SOP TITLE: INSTITUTIONAL REVIEW BOARD (IRB) SUBMISSIONS

1 PURPOSE

1.1 This procedure establishes the process for Principal Investigators (PIs) and study personnel under the PI's supervision to follow when submitting protocols, modifications to approved research, continuing reviews, emergency use submissions, study closure requests, post-approval reports, or other notifications to IRB.

1.2 The process begins when study information that requires or may require IRB review becomes available to the PI.

1.3 The process ends when the study information has been submitted to and reviewed by the IRB, or the IRB has determined that review is not required.

2 REVISIONS FROM PREVIOUS VERSION

2.1 N/A

3 REQUIREMENTS

3.1 UC San Diego IRB uses an electronic submission system (Kuali IRB), which provides PIs and their designees a means of submitting materials to IRB for review, corresponding with IRB during the review process, and receiving IRB communications, notifications, and review outcomes. PIs and their designees can log into the Kuali IRB electronic submission system using a UC San Diego Active Directory account.

3.2 The electronic submission system knowledge base provides resources to guide researchers through the submission process.

3.3 The IRB publishes information For Researchers that includes the most current guidance, forms, and instructions from the Office of IRB Administration (OIA).

3.4 Regulatory definitions applicable to human subjects research are published in the Code of Federal Regulations,[1] with guidance on Food and Drug Administration, Health and Human Services Office for Human Research Protections, and UC San Diego OIA websites.

3.4.1 Commonly used UC San Diego IRB definitions are covered in OIA-001 SOP: Definitions.

4 RESPONSIBILITIES

4.1 All UC San Diego Health Sciences research personnel who are involved in the preparation, submission, and follow-up of IRB applications for human subjects research are responsible for following these procedures.

4.2 The PI is responsible for ensuring that all IRB submissions accurately represent the research activities being conducted and comply with relevant ethical standards, regulatory requirements, and institutional policies.

4.3 The PI is responsible for ensuring that the records required by regulations are maintained securely and retained for the appropriate retention period.

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[1] 21 CFR 50.3 Definitions, 21 CFR 56.102 Definitions, 21 CFR 312.3 Definitions and interpretations, 45 CFR 46.102 Definitions, 45 CFR 160.103 Definitions

4.4 The PI is responsible to accurately describe processes used throughout the study to code or de-identify participant study data and ensure all study records are securely stored to minimize inadvertent sharing of participant identifiers or confidential information.

4.5 The PI is responsible for monitoring the IRB submission process to ensure compliance and to promptly implement appropriate corrective actions for any identified compliance issues.

5 PROCEDURE

5.1 New protocol submission

5.1.1 Pre-submission

5.1.1.1 Review the proposed research protocol to assess whether the research is human subjects research requiring IRB review.

5.1.1.2 If the research is investigator-initiated and requires internal protocol development, select the appropriate protocol and informed consent template from the IRB Forms, Templates and Instructions web page, and populate the templates with the relevant information for the study.

5.1.1.2.1 Consult OIA-103: IRB Handbook for guidance, request specific guidance from the IRB via email at irb@ucsd.edu or, for studies involving reliance on a single IRB (sIRB), email the IRB reliance team at irbrely@ucsd.edu.

5.1.1.3 Gather submission materials, to include, as applicable, the research protocol, consent/assent form(s), investigator brochure/device instructions, FDA documentation, proposed recruitment materials, and data collection instruments.

5.1.2 Initial IRB Submission

5.1.2.1 If the study is human subjects research and appears to meet the requirements for IRB exempt status, submit an application for administrative determination or registration (exempt registration) in the IRB electronic submission system.

5.1.2.2 If the study is human subjects research but UC San Diego is not engaged in the human subjects research, submit an application for administrative determination or registration (UCSD not engaged in research) in the IRB electronic submission system.

5.1.2.3 If the study is human subjects research and does not appear to meet the requirements for IRB exempt status, but is a request to rely on a non-UC San Diego IRB, submit a request for administrative determination or registration (request to rely on non-UCSD IRB) in the IRB electronic submission system.

5.1.2.4 If the submission is for a treatment use[2] of a test article or a device, submit an application in the IRB electronic submission system for emergency use of a test article for treatment, expanded access use of a test article for treatment, or humanitarian use device for treatment, as applicable.

5.1.2.5 If the study is human subjects research and does not appear to meet the requirements for IRB exempt status, submit an application for IRB review (expedited or full-board) in the IRB electronic submission system.

5.1.2.6 Upload supporting documents required to support the selected application, using the file formats and naming conventions requested by IRB.

5.1.2.7 Submit the application and confirm the submission status of the application in the electronic submission system.

5.1.3 IRB Feedback Response

5.1.3.1 The IRB will conduct a review of the submitted materials and may request, via action items in the electronic submission system, clarifications about the research or modifications to the application or the submitted materials.

5.1.3.2 When IRB feedback is received, carefully review and respond to the action item requests in the electronic submission system. The electronic submission system knowledge base includes an article describing the steps in responding to action items.

5.1.3.3 If revisions to submitted documents are requested, create a new version of the document with changes tracked, then upload both the tracked changes document and a clean version of the document into the electronic submission system, using the "replace" function within the submission to submit the documents.

5.1.3.4 Re-submit the application and confirm the submission status of the application in the electronic submission system.

5.1.4 IRB Determination

5.1.4.1 When a determination by the IRB has been made, file a copy of the IRB correspondence with the study regulatory files.

