This Standard Operating Procedure (SOP) describes the procedures followed during a meeting of the full convened Institutional Review Board (IRB).

An abstention is neither a "yes" nor a "no" vote and is cast when a member is not comfortable in voting either way. Any member is free to abstain at any time. An abstention counts toward quorum but does not count toward a majority.

A simple majority of the members listed on the IRB membership roster registered with the federal Office of Human Research Protections (OHRP). A quorum is considered to be half plus one of the members present at a convened IRB meeting.

The IRB member with the most appropriate expertise for reviewing a specific item.

- Provides a brief summary of the item to the IRB.
- Leads a discussion of the criteria for approval with respect to the item, including the identification of any concerns.
- Usually makes the first motion proposing specific IRB actions (for example, approval).
- May assist in writing or reviewing the correspondence to the investigator that communicates the IRB's decisions, requirements, and questions.
- May assist in verifying that the investigator's responses to a request for Information required outcome satisfactorily meet the IRB's conditions.

1.1 The Chair calls the meeting to order.

1.2 The Chair introduces any observers or guests.

1.3 The Chair asks the members for any corrections or revisions to any minutes from previous meetings. A motion is made, and voted upon, to accept, accept with corrections, or not accept the minutes. Voting is not restricted to those members who were present at the meeting described by the minutes.

1.4 The Chair asks the members for any comments or questions regarding Adverse Event reviews or expedited reviews (if any). A motion is made, and voted upon, to accept, accept with corrections, or not accept the report.

1.5 The Chair facilitates the conduct of any other business, including education and training activities, announcements, etc.

2.1 Information presentation

The Chair performs the following actions, in a sequence that is appropriate to the item and circumstances.

2.1.1 Asks the primary reviewer to provide a short descriptive summary of the item.

2.1.2 If the investigator or a member of the research team will be present or available by phone: invites him/her to present information and/or to answer questions from the members.

2.1.3 If a member has a conflict of interest: Invites the R ti 4.1 u (nfB-4 (e14 (o a(.)7 ( )]TJ(ue)3

2.2.5 Any member with a conflict of interest must recuse himself/herself. Members who abstain during voting counts toward quorum.

An IRB member (typically the primary reviewer) makes a motion recommending specific IRB actions. The IRB administrative staff shall provide written notification of its determinations to investigators. If a submitted project is incomplete or requires revisions for greater than 90 days the IRB administrative staff will close the project and notify the Investigator by publishing a decision letter in IRBNet.

IRB actions, upon review of research, include the following:

In the case of an approval with no changes, the research may begin once the investigator receives written documentation of IRB approval.

Unless otherwise specified, the approval period for research approved without changes is one year from the date of the meeting at which approval was granted. The effective date of the initial approval is the date on which the convened committee approves the protocol submission

The IRB may determine that a study may be approved with minor changes or clarifications. Minor changes are those changes that do not involve potential for increased risk or decreased benefit to the human subjects. For minor changes, the IRB administrative staff ensures that the investigator makes the appropriate changes to the research protocol. The research may proceed after the required changes are verified and the investigator receives IRB letter of approval.

The effective date of the initial approval is the date on which the administrative staff has reviewed and accepted as satisfactory requested changes required by the IRB from the investigator.

The primary reviewer and/or secondary reviewer is responsible for reviewing the changes to ensure that the changes are adequately addressed. The IRB protocol receives final approval when all required changes have been submitted and approved by the reviewer(s).

The effective date of the initial approval is the date on which the convened committee approves the protocol submission whereby a designated IRB member has reviewed and accepted as satisfactory requested changes required by the IRB from the investigator.

All outstanding serious adverse event(s) pending review and/or response from the investigator during review of a renewal or amendment submission at the convened meeting will not be granted approval until the adverse event(s) is resolved.

Deferral is used to describe the situation in which the IRB determines that substantive changes must be made before approval may be granted. The investigators response, including any amended materials, must be reviewed at the next convened IRB meeting.

Subject to IRB discretion, a proposal may be withdrawn if the investigator does not respond to a deferral within a reasonable amount of time. If the investigator wishes to conduct a study that has been withdrawn, he/she must sub (a)4 (d)10rueubjethe inv2 (ns)1 (d)1.noch

and either require changes to the protocol, allow the study to restart, or terminate the study.

Though the chair may suspend a study, only the convened IRB can make the decision to terminate a study. When a study is suspended or terminated, the IRB notifies the Institutional Official. If the suspended or terminated study is externally funded, the IRB will notify the Office of Sponsored Programs. The Institutional Official is responsible for all required reports to federal agencies.

IRBNet automatically generates a notification of expiration via email if a study is not closed or renewed by the date of expiration. An expiration document is published in IRBNet and the project status is changed to closed-expired.

Upon receipt of a IRB closure form the IRB Office administratively closes the research project. The researcher will not be permitted to have any further interaction with subjects or their data in ways that would require ongoing IRB approval. If the investigator wishes to enroll new subjects for the study or engage in human subject's research he/she must reactivate the protocol with the IRB Office. The researcher may close a study when he/she is no longer accruing subjects, using research interventions on existing subjects, collecting data (including follow-up data), or performing any other tasks identified as part of the IRB approved research study. However, a researcher may continue to analyz2 (l)4 (l)4 skeontz2 (l)4 (l. (e)9 (d)-4 (r)103 (l)4 s)2 (k)6 qye. urcupntiofi data(()8 e

SOP 301: IRB Meeting Preparation
SOP 401: IRB Meeting Agenda
SOP 501: IRB Review