UWG Institutional Review Board
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IRB Member Roles and Responsibilities

The primary purpose of the Institutional Review Board (IRB) is to ensure that human subjects are not placed at undue risk of harm during the research process.

A balance between freedom of inquiry for scholars and recognition of the ethical concerns of peers, subjects, sponsors, government agencies, and the public at large shall be maintained by the IRB. The members of the IRB maintain that numerous issues tied to human research merit much further attention by the academic community. The IRB strongly encourages faculty, academic staff members, student groups, departments, schools, and colleges to discuss the ethical responsibilities of scholars as they apply to research to ensure awareness and sensitivity of subjects' needs.

A. Membership

The Board shall consist of a minimum of five members, including:

1. One member whose primary concern is in a scientific area
2. One member whose primary concern is in a nonscientific are
3. One member who has no affiliation with The University of West Georgia
4. One member to serve as the Chair of the IRB
5. Additional members to insure ethical treatment of subjects
6. IRB Administrator, ex officio

The regular members will be appointed by the Authorized Institutional Official (AIO) for a term of three years which may be extended by mutual consent. The Board will report to the AIO.

Use of Consultants

Assigned reviewers or the AIO may determine that there is insufficient expertise on the IRB to assess the risks or the benefits of a specific IRB application. Upon this determination, the IRB may ask for an expert consultant. This person will advise the Board but will not vote on the IRB application.

Conflicts of Interest

No IRB member participates (other than to provide requested information) in the initial or continuing review of any study protocol (e.g. IRB application) in which they have a conflicting interest. This includes review of any material submitted over the course of the study or the duration of the member's term.

If a member has a conflict, that member must recuse himself/herself from the deliberation, discussion, and vote on that study takes place. Unless requested to remain in order to provide additional information, it is expected that the member will leave the room until after the vote is taken. Recusal

from the vote is noted in the minutes. Recused members do not count toward quorum. As examples, members may not vote or review study protocols where they:

1. Serve as investigator or co-investigator
2. Supervise or advise the investigator or co-investigator
3. Benefit from the conduct of the study
4. Serve as the subject of study
5. Self-identify conflict of interest

IRB Member Roles

The IRB board may be made up of a Chair and both primary/voting and alternate members.

The Chair of the IRB shall be designated by the AIO of the University based on the recommendations of the IRB members and the IRB Administrator. The Chair of the IRB shall serve a 3-year term as a 12-month appointment (unless there is a period of leave time or time off-contract). This term may be extended upon mutual agreement of the Chair and the AIO.

Primary members are responsible for attending each scheduled IRB meeting during their 3-year term as a 12-month appointment (unless there is a period of leave time or time off-contract). If a primary member will be unable to attend the meeting, they must either: 1) In the case of an assigned alternate, alert their alternate of the alternate's required attendance no less than 5 business days before the meeting; or 2) In the case of no assigned alternate, alert the IRB Chair of their absence from the meeting no less than 5 business days before the meeting. Primary members will participate in convened protocol reviews and expedited or exempt protocol reviews as assigned.

Alternate members are voting members who fill in for a primary IRB member who is not able to vote at an IRB meeting. IRB members who would like to serve as an alternate must notify the IRB Administrator at the beginning of each fiscal year of their 3-year term as a 12-month appointment (unless there is a period of leave time or time off-contract). Alternate status can be assessed on a year-to-year basis. Alternate members will be assigned to a specific primary/voting member. Alternate members are comparable to the primary member they fill in for in background, expertise, knowledge, and status (scientist, non-scientist, unaffiliated). Alternate members may only vote when filling in for the primary member. Alternate members are responsible for attending meetings which their primary cannot attend and participate in convened reviews associated with that meeting. Alternate members will participate in expedited or exempt protocol reviews as assigned.

B. Responsibilities of the IRB Members

Members of the IRB are required to:

1. Complete CITI training;
2. Keep abreast of applicable federal regulations and policies, state laws, the University's FWA, and UWG policies that pertain to human subject protection;
3. Prepare for and actively participate in the review process in full board meetings as well as participate in expedited and exempt reviews as assigned.

4. Review expedited protocols within 10 business days of receipt. Notify the IRB Administrator if planning to be out of town for more than a couple of days. Review of protocol requires the reviewer:
    a. Have effective knowledge of subject populations and other factors involved in determinations of risks and benefits to participants as well as informed consent.
    b. Be able to judge the adequacy and accuracy of information in the informed consent document, recruitment, advertising, and any other materials to be presented to participants.
5. Have the professional competence necessary to review the specific convened research activities presented for approval.
6. Maintain confidentiality of documents submitted for review. Personal, confidential, and proprietary information may not be disclosed to anyone outside of the IRB.
7. Promote positive communication and awareness on campus of the role of the IRB and ethical research principles in regard to human participants research.

Responsibilities of the IRB Chair

The Chair of the IRB shall have the following responsibilities:

1. Maintain an in-depth knowledge of the regulations and regulatory guidance, and expertise in the review of human participants research.
2. Provide leadership and oversight, in partnership with the AIO and IRB Administrator, for the policies, procedures, practices, and functioning of the IRB and human participants research at the institution.
3. In conjunction with the IRB Administrator or AIO:
    a. Design and lead training for IRB members and support orientation for new members.
    b. Provide campus training and educational events coordinated by the IRB office for faculty, staff, and students.
4. Facilitate Board meetings and serve as the lead reviewer for full board reviews.
5. Attend each Board meeting scheduled during their 3-year term. If the Chair will be unable to attend a meeting, the IRB Administrator must be alerted no less than 7 business days before the meeting so that an Alternate Chair may be assigned for that meeting.