5.2 Modifications to Approved Research

5.2.1 Modification Application

5.2.1.1 Prepare a modification application to the IRB for any planned[3] changes in approved research activities, study protocol, consent forms, recruitment materials, or study personnel.

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[2] Data obtained from emergency or compassionate use of a test article or humanitarian use of a device may not be used for research purposes unless a separate research application is submitted to and approved by the IRB.

[3] OIA-103 IRB Handbook describes the reporting requirement for changes to the research without prior IRB review that is needed to eliminate an apparent immediate hazard to a research participant.

5.2.1.2 Prepare a summary of the proposed changes, including the rationale for each change.

5.2.1.3 If revisions to study documents are required, create a new version of the document with changes tracked, then upload both the tracked changes document and a clean version of the document into the amendment application.

5.2.1.4 Submit the modification application and confirm the submission status of the application in the electronic submission system.

5.2.2 IRB Feedback Response:

5.2.2.1 The IRB will conduct a review of the submitted materials and may request, via action items in the electronic submission system, clarifications about the research or modifications to the application or the submitted materials.

5.2.2.2 When IRB feedback is received, carefully review and respond to the action item requests in the electronic submission system. The electronic submission system knowledge base includes an article describing the steps in responding to action items.

5.2.2.3 If revisions to submitted documents are requested, create a new version of the document with changes tracked, then upload both the tracked changes document and a clean version of the document into the electronic submission system.

5.2.2.4 Re-submit the application and confirm the submission status of the application in the electronic submission system.

5.2.3 Wait for a determination by the IRB before implementing the requested change(s).

5.2.4 When a determination by the IRB has been made, file a copy of the IRB correspondence with the study regulatory files.

5.3 Continuing Review

5.3.1 Continuing Review Application

5.3.1.1 Monitor study expiration dates to ensure that continuing review applications are prepared in time to avoid expiration of IRB approval.

5.3.1.2 Prepare a continuing review application to the IRB.

5.3.1.3 Submit the continuing review application at least 30 days in advance of study expiration and confirm the submission status of the application in the electronic submission system.

5.3.2 IRB Feedback Response:

5.3.2.1 The IRB will conduct a review of the submitted materials and may request, via action items in the electronic submission system, clarifications about the research or modifications to the application or the submitted materials.

5.3.2.2 When IRB feedback is received, carefully review and promptly respond to the action item requests in the electronic submission system. The electronic submission system knowledge base includes an article describing the steps in responding to action items.

5.3.2.3 If revisions to submitted documents are requested, create a new version of the document with changes tracked, then upload both the tracked changes document and a clean version of the document into the electronic submission system.

5.3.2.4 Re-submit the application and confirm the submission status of the application in the electronic submission system.

5.3.3 When a determination by the IRB has been made, file a copy of the IRB correspondence with the study regulatory files.

5.4 Study Closure

5.4.1 Study Closure Request

5.4.1.1 Prepare a request to close a study when no further research interaction or intervention with study participants is required, all data/specimen collection has been completed, and analysis of identifiable or coded data/specimens has been completed.

5.4.1.2 Upload any supporting materials relevant to the project closure.

5.4.1.3 Submit the closure request and confirm the submission status of the application in the electronic submission system.

5.4.1.4 When a determination by the IRB has been made, file a copy of the IRB correspondence with the study regulatory files.

5.4.1.5 At study closure, ensure that study data is stored or destroyed in accordance with approved data management procedures, University of California[4] and UC San Diego Health Sciences policies, and applicable sponsor requirements.

5.5 Post-approval reporting

5.5.1 Prepare a reportable event submission for events requiring prompt reporting to the IRB, such as the following:

5.5.1.1 Unanticipated problem

5.5.1.2 Change to the protocol without prior IRB approval to eliminate an apparent immediate hazard to study participant

5.5.1.3 Breach of confidentiality

5.5.1.4 Participant complaint

5.5.1.5 Hold, suspension, or early termination of research

5.5.1.6 Non-compliance

5.5.1.7 Reports from monitor, sponsor, or federal agency

5.5.1.8 Emergency use of a test article

5.5.1.9 Any other information that indicates a new or increased risk, or a new safety issue.

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[4] University of California Records Retention Schedule

5.5.2 Consider whether changes to the protocol or consent are needed to mitigate risk or inform subjects.

5.5.3 Develop a corrective and preventative action plan, if needed.

5.5.4 Submit the reportable event report and confirm the submission status of the application in the electronic submission system.

5.5.5 IRB Feedback Response:

5.5.5.1 The IRB will conduct a review of the submitted materials and may request, via action items in the electronic submission system, clarifications about the research or modifications to the application or the submitted materials.

5.5.5.2 When IRB feedback is received, carefully review and promptly respond to the action item requests in the electronic submission system. The electronic submission system knowledge base includes an article describing the steps in responding to action items.

5.5.5.3 If revisions to submitted documents are requested, create a new version of the document with changes tracked, then upload both the tracked changes document and a clean version of the document into the electronic submission system.

5.5.5.4 Re-submit the event report and confirm the submission status of the application in the electronic submission system.

5.5.6 When a determination by the IRB has been made, file a copy of the IRB correspondence with the study regulatory files.

6 MATERIALS

6.1 N/A

7 REFERENCES

7.1 21 CFR 50.3 Definitions

7.2 21 CFR 56.102 Definitions

7.3 21 CFR 312.3 Definitions and interpretations

7.4 45 CFR 46.102 Definitions

7.5 45 CFR 160.103 Definitions

7.6 OIA-103: IRB Handbook

7.7 Kuali IRB Knowledge Base

7.8 University of California Records Retention Schedule