MINUTES OF CONVENED INSTITUTIONAL REVIEW BOARD MEETINGS

DESCRIPTION

The Institutional Review Board (IRB) will maintain written minutes of its convened meetings in sufficient detail to demonstrate that the IRB's actions were done in accordance with federal, state and local laws and regulations, and University of Cincinnati (UC) Human Research Protection Program (HRPP) policies and that the safety and welfare of research participants are protected.

RESPONSIBILITY

The IRB staff will document minutes of convened IRB meetings. Draft minutes of the IRB meetings must be written and available for review within 3 weeks of the meeting date. The IRB Chair will review the minutes for accuracy. The IRB Chair or designate will review the minutes, identify any changes needed, and approve the minutes either as presented or as revised. The final minutes cannot be altered by anyone, including other authorities or committees. The Institutional Official (IO) and Research and Development Committee have access to the final minutes.

PROCESS

The minutes of convened IRB meetings will be written in sufficient detail to show the following:

1. Documentation of attendance at the meetings
   a. Member names
      (1) Identification of their member category
         (a) Medical Doctor (MD), scientist
         (b) Non-MD, scientist
         (c) Non-MD, non-scientist
      (2) Identification of whether or not they are affiliated with UC
      (3) Identification of any specific role such as VA representative, prisoner advocate, etc.
      (4) When the Member joined and when they left the convened meeting
b. Members who were present remotely (by conference call, videoconference or other means) and specific mention that remote attendees have received the same materials for review as in-person attendees

c. Non-member observer names and the identification of the institution or organization with which they are affiliated

d. The presence of a quorum throughout the meeting
   (1) At least one Member in each of the three categories
       (a) MD, scientist
       (b) Non-MD, scientist
       (c) Non-MD, non-scientist
   (2) At least one Member or consultant (consultant may not vote) with the appropriate expertise to review the research
   (3) No Member who has a conflict of interest with a proposal under discussion will be present for discussion and voting. Minutes will state when such a Member left the room and when they returned, reason for absence, and document that quorum was maintained in their absence

2. Documentation of actions and separate deliberations for each action taken by the IRB
   a. Number of votes for, against, and abstaining
   b. Review and approval of research or other matters brought before the IRB and the frequency of review for each new and continuing review.
   c. If the research is conducted at a VA facility under UC IRB oversight and non-veterans will be included as subjects, justification for including them
   d. Modifications required to secure approval of research or other matters brought before the IRB
      (1) Contingent approval will list the modifications needed to secure approval, and whether the modifications can be reviewed and accepted by the IRB Chair or designee or need to be brought back for full-board review.
      (2) Tabling will list the IRB's concerns and the information needed to permit further full-board review.
      (3) The basis for requiring changes in research will be documented
Human Research Protection Program Procedure

e. The basis for disapproving research

f. Determination of the risk level, rationale for the determination, and the risk/benefit ratio of proposed research and of investigational devices
   (1) Required determinations and protocol-specific findings justifying the determinations as required in applicable regulations and UC HRPP policies and procedures, when appropriate for a research study
      (a) Required determinations required for approval of research involving vulnerable participants with impaired decision-making capacity and protocol-specific findings justifying the determinations
      (b) Review of additional safeguards to protect vulnerable populations and subjects who are likely to be susceptible to coercion or undue influence
      (c) If the research is conducted at a VA facility under UC IRB oversight documentation of determinations must be done as required by VA guidance
   (2) Required determinations and protocol-specific findings justifying those determinations to document significant or non-significant risk devices
   (3) Statements of significant new findings

g. Determination of informed consent requirements and other information to be provided to participants
   (1) Protocol-specific determination of the need for informed consent in accordance with the applicable regulations
   (2) Determination of the need for any other information that would add to the protection of the rights and welfare of research participants
   (3) Protocol-specific findings justifying the determination of the need for documentation (signature) or waiver of documentation of consent in accordance with the applicable regulations

h. Documentation of the IRB's discussion of the use of, and security measures to protect, Social Security Numbers (SSNs), scrambled SSNs, or the last four digits of SSNs that will be used in a research study
   Note: This does not apply if the only use of SSNs is on the informed consent form or the HIPAA authorization as required by VHA guidance.

I. Documentation of the discussion and resolution of controverted issues
Human Research Protection
Program Procedure

3. Documentation that the convened IRB was notified of research proposals which have been approved by expedited review

4. Documentation of continuing education or other training provided to members at the meeting

Electronic minutes will be maintained indefinitely.

Applicable Regulations, Document(s):
45CFR 46.103
45CFR 46.107
45 CFR 46.108
45CFR 46.109
45CFR 46.110
45CFR 46.111
45CFR 46.115-117
UC HRPP Policy I.01
UC HRPP Policy III.01
UC HRPP Policy category V
VHA Handbook 1200.05, 24, 28
VHA Handbook 1907.01
Human Research Protection Program Procedure

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<tr>
<th>Adoption Date:</th>
<th>Created by:</th>
<th>Date of Revision:</th>
<th>Revised By:</th>
<th>Summary of Revision:</th>
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<tr>
<td>10/2010</td>
<td>J. Gerlach</td>
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<td>Added text regarding “within 10 business days for minutes to be distributed to members” and Minutes will be approved at a convened IRB meeting. Posting of IRB minutes on the IRB share drive for IO and Director of ORCRA.</td>
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<tr>
<td>11/2011</td>
<td>J. Osborne</td>
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<td>Added text regarding minutes documentation of conference call or videoconference attendance at meetings and social security numbers used in study.</td>
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<tr>
<td>12/2011</td>
<td>C. Norman</td>
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<td>Major revision to remove redundant and obsolete language and increase clarity.</td>
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<td>5/2012</td>
<td>C. Norman</td>
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<td>Add statement that justification for including non-veterans in VA research will be documented.</td>
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<td>M. Linke</td>
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<td>Removed requirement of full board approval of meeting minutes.</td>
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Date January 2016  Signature signature on file