IRB REVIEW OF RESEARCH AT A CONVENED MEETING

DESCRIPTION

The members of the Institutional Review Board (IRB) will review at a convened meeting all research which is deemed greater than minimal risk or which cannot be approved by reviewers. The IRB has the authority to approve, require modification to or disapprove research involving human participants.

RESPONSIBILITY

The IRB meetings are scheduled to occur once a week with the fifth week acting as a training period for continuing IRB member education. The schedule of meetings, although subject to change, is posted on the website. The IRB Chair or designee and Human Research Protection Program (HRPP) staff are responsible for ensuring that all appropriate documentation is provided to the members of the IRB for review and consideration of approval, and documents for review are provided to members, including alternates and any consultants, in advance of the meeting to provide time for substantive review. The IRB Chair and HRPP staff are responsible for proper conduct of the meeting, in keeping with applicable policies, procedures and federal regulations.

PROCESS

Determining a Quorum

1. The IRB Chair or designee will determine that a quorum is present before calling the meeting to order. A quorum is called when (a) more than half of the IRB members are present; (b) a non-scientific member is present, and (c) member(s) with needed expertise are present.

2. For review of research involving prisoners, a quorum will consist of the requirements listed above in (1) and the member designated to be the prisoner advocate.

3. For review of research conducted at a Veterans Affairs Medical Center (VAMC), a quorum will consist of the requirements listed above in (1) and a member(s) acting as a representative of the respective VAMC.

When reviewing research that involves minors, the IRB will provide adequate expertise among its members. If the necessary expertise is not available among the membership, the IRB will use
consultants to review the research and advise it, in accordance with Institutional Policy III.01, *Review by the IRB of Human Subjects Research.*

The Chair or designee will ensure that a quorum is maintained during the course of the meeting. The Chair will remind the members at the start of the meeting that they should identify when they have a conflict of interest with any protocol on the agenda. Member(s) will be excused from the meeting for discussion and vote of all research for which they have a conflicting interest. Computers with Internet access are provided to the IRB for facilitating the meeting and review requirements. Votes are taken when the IRB Chair calls for hand votes and counted by a HRPP staff person. If at any time quorum is lost, discussion of research protocols will be suspended until such time as the quorum is regained. If a member discloses a conflict of interest with the research under discussion, that member cannot be counted to constitute the quorum for the research which poses the conflicting interest. Any member with a conflict of interest must disclose that conflict of interest before the project is discussed. No member may participate in the initial or continuing discussion or vote of any project in which the member has a conflicting interest (as defined in the IRB Procedure 102, *Managing Conflicts of Interest of Institutional Review Board Members and Consultants*), except to provide information as requested.

If a consultant has been asked to review a full board protocol (see Policy III.01 *Review by the IRB of Human Subjects Research*), the consultant will be available to answer questions at a convened meeting but will not be counted for purposes of a quorum and may not vote on the human subjects research.

**REVIEW OF NEW RESEARCH PROPOSALS**

**Review and Presentation at a Convened Meeting**

After a quorum has been established, the primary or secondary reviewer will present the protocol, giving their thorough review and leading the discussion on the research. The presenter will recommend the appropriate action regarding approval, including the interval for continuing review. The presenter will follow the IRB Presentation Template for New Protocols. If the IRB has questions or needs clarification of a protocol during discussion at a convened meeting, the IRB Chair may call the Principal Investigator (PI) at the number the PI has provided. The PI may attend the meeting at the invitation of the IRB or the Chair or designee. The PI may answer questions or provide additional clarification, but may not be present during deliberations or voting on the study.

IRB presenters lead the discussion of the research proposal. The presenter will make a motion to approve, require modification, or disapprove the proposal and recommend the approval period, if
the motion is to approve or approve with modifications. During discussion, the Chair will lead the IRB to work toward resolution of any controverted issues. Unresolved issues could be reasons for disapproval. At the end of all discussion, the Chair will call for a vote. In order for research to be approved, it must receive the approval of a majority (more than half) of the members present at the meeting. After the meeting, the Chair will notify the investigator in writing of the Board’s decision.

