

 <b>INSTITUTIONAL REVIEW BOARD ADMINISTRATION</b>	<b>OIA-032 SOP: Non-Committee Review Conduct</b>				
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## 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 Office of IRB Administration (OIA) staff member notifies the designated reviewer of the review.
- 1.3 The process ends when the designated reviewer notifies an OIA staff member of the completion of the review.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 GUIDANCE

- 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 *OIA-313 WORKSHEET: Eligibility for Review Using the Expedited Procedure*, or equivalent, to determine whether the research is eligible for non-committee review.
  - 5.2.1 If study is not eligible for non-committee review, discuss with OIA leadership to which committee analyst the study should be assigned.
- 5.3 Complete *OIA-401 CHECKLIST: Pre-Review*, or equivalent, or revise, as needed, the previously completed *OIA-401 CHECKLIST: Pre-Review*, or equivalent.
- 5.4 If consultation is needed, follow *OIA-051 SOP: Consultation to the IRB*.
- 5.5 For initial review, modifications and continuing review, use *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent; *OIA-322 WORKSHEET: Emergency Use*,<sup>1</sup> or equivalent; or *OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD*,<sup>2</sup> or equivalent.
- 5.6 If the request is a continuing review that meets closure criteria:
  - 5.6.1 Confirm with investigator/submitter that information is correct and that study meets closure criteria.
  - 5.6.2 Close the study.
- 5.7 If the request is for study closure and the study does not meet closure criteria, communicate with the investigator to explain the issue and offer the opportunity to withdraw or correct the submission.
  - 5.7.1 If the investigator withdraws the submission, stop processing.
  - 5.7.2 If the investigator will not withdraw the submission, the submission requires review by a convened IRB.
- 5.8 Complete the *OIA-402 CHECKLIST: Non-Committee Review*, or equivalent.
- 5.9 Follow *OIA-052 SOP: Post-Review*.

## 6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-051 SOP: Consultation to the IRB*
- 6.3 *OIA-052 SOP: Post-Review*
- 6.4 *OIA-313 WORKSHEET: Eligibility for Review Using the Expedited Procedure*
- 6.5 *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*
- 6.6 *OIA-322 WORKSHEET: Emergency Use*
- 6.7 *OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD*
- 6.8 *OIA-401 CHECKLIST: Pre-Review*
- 6.9 *OIA-402 CHECKLIST: Non-Committee Review*

## 7 REFERENCES

<sup>1</sup> Will generally only be initial review.

<sup>2</sup> Initial submission requires full board review. Non-committee review may occur for minor modifications or continuing review.

<b>UC San Diego</b> <b>INSTITUTIONAL REVIEW BOARD ADMINISTRATION</b>	<b>OIA-032 SOP: Non-Committee Review Conduct</b>				
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- 7.1 [21 CFR 56.110\(b\)](#)
- 7.2 [45 CFR 46.110\(b\)](#)