

	SOP: Expiration of IRB Approval		
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1 PURPOSE

- 1.1 This SOP establishes the process for determining whether current subjects may continue in expired research.
- 1.2 The process begins when an investigator submits a request to an IRB Chair or designee for current subjects to continue in expired research.
- 1.3 The process ends when the IRB/HRPP Staff has communicated a decision and documented the decision in writing.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version.

3 SOP Statement

- 3.1 If research approval expires before continuing IRB approval is obtained, these procedures are to be followed.
- 3.2 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 The Investigator and IRB Chair or designee is responsible for carrying out these procedures.

5 PROCEDURE

- 5.1 The investigator provides to the IRB/HRPP staff a request explaining why subjects need to continue in the expired research and what procedures are being requested to continue due to an over-riding safety concern or ethical issue.
- 5.2 New subjects are not to be enrolled under any circumstances.
- 5.3 Forward the information to the IRB Chair or designee to determine which subjects can continue in the research based on these principles:
 - 5.3.1 In general, research procedures should be discontinued when this can be done safely.
 - 5.3.2 In general, the only research procedures that should continue are those where the research treatments are not available outside of the research context. If the required procedures can be provided as standard of care treatment, 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 The IRB/HRPP staff will send correspondence to the investigator about the continuation of subjects in expired research.
 - 5.4.1 Include that the continuing review progress report must be submitted as soon as possible.
- 5.5 A copy of the determination is placed in the study records.

6 MATERIALS

- 6.1 None

7 REFERENCES

- 7.1 OHRP 45 CFR §46.109(e)
- 7.2 FDA 21 CFR 56.108(a) and 56.109(f)
- 7.3 AAHRPP elements II.2.E-II.2.E.2, II.2.F-II.2.F.3