

<b>University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures</b>			
<b>Revision #7</b>	<b>TITLE: Minutes of IRB Meetings</b>		<b>Page 1 of 5</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: 05-09-19

## **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 meetings; 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 with sufficient detail to help reconstruct its discussions at a later date, if necessary. Comprehensive minutes also demonstrate respect for 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

## **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 types of information included in the minutes are as follows:
  - The location of the meeting and the time the IRB convened the meeting and adjourned;

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- Documentation of attendance to include:
    - Initial and continued presence of a majority of members (i.e., quorum), including at least one non-scientist (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.
  - Minutes on the review of each protocol include the following:
    - The name(s) of IRB member(s) 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.
  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 submission. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant.

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*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 an alternate substitutes for a primary member, the alternate member is provided access to 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](#)).
  - Waiver of Documentation of Informed Consent: When the convened IRB reviews a procedure which 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](#), [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](#).
  - 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 [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 ([45 CFR 46 Subpart D, 46.404-46.407](#) and [21 CFR Subpart D, 50.50-50.55](#)).
  - 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](#)).

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- Research Involving Pregnant Women, Human Fetuses and Neonates: When the IRB reviews research involving pregnant women, human fetuses and neonates, the minutes document that the IRB made the findings in accordance with federal regulations ([45 CFR 46 Subpart B](#)).
- Research Involving Individuals with Impaired Decision-Making Capacity or with Economically or Educationally Disadvantaged Persons: 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\(b\)](#)) and local policy.
- Investigational New Devices: The minutes document the IRB's determination of significant (SR) or nonsignificant risk (NSR) 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 (HHS) Approved Sample Consent Documents (e.g., NIH-Supported Multi-Center Clinical Trials)*

1. When the IRB reviews HHS-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 HHS-approved sample informed consent document.

#### *Tele/Videoconference Participation*

1. At a meeting in which IRB members participate via tele/videoconference, meeting minutes document that the IRB member:
  - Was provided access to all pertinent material prior to the meeting; and
  - Can actively and equally participate in the discussion of all protocols.

#### *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.

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4. ORI staff provide access to approved minutes, as appropriate, to the Vice President for Research (VPR) and others as deemed appropriate by the ORI/IRB.

#### *Record Keeping*

1. ORI staff maintain an electronic copy of minutes in a secure ORI directory.

#### **REFERENCES**

[45 CFR 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 Subpart B](#)  
[45 CFR 46.305\(a\)](#)  
[45 CFR 46.306\(a\)](#)  
[45 CFR 46.409](#)  
[21 CFR 812.3\(m\)](#)  
[21 CFR 50.23](#)  
[21 CFR 50.24](#)  
[21 CFR 50.56](#)  
[21 CFR 56.109](#)  
[21 CFR 56.111\(b\)](#)  
[21 CFR 812.3\(m\)](#)