**Approve Pending Administrative Review by Chair or other IRB Member**

When the convened IRB is able to stipulate specific revisions that require simple concurrence or changes to the study by the investigator, the IRB may determine that the IRB Chair, designee or other IRB member may administratively review the revised research protocol on behalf of the IRB. The revisions must be directive or non-substantive changes specified by the convened IRB.

**Directive Revisions**—Specific responses or revisions requested of the investigator to secure approval

Examples:
- Include the standard UC template language in the “What Compensation is Available in Case of Injury Section?” of the consent.
- The IRB determines that minors should not be enrolled in a study. The PI is informed of this decision and agrees not to enroll minors in the study
- Include specific risks as directed by the Board

**Non-Substantive Revisions**—A revision which in the judgment of the IRB requires no substantial alteration in the:
- Risks to participants
- Equitable selection of participants
- Informed consent process
- Informed consent documentation
- Safety and monitoring of the study
- Participant’s privacy or data confidentiality

Examples:
- The addition of research activities that would be considered exempt or expedited (independent from the main research protocol)
- A minor increase or decrease in the number of participants
- Narrowing inclusion criteria/Broadening exclusion criteria
- Changes to improve the clarity of statements or to correct typographical errors, without altering the content or intent of the statement
Human Research Protection
Program Institutional Review
Board Procedure

- The addition or deletion of qualified subinvestigators or study sites
- Confirmation of human research protection training requirements by investigators

Review of Advertisements and Recruitment Methods

The IRB will review the content of all submitted proposed advertisements, proposed recruitment methods, and all other recruitment material to be provided (See Policy II.04, Reviewing Recruitment Materials in Human Subjects Research). In clinical studies, no claims should be made either explicitly or implicitly that the investigational drug or device is safe or effective for the purpose under investigation, or that the drug or device is superior to any other drug or device. This is especially critical when a study may involve participants who are likely to be vulnerable to undue influence. When a drug is compared to placebo, recruitment materials must so state.

Designating the Frequency of Continuing Review

For each protocol under discussion, the IRB will determine the frequency of continuing review of the research, designating an interval appropriate to the degree of risk, but not less than once each year from the date of approval for non-exempt federally funded research; and not less than once every two years for non-exempt research that is not federally funded. More frequent review may be appropriate if the research is a Phase I or II study or a Significant Risk device study, if it involves vulnerable populations, if the IRB believes that previous studies indicate high incidence of adverse events, or if the IRB believes that close monitoring is indicated. The reasons for such a determination will be included in the minutes.

For the purpose of determining the approval date and expiration date of a protocol, the approval date is the date upon which the IRB voted for approval or approval with conditions. The expiration date of approval is the same day of the month as the day of approval, after the designated continuing review interval. The expiration date is the first day the protocol is no longer considered an approved study by the IRB.

Voting

Regular members or, in their absence, their designated alternate, may vote. The number of votes for and against the motion and the number of members abstaining from the vote will be recorded in the minutes.
Remote Participation in Meetings

If members cannot be physically present at the meeting, some or all members may participate in the meeting by conference call or videoconference; however, voting members cannot participate in the meeting discussions or voting by email.

Members participating by conference call or videoconference will receive all relevant materials prior to the meeting and be able to participate actively and equally in all discussions. Minutes will clearly document which members were present by conference call or videoconference and that the criteria for a member participating by conference call have been satisfied.

Action by the IRB Following Review

Following the completion of review, the IRB may approve the study, approve the study with modification, table the study to provide time to gather more information or to complete the discussion of the study, or may disapprove the study. The results of the IRB’s action will be promptly communicated in writing to the PI.

Notification to the PI of approvals with conditions, disapprovals, requests for additional information, and similar communications shall include a notification of the manner and time period during which the PI may respond. Complete and timely responses from PI shall be promptly communicated to the Board for action at the next convened meeting as appropriate.

