James Madison University Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
TITLE: Study Closure			
SOP # 9	**Revision # 1**	**Effective Date: 11/8/19**	**Page 1 of 3**

OBJECTIVE

To describe the policies and procedures followed to close a study.

GENERAL DESCRIPTION

A protocol may be closed when the Principal Investigator (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 Report and other related documents to the Institutional Review Board through the electronic Research Administration (eRA) software system.

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 Final Report. All 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 Final Report 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.

This SOP applies to all on-going and future human participant research projects conducted by JMU faculty, staff, or students or by anyone conducting a research activity supported by JMU or where JMU is considered to be engaged in the research [45 CFR 46.109; 45 CFR 46.103].

DEFINITIONS

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: The removal and separation of any and all identifiers, or any other unique items of individually identifying information, from data and specimens.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Study Personnel, ORI, IRB Chair, IRB Members

PROCEDURES

Determining When a Project May Be Closed:

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

1. All collection of data involving interventions and interactions has been completed for all participants. No further contact with participants is necessary; and
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
3. All publications, presentations, additions to web sites derived from individually identifiable private information have been completed; and
4. If the study is funded, the sponsor agrees to or recommends closure.

A 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 PI seeks to engage in an activity such that one of the criteria for closure would no longer be met, he or she must submit a new protocol for IRB review and approval.

Use of Previously Collected and Retained Data and Specimens:

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.

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.

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.

Submission, Review, and Processing of Project Closure Form Documents:

The Final Report and related documents should be submitted to the IRB at some time before or at the time of continuation in place of the continuation application. These related documents could 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.

The IRB Chair or their designee will review the Final Report to determine whether closure of the protocol is appropriate. If closure is determined to be inappropriate or if further documentation is required for review, the IRB Chair or designee will communicate through eRA to the PI those steps needed to make closure appropriate.

If closure of the protocol is appropriate, the status will be updated and an acknowledgement of study closure email will be sent to the PI and faculty advisor, if student, through eRA.

Document Retention and Destruction:

All documents relating to the closure of a protocol will be maintained by ORI for a period of not less than 5 years.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	7/20/2015
01	Revision of SOP	11/8/2019

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

45 CFR 46.103
45 CFR 46.109