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 claimed by a <Regulatory Reviewer>.
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 has completed the review or an investigator has withdrawn the submission.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 the IRB needs to make in order to approve research. (For example. waiver of consent, children, prisoners)
2.1.3. Identify, make, and document regulatory determinations that the institution needs to make in order to approve research (For example, IND/IDE requirements)
2.1.4. Identify any relevant local, state, or international requirements
2.1.5. Arrange for consultation to resolve local, state, or international requirements.
2.1.6. Identify other special review issues.
2.1.7. Determine the likely level of review (<Committee Review> versus <Non-committee Review>)

2.2. The <Regulatory Reviewer> documents <Regulatory Review> findings on "FORM: Regulatory Review (HRP-210)" or equivalent.
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 the submission that are not considered modifications to previously approved research may be processed by a <Regulatory Reviewer>. Such changes include:

2.5.1. Changes in study personnel when the study personnel meet the qualifications described in the IRB approved study.
2.5.2. Closure to enrollment in a manner consistent with the approved protocol (e.g. accrual goal met) and for reasons unrelated to subject safety
2.5.3. Correction of typos and formatting errors in approved study documents
2.5.4. Changes to sponsor name (e.g. sponsor is purchased by another company)
2.5.5. Termination Requests in a manner consistent with the approved protocol and for reasons unrelated to subject safety.

3. RESPONSIBILITY

3.1. <Regulatory Reviewers> carry out these procedures.

4. PROCEDURE

4.1. If the submission is limited to changes that are not considered modifications to previously approved research, document this and follow "SOP: Post-Review (HRP-111)" to notify the submitter.
4.2. If the submission is a response to a decision to conditionally approve research:

4.2.1. Evaluate whether the submitter made the required modifications, obtaining consultation as needed.
4.2.2. If the submitter made the required modifications and no others, follow "SOP: Post-Review (HRP-111)" to issue an approval. Otherwise, process as a modification.

4.3. Determine whether the submission is initial, continuing, or modification. If both continuing and modification, follow both procedures.

4.3.1. For initial submission:

4.3.1.1. Use "WORKSHEET: Regulatory Review (HRP-420)."
4.3.1.2. Document any <Regulatory Review> findings.

4.3.2. For a modification submission:

4.3.2.1. If the submission meets "WORKSHEET: Termination Request Criteria (HRP-413)", terminate the study and follow "SOP: Post-Review (HRP-111)" to notify the investigator.
4.3.2.2. Review the <Regulatory Review> findings associated with prior approval(s).
4.3.2.3. Use "WORKSHEET: Regulatory Review (HRP-420)."
4.3.2.4. Update <Regulatory Review> findings as needed.
4.3.2.5. 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>.

4.3.2.5.1. If so, additionally process under "SOP: New Information (HRP-112)."

4.3.3. For continuing submission:

4.3.3.1. Review the <Regulatory Review> findings associated with prior approval(s).
4.3.3.2. Use "WORKSHEET: Regulatory Review (HRP-420)."
4.3.3.3. Update <Regulatory Review> findings as needed.
4.3.3.4. 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>.

4.3.3.4.1. If so, additionally process under "SOP: New Information (HRP-112)."

4.4. Identify any relevant local, state, or international requirements related to human research.

4.4.1. Arrange for consultation, if needed to resolve local, state, or international regulatory issues.

4.5. Communicate with the submission contact for any potentially resolvable contingencies.

4.5.1. If the submission contact wants to address the contingencies, return the submission and have the PI resubmit when complete.
4.5.2. If the submission contact does not want to address the contingencies, note this and continue processing.

4.6. Determine whether the likely level of review is <Non-Committee Review> or <Committee Review> and route appropriately.

5. REFERENCES

5.1. None