Standards and Guidance for members of the YCU Research Institute-Research Ethics Committees

The primary task of the YCU-Research Institute (YRI) Research Ethic Committees (REC) is the ethical review of research ethical application forms and their supporting documents. Approval or request for adaptation and resubmission is based on the ethical review of the research projects based on the ethics application. This includes review of: does the research projects have an acceptable ratio of potential benefits to risks of harm, the minimization of risks, adequate informed consent procedures, measures to ensure protection of vulnerable populations, fair procedures for selection of participants and attention to the impact of research on the communities from which participants will be drawn, both during the research and after it is complete.

Review Process and decision-making process

The following are procedures to be practiced by the YCU-Research Ethic Committee Team: Research institute assistant should enter the list of applicants in an excel sheet with reference code and create a folder for each round of review meeting. The code should be YCURI-ER-[acceptance year]-[serial number of the entry list for each year]. Example, YCURI-ER-2023-01.

(1) Each application should be reviewed by two reviewers.

(2) Mentors of the research paper should not be reviewers on the same paper.

(3) Decisions on reviewers should be made during the regular REC staff meeting.

(4) The reviewer should use the standard assessment form used by YCU-Research Institute.

(5) The reviewer should finish the reviewing of applications with comments at least 3 days in advance of the Research Ethic Committee meeting for final decision.

(6) The role of secretary within the REC will be rotated among its members

(7) The Secretary of REC should organize the REC meeting in accordance with the schedules fixed by the REC. The Secretary of REC should encourage reviewers to finish the initial review process as agreed timeframe and to collect or upload those assessment forms in the Google Drive. The Secretary should inform the research institute assistant for the readiness.

(8) Once receiving those assessment forms, the research institute assistant should cooperate with the Secretary to circulate the reviewers' assessment forms and the meeting links to the REC team members via email.

(9) During the meeting, the Secretary should facilitate the meeting and encourage the two main reviewers to present the justification for their preliminary assessments.

(10) The two main reviewers should fill the final decision forms after the meeting and sign it. Thereafter, the main reviewers should write any agreed suggested comments made by the REC members for further actions.

(11) The main reviewers should sign the decision form that REC members reviewed and approved within 2 working days and send them to the research institute assistant to communicate to the applicants and to prepare the official certificates.

(12) The research institute assistant also enters the decision status of each applicant before informing the applicant. The research institute assistant should inform the decision to the applicants by sending out the decision forms filled by the reviewer and the response form. Meanwhile, the research institute assistant should try to complete the official certificates, including getting signatures of the Chairperson of the YCU-RI. This process should be completed within 5 working days.

(13) The research institute assistant should include the Secretary in any correspondence for effective services to the applicants.

Basic Rules for Review Process

YCU-Research Ethical Guidelines will inform and provide guidance for determination of the research ethics application. Decision-making process on the application should be based on the following checklists to ensure that all relevant criteria are considered during review;

(1) Scientific design and conduct of the study – The REC should consider the impact on the safety of the participants in the design of the study.

(2) Risks and potential benefits – In ethically acceptable research, risks have been minimized (both by preventing potential harms and minimizing their negative impacts should they occur) and are reasonable in relation to the potential benefits of the study. The nature of the risks may differ according to the type of research to be conducted. The reviewer and REC members should be aware that risks may occur in different dimensions (e.g.

physical, social, financial, or psychological), all of which require serious consideration. The reviewer and REC members shall ensure respect for the principle of do no harm at individual -, family or population level. At the same time, the potential risks that might occur shall be mitigated.

(3) Selection of study population and recruitment of research participants – Ethically acceptable research includes recruitment strategies that are balanced and objectively describe the purpose of the research, the risks and potential benefits of participating in the research, and other relevant details.

(4) It is considered ethically acceptable and appropriate to reimburse individuals for any costs associated with participation in research, including transportation, phone top-up and internet costs.It also believes that it is ethically acceptable to compensate participants for costs that have been incurred directly related to supporting the research or to provide interviews. However, payments or compensation shall not be so large that prospective informants, interviewees or other participants consent to participate in the research against their better judgement or to compromise their understanding of the research.

(5) Protection on research participants' privacy and confidentiality – Invasions of privacy and breaches of confidentiality are disrespectful to participants and can lead to feelings of loss of control or embarrassment, as well as tangible harms such as social stigma, rejection by families or communities or lost opportunities such as employment or housing. REC should therefore examine the precautions taken to safeguards' privacy and confidentiality.

(6) Informed consent – The ethics committee must decide if the consent forms and process are adequate.

Confidentiality

(1) The staff of the YCU-RI and research ethic review team members must not, without the YCU-Research Institute Research Ethic Review Committee decision/ Senior Research Advisor of the YCU-RI prior written consent, disclose any information of the applicants to a third party.

(2) All the personal and research information of the applicant must be shared only within Research Ethic Committee (REC) members and solely used for the purpose of research ethic review.

Data Management Policy

1. The YCU-Research Institute (YRI) will designate the Research Assistant to be responsible for data collection and storage.

2. Data collected by the YCU Research Institute must comply with relevant data protection laws and ethical guidelines.

3. To prevent data loss, all research data collected by YCU Research Institute must be properly stored in online storage.

4. Collected data should be stored securely to prevent unauthorized access or data breaches.

5. Access to research data should be limited to authorized personnel, including members of the REC. Access rights should be clearly defined.

6. Data sharing with external parties or organizations should be done only after obtaining the necessary permissions from the (REC) and ensuring the protection of participants' confidentiality.

7. All the reviewers should use only the recognized email of YCU research ethic review team to assess the applicants data.

8. When the REC decides that data is no longer needed, it should be securely and permanently disposed of by using an eraser application or suitable software.

9. The YCU-Research Institute (YRI) will invite data management experts and learn training on data security and protection at least once a year.

10. After each REC meeting, the Research Institute Assistant or the responsible person of YCU should end the accessibility of the application folders by the reviewers.

Recruitment of Review Members

1. The REC should consist of a diverse group of individuals who are familiar with the local context in Myanmar, have expertise in ethics, research, and relevant subject areas.

2. The REC will assess the members' workload and, if required, discuss expanding the committee's membership at the bilateral meeting with YCU-Research Institute (YRI).

3. Recruitment of REC members may include an application and selection process.

4. Applications should be open to qualified individuals who express an interest in serving on the committee.

5. The governing body of the research institution is responsible for making the final selection.

6. They should have no conflicts of interest that could compromise their impartiality.

7. New REC members should receive training and orientation on their roles and responsibilities and on the institute's ethical policies.

8. REC members may serve for defined terms to ensure fresh perspectives and avoid conflicts of interest.

Conflict of Interest Policy

1. All researchers, committee members, and staff must be vigilant about conflict of interests in any action that could be perceived as conflicting with the best interests of the Research Institute.

2. Conflicts of interest must be reviewed and managed on a case-by-case basis. The REC may conduct a special investigation for any incidents of conflict of interest and take appropriate action.