

College of Micronesia-FSM

Institutional Review Board (IRB): Terms of Reference (TOR)

A. Authority

The Institutional Review Board (IRB) operates through the authority of the college president. The IRB serves as the institutional authority on research requirements.

B. Purpose

The purpose of the IRB is to:

- Protect the rights and welfare of human research participants;
- Facilitate research;
- Apply the fundamental ethical principles from the [Belmont Report](http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) (<http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>);
- Operate in accordance with US federal regulation 45 CFR 46;

C. Membership and Organization

It is important to note that the IRB is a board and not a committee. US federal regulations include specific requirements about the membership of an IRB, thus appointments to serve on the COM-FSM IRB are not made similarly to those of college standing committees.

Membership Requirements in Accordance with US Federal Regulation 45 CFR 46

Membership is composed of at least five members. At least one member must represent scientific areas (e.g., biology, physics, psychology), at least one member must represent nonscientific areas (e.g., education, English, philosophy), and at least one member must come from outside the college. Additionally, the IRB must have diversity of representation, gender, and profession.

The IRB has two officers, a chair and a secretary. The chair is appointed by the college president and the secretary is nominated and elected by a majority vote of the IRB members.

- Frankie Harriss, EdD, IRB Chairperson, and COM-FSM Vice President for Institutional Effectiveness and Quality Assurance, Accreditation Liaison Officer
- Paul Dacanay, MD, IRB Secretary, and Division Chair for the COM-FSM Public Health Division
- Delihna Ehmes, Division Chair for the COM-FSM Social Sciences Division
- Dr. Eliazer Johnson, Medical Officer and Chief, Division of Public Health, Pohnpei State Department of Health Services
- Bernolihna Hedson, RN-Midwife, Clinical Nurse Supervisor, Pohnpei State Hospital

The IRB may invite individuals with specific area expertise to assist in the review of projects that require expertise that is insufficiently represented on the IRB, however such individuals may not vote with the IRB.

D. Responsibilities

The IRB chair's responsibilities are to:

- Ensure the terms of reference for the board are met;
- Ensure board agenda, minutes, reports, recommendations, and decisions are completed and appropriately disseminated in a timely manner (including decisions to the PI(s));
- Preside over meetings;
- Review decisions and/or recommendations for approval/action as required;
- The chair declares a quorum and/or if a meeting can proceed without a quorum for discussion only;
- Answers questions regarding the IRB process;
- Assists researchers in completing their IRB proposals;
- Tracks when ongoing research projects are due for their annual review;
- Communicates with the IRB regarding incoming proposals and/or other board responsibilities;
- Maintains documentation of completed training for IRB members and principal investigators (PIs);
- Ensures federal records and associated IRB documents (e.g., proposals, consent documents, research updates, and communications between the IRB and researchers/<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.115>) are maintained and readily accessible for at least 3 years after the research is completed;
- Ensures current IRB policy, procedures, and forms are updated on the COM-FSM IRB webpage and COM-FSM website (for COM-FSM board policies (BP) and administrative procedures (AP)).

The IRB secretary's responsibilities are to:

- Distribute approved minutes on the IRB web page;
- Distribute the minutes to the IRB members within a week prior to the next meeting;
- Maintain a file of the minutes;
- Prepare and distribute the agenda one week prior to each meeting;
- Take and prepare accurate minutes which includes accurately:
 - Documenting attendance;
 - Recording voting;
 - Providing rationale for accepting, rejecting, or requiring changes to research proposals;
 - Conflicts among members should be recorded and include a summary of the issue and its resolution;

- Ensures IRB member information, including their degrees, area they represent, relevant experience, and association with the college are provided on the COM-FSM IRB web page;

The IRB member responsibilities are to:

- Actively participate in meetings;
- Carry out assignments;
- Regularly prepare for and attend meetings;
- Read the *Belmont Report*, be familiar with US federal regulation 45 CRF 46;
- Participate in training as deemed necessary in order to better understand the basic ethical principles, federal regulations, and history with regard to the protection of human research participants;
- Provide documentation of IRB training to the IRB chairperson;
- Abstain from the review of any project in which the member has a conflict of interest, including researchers involved in that project and administrators involved in the grant of applications;
- Determine, in accordance with US federal regulations, the level of IRB review required for research proposal submissions (e.g., exempt, expedited, or full);
- Participate in the annual follow-up review process for ongoing studies that last longer than 12 months;
- To abstain from judgement on the merits of research proposals and instead remain grounded in the role of ensuring the protection and ethical treatment of human research participants;
- Abstain from judgement and ensure proposals are not declined on the basis of alternative world views such as religious, political, and moral beliefs;

E. Meetings

Meetings are held quarterly and additional meetings are conducted as deemed necessary. The schedule is determined each calendar year and will be posted to the COM-FSM electronic calendar on the college's website. The chair can call special meetings or reschedule the regular meetings. Meetings can be held face-to-face or via teleconferences or other communication technologies.

A majority of 3 out of 5 members is required for a full IRB review. Any member with a conflict of interest in a project under review cannot be counted in the quorum for that given decision. For example, if only 3 members are present, and one member is vested in project X under review, then there is not a quorum for taking a decision on project X.

All votes should be recorded as yes, no, or abstain. When voting is required the chair will work to ensure that all members vote. Results of electronic voting are to be documented in the next committee meeting minutes.

A member must abstain from voting when there is a conflict of interest and may abstain when unfamiliar with a protocol.