*
   - ☐ Yes
   - ☐ No

7. **Will you store/maintain/archive the data or biospecimens as described in the approved protocol and participant consent?** *Note: all documentation including data, related to an approved IRB protocol should be maintained for 3 years, unless there is a special circumstance.*
   - ☐ Yes, some or all data/biospecimens will remain identifiable or re-identifiable.
     - ☐ In accordance with the approved IRB protocol, informed consent, and/or broad consent as applicable, the data will be stored in accordance with OIT standards by the research team.
     - ☐ In accordance with the approved IRB protocol and participant broad consent, the data will be shared with the following repository: **Click or tap here to enter text.**.
   - ☐ Yes, the data/biospecimens are de-identified.
     - ☐ The data will be stored in accordance with OIT standards by the research team.
     - ☐ In accordance with the approved IRB protocol and participant informed consent, the data will be shared with the following repository: **Click or tap here to enter text.**.
   - ☐ No, the data will not be kept or archived.

8. **Do you have plans to use the data for future research (i.e., beyond what was approved in this protocol)?**
   - ☐ Yes, participants have provided "broad consent" to use their identifiable or re-identifiable data for future unspecified research.
   - ☐ Yes, participants have provided "informed consent" to use their de-identified data for future research.
   - ☐ No.

9. **Please attest to the following statement(s) as applicable:**
   - ☐ I attest that no one on the research team will access the stored identifiable or re-identifiable data for this approved protocol, without officially re-opening this protocol with the NC State IRB before accessing the data.
   - ☐ I attest that anyone who will access the stored identifiable or re-identifiable data for which "broad consent" was sought, for future unspecified research, will be reminded to apply for an exemption determination with the NC State IRB before accessing the data.
   - ☐ This is not applicable to me because I will not be storing or archiving the identifiable or re-identifiable data for future research. (*Note: If you select this box, no other boxes in this section should be checked.)*

10. **Does this protocol involve a data use agreement, material use agreement, funding source, or other contractual obligation (e.g., from funding sources, data providers, etc.)?**

☐ No (Skip to question 11)
☐ Yes. **Please attest to the following:**
a. ☐ I attest that the research team has met all requirements that would allow my study to be closed.

11. Is this protocol a clinical trial?
☐ No (Skip to question 12)
☐ Yes. **Please attest to the following:**
a. ☐ I attest that the research team has completed all responsibilities on clinicaltrials.gov.

12. Have any reportable events occurred that must be disclosed to the IRB or that are pending action from the IRB? *This includes noncompliance, protocol deviations, adverse events, participant complaints, etc.*
☐ No
☐ Yes. **Describe**: Click or tap here to enter text.

13. Is there anything about this protocol closure that you would like to share that hasn't already been captured on this form?
Click or tap here to enter text.

13. Please attest to the following:

☐ I understand that once my protocol is closed, IRB approval for my study will cease and no human subjects research should be conducted. If I need to restart this project, I will either need to request the IRB "reopen" and "re-review" the project or submit a new protocol for review to the IRB office.