



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 11/22/2018

## 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