

UWG Institutional Review Board

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IRB Meeting Minutes

Minutes of each IRB meeting shall be recorded by the IRB Administrator or designated IRB staff member. Minutes of each IRB meeting shall document the deliberations, actions, and votes for each protocol (e.g. IRB application under review) whether undergoing initial or continuing review according to federal regulations. The minutes will include the following general information:

- 1. Date and time the meeting begins and ends.
- 2. Members present at the meeting.
- 3. Guests, staff, and ex-officio members that are present.
- 4. Any announcements made by those present.
- 5. Any old business discussed.
- 6. Any informational/educational documents provided to the IRB members.

Votes shall be recorded as the number "For," "Opposed," and/or "Abstaining," the votes of individual members are not recorded in the minutes. For each protocol undergoing initial review, continuing review, and review of change requests, protocol deviation, data and safety monitoring reports and other miscellaneous items on the agenda, the minutes shall include the following details:

- 1. Summary of discussions of controverted issues and their resolution, even when the resolution of the issue is to accept the protocol as submitted.
- 2. Action taken.
- 3. The basis for requiring modifications to the research as presented including, but not limited to, application, informed consent document, advertisements, etc.
- 4. The basis for disapproving research.
- 5. For initial and continuing reviews, the decision for the period of approval.

Any unusual degree of risk or an approval period less than one year shall be documented explicitly in the minutes. Review and action taken on items of expedited review will be recorded in the minutes, including specific permissible category on which the decision was made.

To encourage open and frank discussion at IRB meetings and to have detailed records of IRB business (including confidential issues and matters under investigation), minutes of the IRB normally are not made available to others outside University of West Georgia administration unless otherwise required by law or external regulations. The draft minutes shall be distributed to IRB members and the Authorized Institutional Official for review and comment. Following review and comment, minutes will be finalized and approved at the subsequent IRB committee meeting. The approved minutes will be filed with IRB documentation in the approved file.