

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>			
<b>SOP #4-1 Revision #5</b>	<b>TITLE: Minutes of IRB Meetings</b>		<b>Page 1 of 6</b>
Approved By: ORI Director	Signature	Date	Date First Effective: 06-30-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 08-19-09

## **OBJECTIVE**

To describe policies and procedures for completing the minutes of the convened meetings of the University of Kentucky (UK) Institutional Review Board (IRB)

## **GENERAL DESCRIPTION**

The federal policies for the protection of human subjects [45 CFR 46.115 (a)(2)] require that "Minutes of IRB meetings shall be in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." (Office for Human Research Protections)

Good minutes enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions. They also provide the IRB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary. Comprehensive minutes also demonstrate respect for the human subjects of research. Meeting minutes do not have to contain information provided in protocols the IRB has previously approved. This process assumes that if IRB members do not discuss a particular issue, the IRB deems the issue acceptable.

## **RESPONSIBILITY**

Execution of SOP: Office of Research Integrity (ORI) Staff, IRB, Veterans Affairs Medical Center (VAMC) Associate Chief of Staff (ACOS), VAMC Research Compliance Officer

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## **PROCEDURES**

### *Minutes Preparation*

1. The ORI staff member attending the convened IRB meeting drafts detailed notes to document IRB discussions and determinations. ORI staff use the ORI minutes template as a guide in drafting minutes. Examples of the type of information included in the minutes are as follows:
  - The location of the meeting and the time the IRB convened the meeting and adjourned; Documentation of attendance to include:
    - Initial and continued presence of a majority of members (i.e., quorum), including at least one nonscientist (See Conduct of Meeting SOP for definition of a quorum.);
    - Whether an alternate is voting and for whom he/she is voting;
    - When a member leaves the room or leaves the meeting;
    - That a licensed physician was present for review of all FDA protocols;
    - The attendance of a VAMC representative, if applicable.
  - Minutes on the review of each protocol include the following:
    - The names of IRB member excused from the meeting due to a conflict of interest during the discussion and vote of the study;
    - Separate deliberations for each action taken by the IRB;
    - A summary of the discussion of any controverted issues and their resolutions;
    - The vote on these actions, including the number of voting “for,” “opposed,” or “abstaining”;
    - In order to document the continued existence of a quorum, ORI staff record votes in the minutes using the following format: # (e.g., 1, 2, 3, 4, or 5)/Total = 15; VOTE: For = 14, Opposed = 0, Abstained = 1;
    - The IRB’s determination on frequency of continuation review (based on the degree of risk or the risk/benefit ratio);
    - Name of the investigator and others attending the meeting;
    - The basis for requiring changes in the research;
    - The level of risk determined by the IRB (at initial review; on all other reviews, the minutes only list level of risk if it has changed).
  
2. When the IRB disapproves a protocol, ORI staff document the basis for the disapproval in the minutes and document discussion of the controverted issues.
  
3. ORI staff write IRB meeting minutes impersonally and do not attribute opinions expressed by IRB members. Typically, the minutes only identify members by name when they recuse themselves from a particular review due to conflict of interest or leave the meeting for any reason.

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4. The IRB considers written comments and or information provided by ad hoc or cultural consultants in the review process. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. IRB staff maintain documentation of written comments or reports in the protocol file. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant.

*Alternates*

1. IRB meeting minutes document when an alternate IRB member replaces a voting IRB member and for whom the alternate is substituting.
2. When alternates substitute for a primary member, the alternate member receives and reviews the same material that the primary reviewer received or would have received.

*Specific Findings*

1. When the IRB makes specific findings at convened meetings, ORI staff document these findings in the minutes of the meeting and include protocol-specific information justifying each finding. Examples of specific findings include, but are not limited to:
  - Alteration or Waiver of the Informed Consent Process in Non FDA Requested Research: When the convened IRB reviews a procedure that alters or waives the requirements of informed consent, the minutes document the IRB's determinations required by the federal regulations (45 CFR 46.116, 38 CFR 16.116).
  - Waiver of Documentation of Informed Consent: When the convened IRB reviews a procedure that waives the requirements for obtaining a signed informed consent document, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.117, 38 CFR 16.117, 21 CFR 56.109).
  - Research Involving Deception: When the convened IRB reviews research involving deception, the minutes document that the IRB made the findings in accordance with 45 CFR 46.116 and 38 CFR 16.116.
  - Research Involving Prisoners: When the IRB reviews research involving prisoners, the minutes indicate that the research meets the findings required by 45 CFR 46.305(a) and represents one of the categories of research permissible under Health and Human Services (HHS) regulations required by HHS 45 CFR 46.306(a).
    - At least one member of the IRB is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.
    - In cases where more than one IRB reviews a particular research project, only one IRB need satisfy this requirement.
  - Research Involving Children: When the IRB reviews research involving children, the minutes document that the IRB made the findings in accordance with IRB policy and federal regulations (HHS 45 CFR 46 Subpart D 46.404-46.407 and FDA 21 CFR Subpart D 50.50-50.55).

