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## 1. PURPOSE:

- 1.1. The regulations for protection of human **research** participants state that an IRB must document discussions, decisions, and findings in minutes pertaining to each meeting. The purpose of this **policy** is to establish the process of recording minutes for the University of Georgia Institutional Review Board (UGA IRB) convened meeting, notifying the institution of IRB decisions and determinations, and advising members of research proposals that have been approved using the expedited review procedure.

## 2. DEFINITIONS:

- 2.1. **Meeting Minutes:** A written record of the decisions and discussed topics of a convened meeting.
- 2.2. **Agenda:** A document that describes the topics of discussion for the IRB meeting.
- 2.3. **Controverted Issue:** An issue discussed at an IRB meeting for which there is a disagreement between some IRB members or there are opposing viewpoints among the IRB members that are voiced during the IRB's deliberations.

## 3. POLICY

- 3.1. The University of Georgia IRB creates minutes for each convened IRB meeting that will enable a reader who was not present at the meeting to determine how, and with what justification, the IRB arrived at its decisions. The minutes document that the IRB has considered an approved research in accordance with criteria based on applicable laws, regulations, codes, and guidance. These minutes should also provide the IRB members with sufficient details to help reconstruct its discussions at a later date, if necessary.
- 3.2. The IRB **meeting minutes** will use the *TEMPLATE: IRB Meeting Minutes* and document the following:
  - 3.2.1. Start time and end time
  - 3.2.2. IRB Members attendance and presence of a **quorum**
    - 3.2.2.1. IRB members who arrived late or departed early from the meeting
    - 3.2.2.2. Members present for any aspect of the meeting and when an **alternate** replaces a **regular member**
    - 3.2.2.3. Members absent due to a **conflicting interest** and that the member was recused from the meeting for the discussion and vote
    - 3.2.2.4. When both regular and alternate members are present, only the regular member will vote unless the member is recused or absent from the vote. In this situation, the replacement is noted in the section of the minutes pertaining to the specific project.



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- 3.2.3. Summary of any education/training provided and any announcements
  - 3.2.4. Confirmation that the UGA IRB members were advised of the IRB **expedited review** activities by providing each member access to a 45-day report that lists the research activities approved by expedited procedure
  - 3.2.5. Studies, modifications, continuing reviews, and reports discussed at the meeting with the respective information recorded and separate deliberations for each **agenda** item.
  - 3.2.6. Actions taken (Approved, Modifications Required to Secure Approval, Deferred, Tabled, or Disapproved), including the number of votes for and against, abstentions, and recusals.
  - 3.2.7. Any **tabled** items and the reason for this action
  - 3.2.8. The specific **modifications** required prior to granting final approval and the basis for requiring the modifications or if there were none, a statement reflecting this
  - 3.2.9. For initial review, the level of risk as minimal or greater than minimal and a justification of this determination
  - 3.2.10. If the action is "Disapproved," the basis for this action
  - 3.2.11. Summary of discussion of **controverted issues** and their resolutions or, if there were none, a statement reflecting this
  - 3.2.12. For initial and **continuing review**, the approval period or timeline for requiring progress report, as applicable.
  - 3.2.13. Where applicable, required determinations and protocol-specific findings justifying the determinations for:
    - 3.2.13.1. Waiver or alteration of informed consent
    - 3.2.13.2. Waiver of the requirement to document informed consent
    - 3.2.13.3. Research involving pregnant women, fetuses, and neonates
    - 3.2.13.4. Research involving prisoners
    - 3.2.13.5. Research involving children
    - 3.2.13.6. Research involving participants with diminished capacity to consent
    - 3.2.13.7. Determination of significant risk/non-significant risk device
  - 3.2.14. Members present by teleconference, videoconference or similar technology received all materials and were able to actively and equally participate in the discussion, if applicable
  - 3.2.15. Summary of the key information provided by a **Consultant**, if applicable.
  - 3.2.16. Summary of any other business not already described
  - 3.2.17. Summary of the discussion and determination for each report of new information (RNI) including any related investigation, determination of non-compliance, consideration of whether the event constitutes an unanticipated problem involving risk to subjects or others, whether the members considered termination of IRB approval, and any required corrective actions.
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- 3.3. The meeting minutes are written impersonally, without attributing opinions and votes to specific members.
- 3.4. Minutes are approved on behalf of the IRB by the IRB Chairperson or designee.
- 3.5. The IRB meeting minutes are made available for member review within 14 days of the meeting date. The IRB meeting minutes are considered approved at the end of the first IRB meeting after the prepared minutes have been distributed unless objections are raised by an IRB member. The IRB members do not vote to approve the minutes.
- 3.6. The IRB meeting minutes are considered to be UGA archival records and are permanently retained.

#### 4. PROCEDURES: IRB Staff

- 4.1. The designated IRB staff member must take notes during a convened IRB meeting.
  - 4.2. The designated IRB staff member may take notes in any format or by any method as long as the method captures all required information in sufficient written detail to prepare review letters and meeting minutes.
  - 4.3. The designated IRB staff member must draft the meeting minutes using the *TEMPLATE: IRB Meeting Minutes* and distribute them to the Human Subjects Office (HSO) Director within two business days after the meeting.
  - 4.4. The HSO Director must confirm the draft meeting minutes and return to the designated IRB Staff Member within five days.
  - 4.5. Once received from the HSO Director, the designated IRB staff member must upload the draft meeting minutes to the electronic meeting record and notify the IRB Chairperson via email within two business days.
    - 4.5.1. The draft can be sent to the IRB Chairperson via e-mail if requested.
  - 4.6. The IRB Chairperson or designee must review the meeting minutes within five business days and notify the designated IRB staff member via e-mail if the meeting minutes are approved or need any modifications/corrections.
  - 4.7. Upon approval or making the needed revisions, the designated IRB Staff Member must upload a copy of the meeting minutes, and close the electronic meeting record.
  - 4.8. The IRB members may make corrections to or raise questions about the minutes at the next convened IRB meeting. The IRB Chairperson must request for any corrections or questions at the beginning of the convened meeting and the IRB staff must make note of these accordingly.
  - 4.9. The designated IRB staff member must address any member corrections, convert the minutes to PDF, upload the final PDF version to the appropriate meeting record, and execute the meeting minutes approval activity.
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4.10. The HSO Director must e-mail notification to the Institutional Official or designee once the minutes are approved.

## **5. MATERIALS**

- 5.1. TEMPLATE: IRB Meeting Minutes
- 5.2. WORKSHEET: Approval Intervals

## **6. REFERENCES**

- 6.1. 45 CFR 46.115(a)(2)

### Revision History:

11/13/2015: REV0 New Document  
10/19/2016: REV1  
10/04/2021: REV2

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