



SOP: Expiration of IRB Approval				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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1 PURPOSE

- 1.1 This procedure establishes the process for a Designated Reviewer to determine whether current subjects may continue in research for which IRB approval has lapsed.
- 1.2 The process begins when the Designated Reviewer is notified of a request by an investigator for current subjects to continue in research for which IRB approval has lapsed.
- 1.3 The process ends when the Designated Reviewer has communicated a decision and documented the decision in writing.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 GUIDING PRINCIPLES

- 3.1 If no continuing review has been submitted or approved or if research is granted “Modifications Required to Secure Approval” and expires before responsive materials are reviewed and approved, these procedures are to be followed.

4 RESPONSIBILITIES

- 4.1 A Designated Reviewer is responsible to follow these procedures.

5 PROCEDURE

- 5.1 Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why.
- 5.2 Do not allow new subjects to be enrolled under any circumstances.
- 5.3 Determine which subjects can continue in the research based on these principles:
 - 5.3.1 In general, research procedures should be safely discontinued.
 - 5.3.2 In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.
 - 5.3.3 In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.
 - 5.3.4 In some cases, an ethical issue may be raised where the above general principles may not be followed.
- 5.4 Communicate with the investigator using “TEMPLATE LETTER: Continuation of Subjects in Expired Research (HRP-532), or equivalent.”

6 MATERIALS

- 6.1 TEMPLATE LETTER: Continuation of Subjects in Expired Research (HRP-532)

7 REFERENCES

- 7.1 None