UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	**OIA-063 SOP:** Expiration of IRB Approval				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-063	09/06/2023	B. Mooso	G. Firestein	1 of 1

1 PURPOSE

1.1 This procedure establishes the process for a designated reviewer to determine whether current human subjects may continue in expired research.

1.2 The process begins when the designated reviewer is notified of a request by an investigator for current human subjects to continue in expired research.

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 GUIDANCE

3.1 If research is granted an "approve pending" determination and expires before responsive materials are reviewed and approved, these procedures are to be followed.

3.2 If a study's IRB approval expires due to a delay in continuation approval, these procedures are to be followed.

3.3 The designated reviewer, if not themselves a chair, vice-chair, medical director, or Office of IRB Administration (OIA) director[1] carries out these steps in consultation with one of the aforementioned roles.

4 RESPONSIBILITIES

4.1 A designated reviewer is responsible to follow these procedures.

5 PROCEDURE

5.1 Determine from the investigator which human subjects need to continue in the expired research, what procedures are being requested to continue, and the reason(s) for the continuation request.

5.2 Do not allow new human subjects to be enrolled under any circumstances.

5.3 Determine which human subjects may 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. Required procedures that can be provided as standard of care 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, ethical issues may apply such that the above general principles may not be followed.

5.4 Communicate with the investigator using *OIA-532 TEMPLATE LETTER: Continuation of Subjects in Expired Research*, or equivalent.

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*

6.2 *OIA-532 TEMPLATE LETTER: Continuation of Subjects in Expired Research*

7 REFERENCES

7.1 None

[1] Chair, vice-chair, medical director, or OIA director, as available to assist, is the hierarchy that should be followed to assess which participants/procedures may be allowed to continue in expired research.