IRB Standard Operating Procedures		
SOP#: 19 Revision#:	**Title: Lapsed Research**	**Effective Date: October 19, 2021**
Approved By:	**Institutional Review Board**	**Approval Date: October 19, 2021**

PURPOSE

To define policies and procedures for expedited and convened review human subjects research after IRB approval has expired.

DEFINITIONS

Class projects - any collection and/or analyses of human subjects data that are assigned as an educational exercise in the context of a specific course.

Generalizable knowledge - information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

Identifiable private information - private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

Minimal risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research means - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Lapsed research - any IRB approved human subject research that is conducted past the IRB assigned expiration date

POLICY

1. IRB approved human subject research is approved for one year.
2. IRB approved exempt human subject research is approved for five years.
3. Research that is nearing the expiration date will need to have an "Annual Review" submitted. PIs may submit either: a) an "Annual Review" detailing the progress of the study and requesting a date extension; or b) a "Terminate Protocol" closing out the research protocol.
4. Research is lapsed and researchers are in violation of federal regulations if research is conducted past the IRB assigned expiration date.
5. If the IRB approval of human subject research lapses, all study procedures must stop immediately, including every aspect of data collection (i.e., recruitment, interviews, survey research), intervention, and/or interaction with human subjects.
6. If lapsed research is to be continued post-expiration, researchers will need to submit an "Annual Review" describing the current state of the research and requesting an expiration date extension.
7. Lapsed research activities can only be resumed once the "Annual Review" has been approved by the IRB and a new expiration date has been issued.
8. IRB approval of any amendment added to the originally submitted research does not change the original expiration date.

RESPONSIBILITIES

1. The principal investigator is responsible for completing the research within the approved time.

2. The principal investigator is responsible to submit an "Annual Review" to secure an extension (secondary expiration date) from IRB of their human subject research study beyond the original expiration date.

3. The principal investigator is responsible to submit an "Annual Review" and to request an expiration date extension.

Regulations

45 CFR 46.102

Author Reference

NEIU IRB

George Mason Univers it y S OP "Classroom Projects"

Contact Information

Please direct questions or concerns about this policy to:

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Disclaimer

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.