

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 an IRB Project Closure Form and other related documents to the Institutional Review Board (IRB). The closure of a study is a change in activity for a research protocol, which must be reported to the IRB under federal regulations. The key document related to the closure of a protocol is the Project Closure 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. The scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by CCC-UPR faculty, staff, or students or by anyone conducting a research activity supported by CCC-UPR or where CCC-UPR is considered to be engaged in the research.

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 ID 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 or all* identifiers, or any other unique items of individually identifying information, from data and specimens.

Also, all parties to whom this policy applies (*e.g.*, faculty, students, staff, IRB members) should consult the [IRB Glossary](#).

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 approval period given by the given by the IRB, 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 approval period given by the given by the IRB, 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 or 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., a 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. It is often difficult to achieve. If de-identification is not done carefully, the investigator is reviewing the data or specimens' risks researching 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 are 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 Project Closure Form Documents

- 7.1.** The Project Closure form and related documents should be submitted to IRB at some time before or at the time of continuation in place of the continuation report. These related documents could include the approved protocol, any documentation received from the sponsor regarding the closure of the study, and any new findings or publication citations that relate to the study.
- 7.2.** IRB will review the **Project Closure form** and additional documents to determine whether the closure of the protocol is appropriate. If the closure is determined to be inappropriate or if further documentation is required for review, the IRB will communicate to the Protocol PI the steps needed to make closure appropriate.
- 7.3.** If closure of the protocol is appropriate, IRB will send a closure notification to the PI and update the status of the protocol in the IRB records.

8. Documentation Relating to Closure of a Research Protocol

All documents relating to the closure of a protocol will be maintained by the IRB office for no less than 3 years.