

**College of Micronesia-FSM Institutional Review Board**

**Date: 12 April 2017**

**Time: 2:00 pm**

Location: COM-FSM Board Conference Room

<b>Members</b>	<b>Name</b>	<b>Present</b>	<b>Absent</b>
Chairperson	Frankie Harriss	X	
Member	Delihna Ehmes	X	
Member	Bernolina Hedson	X	
Member	Eliazer Johnson		X
Secretary	Paul Dacanay	X	

**Additional Attendees:**

**Agenda/Major Topics of Discussion:**

1. Review of January minutes
2. Update on actions committed to by IRB members
3. Old Business
4. New Business
  - A. Terms of Reference
    - a. Membership and organization
    - b. Responsibilities of the Chairperson
    - c. Responsibilities of the Secretary
    - d. Minute Requirements
    - e. Responsibilities of the Members
    - f. Meetings
  - B. IRB procedures
  - C. Human Subject Research Projects Template
  - D. Miscellaneous

**Discussion of Agenda/Information Sharing:**

1. Welcome and call for meeting to proceed
  - a. Review of minutes per January meeting
  - b. Tasks discussed in a meeting must be included in the minutes so that in the next meeting members can go back and see if proper action has been taken.

c. Motion for January 12<sup>th</sup> minute approval was passed.

## 2. Old Business

- a. PHRP Certificates of Completion was submitted by all members.
- b. Biographical profiles been submitted to chairperson except for Dr. EJ's.
- c. Belmont Report to be read by all members present.
- d. Dental Research was given approval to start in Pohnpei

## 3. New Business

### A. Review draft College of Micronesia-FSM Institutional Review Board [COM-FSM IRB] Terms of Reference [TOR]

- IRB performs with the authority of the COM-FSM President, however, it is not under the college governance.
- Purpose of IRB is to protect rights and welfare of human subjects and research ethics
- IRB is not responsible for critiquing quality of researches.
- IRB is to ensure researches are conducted in accordance US regulations, and that these researches protect human welfare and rights.

#### a. Membership and Organization

- IRB is a board not committee
- At least 5 members
- 1 member from the sciences
- 1 member from the non-sciences
- 1 member from outside of the college
- Diversity of representation
- Chair-Frankie (appointed by the college President)
- Secretary-Paul (selected by IRB members)
- Members may invite a non-member with the expertise for a certain project, however, that person does not vote. He/she may advise but not vote.

#### b. Responsibilities

- Chairperson
  - Ensures terms of reference for IRB are met
  - Ensures board agenda, reports, recommendations, and decisions, are completed and disseminated in a timely manner. This also includes decisions to principle investigators.
  - Preside over meetings.
  - Review Decisions and recommendations for further action as required.
  - Declaring Quorum.
  - Answering questions regarding IRB process.
  - Assist researchers in completing their proposals
  - Tracking research process
  - Communicating with IRB regarding incoming proposals or board responsibilities.

- Maintain documentation for completed IRB trainings for members and principle investigators.
- Ensure federal records and associated IRB documents are maintained and accessible for at least 3 years after project is completed.
- Ensure current IRB policies, procedures, and forms are updated on website.
- Ensure IRB profiles and their association with the college are posted on the IRB webpage.

c. Secretary

- Distribute approved minutes to members 1 week prior to next meeting.
- Maintain file on minutes.
- Prepare and distribute agenda 1 week prior to next meeting. (still to be determined if this would be the secretary's or the chairperson's responsibility)
- Take and prepare minutes accurately.

d. Minute Requirements

- Document attendance.
- Voting reported.
- Rationale provided for accepting/rejecting or requiring changes for research proposals.
- Should there be disagreement from members; conflict must be reported along with a summary of the issue and resolution.
- Names of individuals will only be disclosed when members do not agree with each other and when a rationale is needed to explain a decision made by members.

e. Members

- Actively participate in meetings
- Carry out assignments
- Regularly prepare for and attend meetings
- Read the Belmont report
- Participate in training as deemed necessary
- Provide documentation for IRB training to the chairperson
- Abstain from review of project with conflict of interest
- Determine the level of IRB in accordance with U.S regulations (whether a project needs full review, is expedited, or exempt)
- Participate in annual follow-up review process for ongoing studies that last more than 12 months
- Abstain from judgement on merits of research proposals
- Abstain from judgement and ensure proposals are not declined on the basis of religion, ethical or moral beliefs, or other alternative world views

f. Meetings

- 4 quarterly meetings, and other meetings as deemed necessary (face to face meetings, or through other methods like skype)
- Schedule of meetings will be posted on the COM-FSM electronic calendar as well as on the IRB website
- Chairperson is responsible for scheduling special meetings (moved to Chair responsibility]
- IRB quorum is at least four of the members
- Voting
  - one may abstain if there is a conflict of interest
  - if member is not able to attend a meeting, he/she may vote electronically (this vote must be included in the next board meeting minutes)
- Votes should be recorded as yes, no, or abstain

MOTION TO ADOPT TOR PASSED.