Tabled Pending Review by the Convened IRB

When the convened IRB requests non-directive or substantive modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required discussion by the IRB under HHS regulations at 45 CFR46.111, the proposed research must be tabled, pending subsequent review by the convened IRB of responsive material.

Non-directive Revisions

Non-directive revisions occur when responses or revisions from the PI require evaluation by the IRB.

Examples of non-directive revisions include:

- Provide the names and expertise of members of a Data and Safety Monitoring Board (DSMB);
Human Research Protection
Program Institutional Review
Board Procedure

- Indicate how often the DSMB will meet;
- Provide animal data for the study drug;
- Clarify what type of counseling services will be offered to participants; and
- Justify why it is necessary to enroll participants from vulnerable populations.

Substantive Modifications

Revision to the protocol which, the IRB determines substantially modifies the:

- Risks to participants,
- Equitable selection of participants,
- Informed consent process,
- Informed consent documentation,
- Safety and monitoring of the study, or
- Participants’ privacy or data confidentiality

Examples:

- Addition of diagnostic procedures to ensure participant safety
- Addition of a DSMB

Release of IRB Approved Documents

For research to be approved at a convened meeting it has to receive the approval of a majority of members present at the meeting and at least one unaffiliated member must be present. There must also be at least one member who represents the general perspective of participants is present for convened meetings. If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, other than prisoners or children which are included in policy, one or more individuals who are knowledgeable about or experienced in working with such participants are present. For example, pregnant women or handicapped or disabled persons should be represented.

The agenda will serve to inform the IRB members of research protocols approved using the expedited process. The minutes of the IRB meetings shall document quorum, separate deliberations, actions, and votes for each protocol under review. For each new protocol which has received full approval by the IRB and is not pending any further changes, clarifications or other restrictions, the IRB approval letter, informed consent document(s) (if applicable) and any other approved documents will be released to the investigator. IRB approval letters will contain the approval date, expiration date (no more than one year from date of approval), and other pertinent information related to that protocol. The informed consent document(s) will contain the IRB approval stamp on all page(s).
For VAMC research, the informed consent statement will be placed onto the VAMC form 10-10-86 and the IRB approval stamp will be placed on each page of the 10-10-86.

**Applicable Regulations, Document(s):**
21 CFR 56.111
45 CFR 46
HRPP Policy II.04 Reviewing Recruitment Materials in Human Subjects Research
HRPP Policy III.01 Review by the Institutional Review Board of Human Subjects Research

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<th>Date of Revision</th>
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<tr>
<td>03/2005</td>
<td>C. Fabby</td>
<td>07/2007</td>
<td>M. Linke</td>
<td>Updated the Board review outcomes to clarify follow-up action.</td>
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<tr>
<td>05/2008</td>
<td></td>
<td>05/2008</td>
<td>J. Lindwall</td>
<td>Updated text regarding IRB approval letters may be signed by the Chairperson or his/her designee.</td>
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<td>07/2009</td>
<td>J. Gerlach</td>
<td>Revise text to indicate that SBR IRB will utilize primary reviewer system. Deleted text describing SBR convened meeting.</td>
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<td>07/2010</td>
<td>J. Gerlach</td>
<td>Removed text- last paragraph 1st page, regarding requirement of two IRB members who are members of Dept. of Psychiatry to review behavioral research</td>
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<td></td>
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<td>11/2011</td>
<td>J. Osborne</td>
<td>Added text regarding Remote Participation in Meetings at top of page 5.</td>
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<td></td>
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<td>12/2011</td>
<td>J. Osborne</td>
<td>Added language regarding documentation of conference calls and meeting minutes top of page 5</td>
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<td>5-31-12</td>
<td>C. Norman</td>
<td>Revised definition of quorum.</td>
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<td>06/2014</td>
<td>A.Braggs-Brown</td>
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<td>3/2015</td>
<td>J. Strasser</td>
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Date Adopted  March 2015  Signature  __signed copy on file____________________________