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- Wards of the State or Other Agency: When the IRB reviews research involving children who are wards of the state or any other agency, institution, or entity, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.409 and 21 CFR 50.56).
- Research Involving Pregnant Women, Human Fetuses and Neonates: When the IRB reviews research involving pregnant women, human fetuses, and neonates, the minutes must document that the IRB made the findings in accordance with federal regulations (45 CFR 46 Subpart B).
- Research Involving Individuals with Impaired Consent Capacity: When the IRB reviews research involving individuals who are determined to be cognitively impaired and/or lack consent capacity, the minutes document that the IRB made the findings in accordance with federal regulations [45 CFR 46.111(b), 21 CFR 56.111(b), 38 CFR 16.111(b)], and local policy.
- Investigational New Devices: The minutes document the IRB's determination of significant or nonsignificant risk for Investigational New Devices and the rationale for that decision, in accordance with federal regulations [(21 CFR 812.3(m))].

*Department of Health and Human Services (DHHS) Approved Sample Consent Documents (e.g., NIH-Supported Multi-center Clinical Trials)*

1. When the IRB reviews DHHS-approved informed consent documents (e.g., NIH-supported multi-center clinical trials), the minutes include justification for any instance in which the IRB requested or approved the investigator's deletions or substantive modifications of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent document.

*Tele/Videoconference Participation*

1. At a meeting in which IRB members participate via telephone, meeting minutes document that the IRB member:
  - Has received all pertinent material prior to the meeting; and
  - Can actively and equally participate in the discussion of all protocols.

*Documentation of IRB Review of Veterans Affairs Medical Center Research*

1. ORI staff prepare and maintain documentation of the IRB's activities, including copies of all items reviewed. (See also Veterans Health Administration Handbook 1200.05, section 7i, IRB Records.)
2. ORI staff provide minutes of the meetings in which the IRB reviews VAMC protocols to the VA Research Compliance Officer, and to the VAMC ACOS, who is responsible for providing copies to the VA Research and Development Committee.

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3. If the convened IRB approves research contingent on specific minor conditions, the IRB Chair or designee may approve the revised research protocol on behalf of the IRB. ORI staff document approval in such cases in the agenda of the first IRB meeting that takes place after the date of approval.
4. Minutes documenting IRB review of VAMC protocols contain all information specified in standard procedures for IRB review of UK research and this SOP.
5. ORI staff make pertinent sections of the draft minutes of IRB meetings that pertain to review of VAMC protocols available to the VA Research and Development Committee in writing within three weeks of the meeting date.
6. Once the IRB approves the minutes involving a VA study, no one, including a higher authority, may alter the minutes of the meeting except the IRB.

*Distribution of Minutes*

1. ORI staff complete a draft of the IRB meeting minutes according to the ORI Customer Service Standards.
2. ORI staff disseminate the minutes as part of the IRB agenda for the meeting at which the minutes are scheduled to be approved.
3. Each IRB member present during the convened meeting reviews the minutes and forwards any necessary revisions to the appropriate ORI staff member. The IRB approves the minutes at a subsequent convened meeting. The IRB delegates to ORI staff the authority to correct administrative errors in meeting minutes as appropriate.
4. ORI staff distribute copies of approved minutes, as appropriate, to the Vice President for Research, the VA Research and Development Committee through the ACOS, the VA Research Compliance Officer, and others as deemed appropriate by the ORI or the IRB.

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*Record Keeping*

1. ORI staff maintain one set of paper copies of all minutes and an electronic copy in a secure ORI directory. ORI staff maintain copies indefinitely.

**REFERENCES**

45CFR 46.107

45 CFR 46.108

45 CFR 46.111

45 CFR 46.115 (a)(2)

45 CFR 46.116

45 CFR 46.117

45 CFR 46.409

21 CFR 812.3(m)

21 CFR 50.23

21 CFR 50.24

21 CFR 50.56

Veterans Health Administration Handbook 1200.05