SOP 408: RESEARCH PROJECT COMPLETION

1. POLICY

The completion, premature completion, or termination of a research project is a change in activity that must be reported to the IRB. The investigator shall report completion, premature completion, or termination of a research project to the IRB.

Specific Policies

1.1 Determining When a Project is to be Closed

Research projects may be closed when individually identifiable follow-up data are no longer being collected about participants and analysis that could indicate new information has been completed.

1.2 Closure of Studies

The investigator may close a research project by submitting the Continuing Review/Final Report form requesting inactivation or closure. The investigator may close an Exempt research project by submitting an Exempt Study Closure Report form requesting closure.

2. SCOPE

This SOP applies to all human research projects submitted to the IRB.

3. RESPONSIBILITY

The IRB Administrator is responsible for verifying all research project completion documentation is received and reviewed by and presented to the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109
45 CFR 46.103, 46.109

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 401: Research Exempt from Federal Regulations
SOP 402: Expedited Review

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist
408-A Exempt Study Closure Report

7. PROCESS OVERVIEW

Upon receipt of the closure documentation submission, IRB Staff will conduct a pre-review to confirm all documents are reviewed for submission, per SOP 301: Research Submission Requirements.

The IRB Administrator will forward the submission to the IRB Chair or IRB designee for review.
7.1 Convened Board and Expedited Research Projects

7.1.1 The investigator will submit the Continuing Review/Final Report to the IRB within 30 University business days after completion or termination of the research project. The IRB Administrator will review the submission for completeness and, if needed, request further information from the investigator to obtain missing data or to clarify any questions that arise. The IRB Administrator will then forward the submission to the IRB Chair or IRB designee for review.

7.1.2 The IRB Chair or IRB designee will review the submission the Continuing Review/Final Report form in accordance with SOP 402: Expedited Review. The IRB Administrator will post the research project closure to the next appropriate IRB agenda and generate a letter to send to the Investigator. The IRB Administrator will then change the research project status to "Inactive-Principal Investigator."

7.2 Exempt Projects

The Exempt Study Closure Report form will be accepted at any time by the IRB at the time of study closure.

The investigator will submit the Exempt Study Closure Report form. The IRB Administrator will review the submission for completeness and forward the submission to the IRB Chair or IRB designee, who will review it in accordance with SOP 401: Research Exempt from IRB Review. The IRB Administrator will post the research project closure to the next appropriate IRB agenda and generate a letter to send to the investigator. The IRB Administrator will then change the research project status to "Inactive-Principal Investigator."

APPROVED BY:________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020