UC DAVIS
UNIVERSITY OF CALIFORNIA

SOP: Non-Committee Review Conduct				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-032	06/15/2017	C.Gates	C. Kiel	1 of 1

1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review.

1.2 The process begins when an IRB staff member notifies the Designated Reviewer of the review.

1.3 The process ends when the Designated Reviewer notifies an IRB staff member of the completion of the review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Administrative Updates

3 POLICY

3.1 The Designated Reviewer may not disapprove research.

4 RESPONSIBILITIES

4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Review all materials.

5.2 Use WORKSHEET: Eligibility for Review Using the Expedited Procedure (HRP-313) to determine whether the research is eligible for Non-Committee Review.

5.3 If the request is a continuing review that meets closure criteria, close the study.

5.4 If the request is for study closure that does not meet closure criteria, communicate with the investigator to explain the issue and offer the opportunity to withdraw or correct the submission.

5.4.1 If the investigator withdraws the submission, stop processing.

5.4.2 If the investigator will not withdraw the submission, the submission requires review by a convened IRB.

5.5 If consultation is needed, follow SOP: Consultation (HRP-051).

5.6 Complete the CHECKLIST: Non-Committee Review (HRP-402) or equivalent.

5.7 For initial review, modifications and continuing review, use WORKSHEET: Criteria for Approval and Other Considerations (HRP 314)

5.8 Check the accuracy of CHECKLIST: Pre-Review (HRP-401) or equivalent and revise as needed.

5.09 Follow WORKSHEET: Calculation of Approval Intervals (HRP-302)

5.10 Follow WORKSHEET: Communication of Results (HRP-303)

6 MATERIALS

6.1 CHECKLIST: Pre-Review (HRP-401)

6.2 CHECKLIST: Non-Committee Review (HRP-402)

6.3 SOP: Consultation (HRP-051)

7 REFERENCES

7.1 21 CFR §56.110(b)

7.2 45 CFR §46.110(b)