SOP: Lapse (Expiration) of IRB Approval (Continuation of Current Participants)			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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1 PURPOSE

1.1 This procedure establishes the process for determining whether current participants may or may not continue in expired research.

1.2 The process begins when an investigator submits a request to the IRB for current participants to continue in expired research.

1.3 The process ends when the IRB Office has communicated a decision and documented the decision in writing.

2 PREVIOUS VERSION

2.1 Revised from previous version 05/20/2020

3 POLICY

3.1 If research approval lapses, new participants are not allowed to be enrolled under any circumstances.

3.2 Research procedures should be safely discontinued

3.3 Research procedures conducted to collect data with no direct benefit to the participant should not continue.

3.4 If the Principal Investigator believes that current participants are at risk of harm from stopping the research procedures, the Principal Investigator will submit the following to the IRB Office:

3.4.1 A list of participants who may be harmed, using their participant ID only

3.4.2 Identify the research procedures that need to continue and explain the reasons why

3.5 If the research is granted “Modification Required to Secure Approval” and expires before responsive materials are reviewed and approved, research activities may continue for current participants.

4 RESPONSIBILITIES

4.1 The Principal Investigator and an IRB Chair are responsible to follow these procedures.

5 PROCEDURE

5.1 The Principal Investigator provides to the IRB Office a request explaining why continuation is necessary, which participants need to continue in the expired research, and which procedures are to be considered for continuation.

5.2 An IRB Chair will decide whether there is an over-riding safety concern or ethical issue involved such that continuation is in the best interest of individual participants.

5.3 The IRB Office staff will include a written copy of the determination in the eIRB+ history of the project.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None