1 PURPOSE

1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, continuing review of research, or modification to previously approved research) or a determination whether an activity is not Human Research or is Human Research that does not engage the Institution.

1.2 The process begins when the IRB receives a request for approval.

1.3 The process ends when the information has been placed on the agenda for an IRB meeting, will be handled by Non-Committee Review, or will be handled by administrative review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revised to include process for referring submission for full committee review.

2.2 Revised to include process for closing studies in response to request for study closure.

2.3 Revised to include process for acknowledging administrative modifications.

3 POLICY

3.1 The addition of a new site to a previously approved protocol is considered a modification to previously approved research, including when the site is overseen by a principal investigator who takes full responsibility for that site.

3.2 Updates to the list of study personnel that meet the personnel qualifications described in the IRB approved protocol are not considered a modification to previously approved research.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the item includes an updated list of study personnel submitted between approvals:

5.1.1 If the change involves only changes to the personnel but not the PI, Co-PI, or Faculty Advisor and is not reflected in the protocol or consent documents, withdraw the submission.

5.1.2 If the changed personnel include the PI, Co-PI, or Faculty Advisor or is reflected in the protocol or consent form, proceed to section 5.6.

5.1.3 If there are financial disclosures, follow “SOP: Financial Conflicts of Interests (HRP-055)”.

5.2 If the item includes only administrative modifications to human research previously determined to be exempt or previously approved by the IRB:

5.2.1 If all changes are listed as administrative modifications on the IRB’s website, send “TEMPLATE LETTER: Acknowledgement of Report (HRP-524)” or equivalent.

5.2.2 If all changes are not listed as administrative modifications on the IRB’s website, consult with a Designated Reviewer to determine whether the unlisted changes qualify as administrative modifications.

5.2.2.1 If the Designated Reviewer confirms that the changes qualify as an administrative modification, send “TEMPLATE LETTER: Acknowledgement of Report (HRP-524)” or equivalent.

5.2.2.2 If the Designated Reviewer indicates that the changes do not qualify to be considered an administrative modification, proceed to section 5.6.

5.3 If the submission is a response to modifications required to secure approval received within 25 business days of the IRB review date:

5.3.1 Evaluate whether the investigator made the required modifications.

5.3.2 If the investigator made the required modifications and did not make unrequested modifications, follow “SOP: Post-Review (HRP-052)” to issue an approval.

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

5.4.1 Confirm all research activities and all identifiable data analysis is complete.

5.4.2 If Reportable New Information indicated or included in submission, follow "SOP: New Information (HRP-024)".

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

5.4.4 Once the submission is complete, close the study and send "TEMPLATE LETTER: Acknowledgement of Research Closure (HRP-511)" or equivalent.

5.5 If the request is for study closure that does not meet closure criteria, contact the investigator.

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

5.5.2 If the investigator withdraws the submission, stop processing.

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

5.6 Use "WORKSHEET: Pre-Review (HRP-308)," or equivalent and complete "CHECKLIST: Pre-Review (HRP-401)" or equivalent, or revise, as needed, the previously completed "CHECKLIST: Pre-Review (HRP-401)," or equivalent.

5.7 Consider whether the investigator needs to be contacted.

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

5.7.1.1 The investigator has requested that the study be closed and the study does not meet closure criteria.

5.7.1.2 In response to modifications required to secure approval, the investigator did not make the required modifications or made unrequested modifications.

5.7.1.3 The request is for an initial approval and principal investigator is Restricted.

5.7.1.4 The type of research is not conducted or overseen by the Institution.

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

5.7.1.6 Submitted information is incomplete.

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

5.7.3 If the investigator withdraws the submission, stop processing.

5.7.4 If the investigator will not withdraw the submission, handle, place the submission on the agenda for a convened IRB meeting in an IRB with appropriate scope.

5.8 Evaluate the most likely level of review:

5.8.1 If the research appears to meet the requirements for a determinations of not research involving human subjects (NHSR) follow HRP: Human Research Determination (HRP 310) to complete the review administratively.

5.8.2 If the research is Human Research but UC Davis is not engaged, follow WORKSHEET: Engagement Determination (HRP-311)) to complete the review administratively.

5.8.3 If the research appears to meet the requirements for an exemption and the investigator is not restricted, follow WORKSHEET: Exemption Determination (HRP 312) to complete the review administratively.

5.8.4 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, follow "SOP: Non-Committee Review Preparation (HRP-031)."

5.8.5 If the request requires review by a convened committee and the principal investigator is not Restricted, move the submission to the queue in the electronic system designated for Full Committee Review and follow SOP: IRB Meeting Preparation (HRP 040)

5.8.6 If the request involved an investigator who would not correct or withdraw a submission or otherwise cannot be handled as a Non-Committee Review, place the submission on the agenda for a convened IRB meeting in an IRB with appropriate scope.

6 MATERIALS

6.1 CHECKLIST: Pre-Review (HRP-401)
6.2 SOP: New Information (HRP-024)
6.3 SOP: Non-Committee Review Preparation (HRP-031)
6.4 SOP: Post-Review (HRP-052)
6.5 SOP: Financial Conflicts of Interests (HRP-055)
6.6 TEMPLATE LETTER: Acknowledgement of Research Closure (HRP-511)
6.7 TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)
6.8 TEMPLATE LETTER: Acknowledgement of Report (HRP-524)
6.9 WORKSHEET: Pre-Review (HRP-308)

7 REFERENCES

7.1 None