

Cornell University
Office of Research Integrity and Assurance
Human Research Participant Protection Program

SOP 8: CLOSURE OF A RESEARCH PROTOCOL

1. Subject of Policy & Procedure

A protocol may be closed when the Protocol Principal Investigator (Protocol PI) (1) determines that the research protocol and all related publications, presentations, and websites derived from individually identifiable private information have been completed; and (2) submits a Final Closure Report Form and other related documents to the IRB. The closure of a study is a change in activity for a research protocol, which must be reported to the Institutional Review Board (IRB) under federal regulations. The key document related to the closure of a protocol is the Final Closure Report Form. All Protocol PIs must submit a closure form when a protocol is completed or otherwise closed. This form not only formalizes and documents the closure of a study file, but also provides the IRB with information pertinent to its review and approval of similar or related studies. Failure to submit a closure form for all closed studies, including those that have expired or lapsed, may cause the IRB to postpone the review and approval of future research protocols.

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by Cornell faculty, staff, or students or by anyone conducting a research activity supported by Cornell or on property maintained by Cornell.

3. Terms and Definitions

Identifiers: Identifiers include (1) name; (2) address; (3) elements of dates related to an individual (*e.g.*, birth date); (4) email address; (5) numbers, such as telephone, fax, social security, medical record, health insurance/health beneficiary, certificate or license numbers, vehicle, accounts (*e.g.*, bank, credit card), device i.d. numbers, serial numbers, and any other unique identifying numbers, characteristics, or codes (*e.g.*, Global Positioning System (GPS) readings); (6) web URLs; (7) internet protocol (IP) addresses; (8) biometric identifiers (*e.g.*, voice, fingerprints); and (9) full face photographs or comparable images.

De-identification: De-identification means the removal and separation of *any* and *all* identifiers, or any other unique items of individually identifying information, from data and specimens.

In addition, all parties to whom this policy applies (*e.g.*, faculty, students, staff, IRB members) should consult the IRB Glossary at <http://www.irb.cornell.edu/glossary/>.

4. Attachments

All parties to whom this policy applies should also consult the Final Closure Report Form (*to be created*)

5. Regulations Applicable to Reporting Requirements

- 5.1. 45 CFR 46.109; 21 CFR 56.109: IRB Review of Research, mandating IRB review and approval of human participant research.
- 5.2. 45 CFR 46.103(b)(4)(iii), mandating compliance with “written procedures...for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.”
- 5.3. 21 CFR 56.108(a)(3)&(4), mandating compliance with “written procedures...(3) for ensuring prompt reporting to the IRB of changes in research activity; and (4) for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.”

6. Determining When a Project May Be Closed

6.1. Criteria for Closure: A study may be closed when all of the following apply:

- 6.1.1. All collection of data involving interventions and interactions has been completed for all participants. No further contact with participants is necessary; and
- 6.1.2. All collection of individually identifiable private information has been completed for all study participants. No further collection of data/information from or about the individuals will be obtained; and
- 6.1.3. All publications, presentations, additions to web sites derived from individually identifiable private information have been completed; and
- 6.1.4. If the study is funded, the sponsor agrees to or recommends closure.

A Protocol PI cannot close a study as long as he or she is making any use of individually identifiable private information collected as part of the protocol. If after a study is closed, the Protocol PI seeks to engage in an activity such that one of the criteria in 6.1 would no longer be met, he or she must submit a new protocol for IRB review and approval.

6.2. Use of Previously Collected and Retained Data and Specimens:

De-identification means to remove any and all of the identifiers listed in Section 3 above or any other unique items of individually identifying information. Investigators should pay special attention where items of information that may not be identifying in and of themselves are combined to create new data that could identify a research participant (*e.g.*, person over 80 in zip code area 14850). Furthermore, in none of these categories below may new data or specimens be collected or new identifiers added to the collection of retained data/specimens.

- 6.2.1. *Use of De-Identified Data and Specimens*: A Protocol PI's use or transfer of previously collected but fully de-identified data or specimens does not constitute human participant research; therefore, neither postponement of study closure nor IRB review and approval is required for the use, transfer, or receipt of fully de-identified data, even if the protocol for which the data was collected is closed. Nor is obtaining the re-consent of a specimen donor required when the data has been fully de-identified. A Protocol PI, however, should take all precautions necessary to ensure that data and specimens are fully de-identified.

This is often difficult to achieve. If de-identification is not done carefully, the investigator reviewing the data or specimens risks conducting research without IRB approval.

6.2.2. *Use of Individually Identifiable Data and Specimens:* Postponement of study closure and IRB review and approval is required where a Protocol PI seeks to use or transfer previously collected and still-identifiable data/specimens to another investigator. IRB review and approval is not required for either investigator where the transferee does not receive or need identifiers *and* he or she enters into a written agreement with the Protocol PI stating that the Protocol PI will not provide any identifiers in his or her possession. In this case, however, the Protocol PI is required to notify and provide a copy of the written agreement to the IRB before the transferee's research can be initiated.

7. Submission, Review, and Processing of Final Closure Report Documents

- 7.1.** The Final Closure Report Form and related documents should be submitted to ORIA at some time before or at the time of continuation in place of the continuation application. These related documents should include the approved protocol, any documentation received from the sponsor regarding closure of the study, and any new findings or publication citations that relate to the study. ORIA will review these documents for completion, request additional materials as necessary, and present any questions of clarification to the Protocol PI.
- 7.2.** ORIA will review the Final Closure Report Form to determine whether closure of the protocol is appropriate. If ORIA has any questions regarding this matter, it will consult the Protocol PI and the IRB Chair to resolve them. If closure is determined to be inappropriate or if further documentation is required for review, ORIA will communicate to the Protocol PI those steps needed to make closure appropriate.
- 7.3.** Upon notification by the IRB Chair or other reviewer of a determination that closure of the protocol is appropriate, ORIA will change the status of the study in the IRB database to reflect closure. ORIA will note the closure on the agenda of the next available IRB meeting.
- 7.4.** ORIA will generate a closure letter and obtain the signature of the IRB Chair. ORIA will send a copy of the signed letter and the Final Closure Report Form to the Protocol PI for his or her records. ORIA will then file the closure letter, Final Closure Report Form, and accompanying documents in the study file. ORIA will also notify Sponsored Programs Services of the study completion, so that all corresponding grants and/or contracts can be identified and handled appropriately.
- 7.5.** ORIA will stamp the study file with the date of closure on the front cover and place the file in the area for inactivated study files.

8. Documentation Relating to Closure of a Research Protocol

All documents relating to the closure of a protocol will be maintained by ORIA for a period of not less than 5 years, in accordance with SOP ____: Document Management. These documents include but are not limited to: Final Closure Report Form and accompanying documents; protocol; any audit reports or quality control reports; and any related correspondence with the Protocol PI.