Responsibilities of the IRB Administrator & Staff

The Office of Research and Sponsored Projects shall have an IRB Administrator and staff (as appropriate). Appropriately trained IRB staff members, regardless of whether they are members of the IRB, may perform preliminary reviews of documents and complete IRB files in order to facilitate the review of research by the IRB. As part of this preliminary review, IRB staff may perform the following functions, among others:

1. Confirm that all documents required by the IRB have been submitted by the investigator;
2. Assess whether the information and documents submitted by the investigator for Continuing Review are consistent with the research protocol (e.g. IRB application) previously approved by the IRB;
3. Confirm that the informed consent document submitted by the investigator matches the current IRB-approved informed consent document;

4. Aid the IRB in identifying important issues and concerns that the IRB may wish to consider;
5. Provide technical assistance and guidance to the IRB at convened meetings and to the IRB chairperson (or designated IRB member(s)) during an expedited review process; and
6. Conduct reviews of exempt protocols (e.g. applications) (as assigned).

IRB staff members who are *not* IRB members may not be delegated responsibility for making the determinations that must be made by the IRB for expedited or convened review or at the time of continuing review and may not approve research on behalf of the IRB (45 CFR 46.109).

The **IRB Administrator** serves as the Institution's Human Protections Administrator, the primary contact for investigators and administration at UWG. Administrative responsibilities fall into three categories: IRB Communication and Education, Record Keeping and Reporting, and Monitoring and Oversight. Responsibilities of the IRB Administrator include:

1. Maintain UWG's Federalwide Assurance (FWA) and IRB Registration while ensuring compliance with their terms, as well as UWG policies and procedures, federal regulations, and state and local laws relative to the conduct of human research studies.
2. Provide guidance regarding the interpretation of regulations, laws, and policies to the IRBs, researchers, staff, and administrators.
3. Develop and implement UWG human research protection policies and procedures.
4. Oversee and coordinate Human Research Protection Program (HRPP) activities across the various offices and staff that have roles in protecting research participants.
5. Complete all required human research protection training and HIPAA training.
6. Ensure that human research protection training is available and completed by investigators, key study personnel, the Institutional Signatory Official, and all UWG staff who participate in human subjects research.
7. Oversee the quality assurance monitoring of the HRPP, including research protocols (e.g. applications) and investigation of matters of non-compliance. Ensure implementation of corrective action, as needed, in accordance with UWG policies and IRB policies and procedures.
8. Maintain current knowledge of human research protection guidance and regulations as they evolve. Stay current on emerging issues. Monitor federal regulatory websites and other research-related resources so as to stay current with regulatory changes in human research protections guidelines and policies. Communicate pertinent information in a timely manner.

C. Terms of Meeting Attendance

Quorum

Quorum (half + 1) is the minimal number and type of IRB members that must be present at a convened meeting. This is the majority of the designated primary members (or appropriate alternates) and the nonscientist. The Chair of the IRB (or a designated Alternate Chair) must also be present to achieve Quorum. While an unaffiliated member is not essential for quorum to be met, the IRB staff will make an effort to ensure an unaffiliated member be present for the majority (half + 1) of meetings during the year. The unaffiliated member must be present for any meeting during which they would be the only non-scientific member on the committee.

When the agenda includes research involving vulnerable populations, IRB staff will ensure that all discussions during the meeting are confidential. The IRB Chair will also remind members that anyone who is involved in the research listed on the agenda may not be present during discussions or voting except to provide information about that research.

Quorum must be maintained throughout the meeting, if quorum is lost, then the IRB may not vote on the proposed research. IRB members may leave during the meeting, either arriving late, departing early, or needing to step out. The meeting minutes shall specifically document the names of members who left the room due to a conflicting interest. The minutes should provide sufficient information that quorum is maintained. Should a quorum be lost during a meeting, the IRB may not take further action or vote until the quorum has been restored.

Voting

To vote on an action, there must be quorum. The minutes must be detailed enough to show the voting on each action reviewed, including the number of members voting for, against, and abstaining (e.g. 7 primary voting members present total: 5 for; 1 against; 1 abstain). When a member recuses themselves due to a conflict of interest, the minutes should state which action item, the reason for the recusal, and the vote count. Recused members do not count towards quorum. This is different from abstention (e.g. 8 primary total [minus 1 for excused to COI]: 6 for, 1 against, 1 recused; 7 members present for quorum purposes).

Initial and continuing reviews of more than minimal risk research will be conducted at meetings of the IRB convened monthly. Expedited reviews can be performed in the absence of an IRB meeting. Tele/video conferencing may be used for any members to participate in the meeting, and they shall be counted toward the quorum. Approval of research is by a majority vote of the quorum.

Review of proposed protocol changes will be conducted at IRB meetings with a quorum present, except where expedited review is appropriate. Minor changes in previously approved research can be approved under an expedited review procedure. Any revisions to a protocol should be incorporated into the written protocol with the revision dates noted on the protocol itself.

D. Training

IRB members receive orientation to the responsibilities of IRB service. New IRB Members complete a period of training where they work with an experienced IRB Member as a mentor to review no less than 3 expedited or convened applications. All IRB members are also encouraged to attend an annual training/educational workshop to enhance their knowledge on IRB issues and procedures as well as completing the required IRB Members CITI training course. In addition, educational updates are routinely provided at IRB meetings.