SOP 303: IRB REVIEW OF SUBMISSIONS

POLICY

A thorough evaluation of all research proposals submitted for review is conducted by IRB members allowing the IRB to determine if the study meets the minimum criteria for initial approval (see SOP 403: Initial Review - Criteria for IRB Approval) and the minimum criteria for continuing approval (see SOP 404: Continuing Review). IRB members review changes in approved research during the period for which approval has already been given to determine if the study meets minimum criteria for ongoing review (see SOP 405: Review of Amendments to Research Studies).

At a minimum, all members of a convened board are expected to be familiar with all IRB applications scheduled for review in advance of convened board meetings. Board members are expected to be familiar with the agenda and items (as described above) for the meeting they will attend.

Additionally, the IRB relies upon an assigned reviewer system. A primary reviewer is assigned to each application (e.g. new study, continuing review, amendment, report form, etc.) reviewed at the convened board. A secondary reviewer may be assigned to new studies reviewed at the convened board as outlined in SOP 302: Administrative Review and Distribution of Materials. For studies eligible for expedited review, the primary reviewer is a designated expedited reviewer.

Assigned IRB reviewers perform an in-depth review of all documentation and materials submitted by the IRB staff and Investigator. Assigned reviewers may be required to review additional material requested by the IRB for the purpose of study approval.

Comments are not limited to the assigned reviewer(s). All members of the IRB panel have access to the submitted documents and may provide comments regarding any proposed research. Any board member, at his/her discretion, can request any of (but are not limited to) the following:

- Ad hoc consultant review;
- Any additional necessary information beyond what has been provided by the investigator;
- Third-party verification of information submitted by the Investigator.

PROCEDURES FOR IRB REVIEW

1. Primary reviewers are required to review all submitted documents in advance of convened meetings in enough depth to be familiar with and be prepared to discuss the protocol. Primary reviewers are responsible for presenting his/her findings, providing an assessment of the merits and safety of the protocol, reviewing the consent process (in the absence of a secondary review) and recommending specific actions to the IRB. He/she leads the discussion of the study at the convened meeting.

   1.1. For studies qualifying for expedited review, designated expedited reviewers are expected to perform an in-depth review of all documents submitted by the Investigator. In addition

to completing the Board Member checklist, the reviewer indicates the applicable expedited category. If the expedited reviewer determines the study does not qualify for an expedited review, the expedited reviewer notifies the IRB coordinator. The study will then be referred to the convened board for review.

2. Secondary reviewers, if assigned, are expected to review all submitted documents in advance of the meeting, are responsible for reviewing the consent process outlined by the protocol, and add to the discussion as necessary.
3. Each assigned reviewer completes a Board Reviewer Checklist that describes his/her findings, and determines whether the study meets the minimum criteria for initial approval, the minimum criteria for continuing approval, or the minimum criteria for ongoing review. Additional checklists are required when a study necessitates additional consideration by the IRB (e.g. the study involves a vulnerable group, use of a medical device, use of an investigational drug, etc.). Completed Board Reviewer Checklists are submitted via ERICA, becoming part of the electronic record and forming the basis for communication to the Investigator.
4. **Notification of IRB Review.** The IRB coordinator notifies the Investigator of the IRB's determination within seven business days of the convened board meeting. For studies reviewed using expedited procedures, the IRB coordinator notifies the Investigator of the IRB's determination within seven business days of the expedited review. The written notification includes the IRB's decision with requested revisions or requested clarification, when applicable.
5. **Review of Requested Revisions.** Based on the terms of approval at the time of initial review, the IRB will review the Investigator's response to requested revisions as outlined in SOP 407: Categories of Action. Final approval will not be granted until all of the board or expedited reviewer recommendations and requests are appropriately addressed.