B. Procedures

- All members will review project proposal to classify is as full, expedite, or exempt
- When a decision is made, the chairperson will send a memo to the principle investigator
- Any changes to study by the principle investigator must be communicated to IRB via the secretary (the secretary will file and then distribute the communication to the rest of the members)
- For expedited research, members agreed that a subcommittee will do the review
- Unanticipated problems occurring throughout an approved research project must be reported to the COM-FSM President by the chairperson
- Project proposals must be submitted to IRB at least 4 weeks prior to the next meeting
- Minimum IRB Training for members would be reading the Belmont report and attend at least one annual IRB training (plans to bring in a trainer to Pohnpei is being discussed)
- Members must have the PHRP certificate and read the Belmont report
- Members to renew their PHRP certificates every couple of years
- Members may also use HRSA video training modules on protecting human subjects
- Compensation for meetings
  - Release time for COM-FSM faculty (1 credit hour)
  - \$100 stipend for non-COM-FSM personnel
- Federal Records
  - Records must be kept for at least 3 years after completion of project
  - IRB electronic records are stored via Dropbox and they are accessible to the chairperson, secretary, and COM-FSM IT staff

- COM-FSM projects for in house use does not need IT approval, however if the project would be disclosed to the outside, like through publication, then it must go through IRB.
- Outside entities using COM-FSM personnel and students does require COM-FSM IRB approval
- COM-FSM researchers conducting researches with other agencies must ensure that they are in compliance with the other agencies' expectations.

C. Human Subject Research Projects Template

- ❖ Review application for Human Subject Research Projects Template for adaptation and adoption
- ❖ Members agreed to adopt template to use for IRB proposal submissions
- ❖ Template to be modified by the chairperson

D. Miscellaneous

- ❖ Meeting scheduled for a day between July 11 to July 13.

Meeting Adjourned

**Handouts/Documents Referenced:**

Belmont Report

**College Web Site Link: <http://www.comfsm.fm/?q=IRB>**

<b>Prepared by:</b>	<i>Paul Dacanay</i>	<b>Date Distributed:</b>	<i>16 October 2017</i>
---------------------	---------------------	--------------------------	------------------------

**Approval of Minutes Process & Responses:** Minutes approved during 02 November 2017 meeting by the four members present.

➤ Electronic votes:

<b>Submitted by:</b>	<i>Pau Dacanay</i>	<b>Date Submitted:</b>	<i>02 November 2017</i>
----------------------	--------------------	------------------------	-------------------------

**Summary Decisions/Recommendations/Action Steps/Motions with Timeline & Responsibilities:**

- Motion for January 12<sup>th</sup> minute approval was passed
- Names of individuals will only be disclosed when members do not agree with each other and when a rationale is needed to explain a decision made by members.
- 4 quarterly meetings, and other meetings as deemed necessary (face to face meetings, or through other methods like skype)

- Chairperson is responsible for scheduling special meetings to be moved to Chair responsibility
- IRB quorum is at least four of the members
- On voting, one may abstain if there is a conflict of interest
- if member is not able to attend a meeting, he/she may vote electronically (this vote must be included in the next board meeting minutes)
- Votes should be recorded as yes, no, or abstain
- MOTION TO ADOPT TOR PASSED
- All members will review project proposal to classify is as full, expedite, or exempt
- For expedited research, members agreed that a subcommittee will do the review
- Project proposals must be submitted to IRB at least 4 weeks prior to the next meeting
- Compensation for meetings
  - Release time for COM-FSM faculty (1 credit hour)
  - \$100 stipend for non-COM-FSM personnel
- Records must be kept for at least 3 years after completion of project
- Members agreed to adopt template to use for IRB proposal submissions
- Meeting scheduled for a day between July 11 to July 13.