



SOP: Regulatory Review

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1. PURPOSE

- 1.1. This procedure establishes the process to review IRB submissions for regulatory issues.
- 1.2. This procedure begins when an IRB submission for a review or determination has been checked by office staff.
- 1.3. This procedure ends when the <Regulatory Reviewer> has completed the review or an investigator has withdrawn the submission.

2. POLICY

- 2.1. As part of IRB review, all submissions are reviewed by a <Regulatory Reviewer> to:
 - 2.1.1. Identify submissions with missing materials
 - 2.1.2. Identify and document the determinations that need to be made to approve research. (For example. waiver of consent, children, prisoners, IND/IDE)
 - 2.1.3. Identify any relevant local, state, or international requirements
 - 2.1.4. Arrange for consultation to resolve local, state, or international requirements.
 - 2.1.5. Identify other special review issues.
 - 2.1.6. Determine the likely level of review (<Committee Review> versus <Non-committee Review>)
 - 2.1.7. Handle responses to modifications required to secure approval
- 2.2. The <Regulatory Reviewer> documents <Regulatory Review> findings.
- 2.3. The <Meeting Chair> ensures that issues raised by <Regulatory Review> are covered at meetings.
- 2.4. The addition of a site to a previously approved study is considered a modification to previously approved research.
- 2.5. Changes to study personnel are not considered a modification to previously approved research when the study personnel meet the qualifications described in the IRB approved study.
- 2.6. Changes in the number of subjects to be enrolled at a local site of a multicenter study are not considered to be modifications to previously approved research when the number of subjects to be enrolled in the entire study is unchanged.
- 2.7. The IRB can provide generic approval for materials not tied to a specific protocol (such as generic advertisements or generic pre-screening consent forms).

3. RESPONSIBILITY

- 3.1. <Regulatory Reviewers> carry out these procedures. Qualified IRB staff who are not <Regulatory Reviewers> can review responses to a decision to conditionally approve research.

4. PROCEDURE

- 4.1. If the submission is a response to a decision to conditionally approve research:
 - 4.1.1. Evaluate whether the submitted materials meet the conditions necessary for approval and evaluate if any other changes have been made.
 - 4.1.2. If the submitted materials meet the conditions necessary for approval and nothing else in the submission has changed, document that the submission is approved and follow "SOP: Post-Review (HRP-111)." Otherwise, process as described in this SOP.
- 4.2. If the submission meets "WORKSHEET: Closure Criteria (HRP-413)", close the study, follow "SOP: Post-Review (HRP-111)" to notify the investigator, and stop further processing.
- 4.3. If the investigator is <Restricted> and the submission satisfies all outstanding delinquent submissions, remove the investigator's <Restricted> status.



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- 4.4. If the investigator is <Restricted> and the submission is an initial submission, notify the submission contact of IRB policy to disapprove those submissions:
 - 4.4.1. If the submission contact wants to address the <Restricted> status, have the contact provide additional information as appropriate to resolve the issues, or withdraw the submission and resubmit when complete.
 - 4.4.2. If the submission contact does not want to address the <Restricted> status, note this and continue processing.
- 4.5. Determine whether the submission is initial, continuing, or modification. If both continuing and modification, follow both procedures.
 - 4.5.1. For initial submission:
 - 4.5.1.1. Use "WORKSHEET: Regulatory Review (HRP-420)."
 - 4.5.1.2. Document any <Regulatory Review> findings.
 - 4.5.2. For a modification submission:
 - 4.5.2.1. Review the <Regulatory Review> findings associated with prior approval(s).
 - 4.5.2.2. Use "WORKSHEET: Regulatory Review (HRP-420)."
 - 4.5.2.3. Update <Regulatory Review> findings as needed.
 - 4.5.2.4. Determine whether the submission includes information that might represent an <Unanticipated Problem Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, or <Termination of IRB Approval>.
 - 4.5.2.4.1. If so, additionally process under "SOP: New Information (HRP-112)."
 - 4.5.3. For continuing submission:
 - 4.5.3.1. Review the <Regulatory Review> findings associated with prior approval(s).
 - 4.5.3.2. Use "WORKSHEET: Regulatory Review (HRP-420)."
 - 4.5.3.3. Update <Regulatory Review> findings as needed.
 - 4.5.3.4. Determine whether the submission includes information that might represent an <Unanticipated Problem Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IRB Approval>, or <Termination of IRB Approval>.
 - 4.5.3.4.1. If so, additionally process under "SOP: New Information (HRP-112)."
- 4.6. Identify any relevant local, state, or international requirements related to human research.
 - 4.6.1. Arrange for consultation, if needed to resolve local, state, or international regulatory issues.
- 4.7. Communicate with the submission contact for any potentially resolvable contingencies.
 - 4.7.1. If the submission contact wants to address the contingencies, have the contact provide additional information as appropriate to resolve the issues, or withdraw the submission and resubmit when complete.
 - 4.7.2. If the submission contact does not want to address the contingencies, note this and continue processing.
- 4.8. Determine whether the likely level of review is <Non-Committee Review> or <Committee Review> and route appropriately.

5. REFERENCES



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5.1. None