1 PURPOSE

1.1 This procedure establishes the process to pre-review requests for approval or determination regarding:

1.1.1 New research/expanded access/humanitarian use device (HUD)

1.1.2 Continuing review of research/expanded access/HUD

1.1.3 Modification to previously approved research/expanded access/HUD

1.1.4 Study closure

1.1.5 Response to an approved pending determination

1.1.6 Response to a deferral

1.1.7 Whether an activity is not human research, is exempt human research, or is human research that does not engage the institution.

1.2 The process begins when the Office of IRB Administration (OIA) receives a request for approval.

1.3 The process ends when the information has been placed on the agenda for an IRB or Stem Cell Research Oversight (SCRO) meeting, will be handled by non-committee review, or will be handled by administrative review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 GUIDANCE

3.1 For single IRB (sIRB) protocols, the addition of a participating site to a previously approved protocol is considered a modification to previously approved research.

4 RESPONSIBILITIES

4.1 OIA staff members carry out these procedures.

5 PROCEDURE

5.1 If the request indicates that review by the SCRO committee is required, assign the submission to the SCRO analyst. SCRO analyst follows *OIA-022 SOP: SCRO Pre-Review*.

5.2 Use *OIA-301 WORKSHEET: Review Materials*, or equivalent, to determine if the submission is complete.

5.3 Consider whether the investigator needs to be contacted.

5.3.1 Communicate with the investigator if any of the following are true:

5.3.1.1 The investigator has requested study closure and the study does not meet closure criteria.

5.3.1.2 The request is for an initial approval and principal investigator is restricted.

5.3.1.3 The type of research is not conducted or overseen by the institution.

5.3.1.4 The type of research is reviewed by an external IRB.

5.3.1.5 Submitted information is incomplete.

5.3.1.6 Study has been expired longer than one year and continuing review is requested.

5.3.2 Explain the issue and offer the investigator the opportunity to withdraw or correct the submission.

5.3.3 If the investigator withdraws the submission, stop processing.

5.3.4 If the investigator will not withdraw or correct the submission, assign the submission to the committee analyst and/or committee support analyst who may place the submission on the agenda for a convened IRB meeting in an IRB with appropriate scope.

5.4 If the submission is a response to an IRB approved pending determination that was not required to undergo convened IRB review, assign to the committee analyst and/or committee support analyst for the IRB that reviewed and issued the approved pending determination. The committee analyst and/or committee support analyst will:

5.4.1 Evaluate whether the investigator made the required modifications.

5.4.1.1 If the IRB requested additional documents to be submitted, evaluate whether the additional documents indicate new issues for the IRB to consider [e.g., a previous clinical hold imposed by the Food and Drug Administration (FDA), which may indicate additional risks].

5.4.1.2 If new issues are not indicated by the documents, proceed to Section 5.4.2.

5.4.1.3 If new issues are indicated by the documents, proceed to Section 5.6.

5.4.2 If the investigator made the required modifications and did not make unrequested modification(s), follow *OIA-052 SOP: Post-Review* to issue an approval.

5.4.3 If the investigator did not make the required modification(s) and/or made unrequested modifications, follow Section 5.6.

5.5 If the request is a submission for IRB study closure or a continuing review that meets closure criteria, perform the following steps:

5.5.1 Confirm all research activities and all identifiable data analysis are complete.

5.5.2 If reportable events are indicated or included in the submission, follow *OIA-024 SOP: Reportable Events*.

5.5.3 If the submission is missing information, contact the investigator.

5.5.4 Once the submission is complete, close the study and send *OIA-511 TEMPLATE LETTER: Acknowledgment of Research Closure*, or equivalent.

5.6 Evaluate the most likely level of IRB review:

5.6.1 If the research appears to meet the requirements for a determination of not human subjects research (NHSR), assign to an OIA staff member who may follow *OIA-310 WORKSHEET: Human Research Determination*, or equivalent, to complete the administrative review. OIA staff members may use *OIA-401 CHECKLIST: Pre-Review*, or equivalent, and *OIA-402 CHECKLIST: Non-Committee Review*, or equivalent, to document their determinations.

5.6.2 If the research is human research but UCSD or another site relying on UCSD's IRB is not engaged, assign to an OIA staff member who may follow *OIA-311 WORKSHEET: Engagement Determination*, or equivalent, to complete administrative review. OIA staff members may use *OIA-401 CHECKLIST: Pre-Review*, or equivalent, and *OIA-402 CHECKLIST: Non-Committee Review*, or equivalent, to document their determinations.

5.6.3 If the research appears to meet the requirements for an exemption and the investigator is not restricted, assign to an OIA staff member who may follow *OIA-312 WORKSHEET: Exemption Determination*, or equivalent, to complete the administrative review. OIA staff members may use *OIA-401 CHECKLIST: Pre-Review*, or equivalent, and *OIA-402 CHECKLIST: Non-Committee Review*, or equivalent, to document their determinations.

5.6.4 If the request can be handled as a non-committee review and the principal investigator is not restricted, follow *OIA-031 SOP: Non-Committee Review Preparation*.

5.6.5 If the request requires review by a convened IRB and the principal investigator is not restricted, assign the submission to the appropriate analyst working with the relevant IRB in the electronic submission system and follow *OIA-040 SOP: IRB Meeting Preparation*.

5.6.6 If the request involves an investigator who would not correct or withdraw a submission, or the submission otherwise cannot be handled as a non-committee review, assign the submission to the committee analyst and/or committee support analyst who may place the submission on the agenda for a convened IRB meeting in an IRB with appropriate scope.

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*

6.2 *OIA-022 SOP: SCRO Pre-Review*

6.3 *OIA-024 SOP: Reportable Events*

6.4 *OIA-031 SOP: Non-Committee Review Preparation*

6.5 *OIA-040 SOP: IRB Meeting Preparation*

6.6 *OIA-052 SOP: Post-Review*

6.7 *OIA-301 WORKSHEET: Review Materials*

6.8 *OIA-310 WORKSHEET: Human Research Determination*

6.9 *OIA-311 WORKSHEET: Engagement Determination*

6.10 *OIA-312 WORKSHEET: Exemption Determination*

6.11 *OIA-401 CHECKLIST: Pre-Review*

6.12 *OIA-402 CHECKLIST: Non-Committee Review*

6.13 *OIA-511 TEMPLATE LETTER: Acknowledgment of Research Closure*

7 REFERENCES

7.1 None