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 has completed the review or an investigator has withdrawn the submission.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 an amendment to previously approved research.
2.5. Changes to study personnel are not considered an amendment 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 amendments 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)”, notify the investigator that the study qualifies for closure. If the investigator agrees to closing the study, 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.

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 amendment. If both continuing and amendment, 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 an amendment 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. the submission includes information that might represent an Update <Regulatory Review> findings as needed.

4.5.2.4. Determine whether <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

5.1. None