



## Ethics Review Committee (ERC)

### Process of Review

- The protocols should be submitted **at least 6 weeks** before the study team plans to start the study.
- The ethical review is done through **online communication** and the decision will be made on the regular meeting.
- **Two primary reviewers are assigned** to review the full proposals for provision of comments and suggestions. Chairperson and all members have to review at least the summary of the proposals to provide the comments.
- **The principal investigator** is the primary contact person who required to take the responsibility of submitting the proposal and responding the comments and suggestions from the ERC.
- Decision is made through consensus, where possible, when it appears unlikely, ERC voting is recommended.
- Most of the studies require clarifications, minor amendments, scientific justifications, or major amendments. ERC's suggestions/comments have to be incorporated into the revised version which is to be sent **within 2 weeks after receiving the communication letter from ERC.**
- A conditional decision on applications will be re-reviewed following revision.
- A negative decision on an application will be supported by clearly stated reasons.

- The ERC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the risk/benefit ratio.
- The discontinuation of a trial may be recommended if the ERC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
- **Subject experts may be invited** to offer their views and will be recorded and considered in the decision-making process.
- Investigators can contact to the secretariat team for clarification of the submission to ERC and its review process. ([erc@moh.nugmyanmar.org](mailto:erc@moh.nugmyanmar.org))