



Institutional Review Board
Department of Medical Research
IRB Communication Letter to Investigators

DATE:	10.9.2019
TO:	Dr. Phone Thit
FROM:	IRB, DMR
RE:	ERC#2019-52 15 years of HIV care delivery in a multi-centre cohort: health workforce burden outcomes and continued positive programme outcomes following implementation of task shifting and a differentiated model of care in Myanmar

Action taken	Minor modifications and revision
Type of Submission	New study
Date of Review	27.8.2019
Meeting of Review	8/2019

Comments
<p style="text-align: center;">ERC decision is to do minor modifications and revision regarding the following facts.</p> <p>Scientific and technical issues</p> <ul style="list-style-type: none"> - To choose “No” in 1(c),(d), 2(b),(c) in ethics review proposal form - To attach record and retreat form <p><i>Objective</i></p> <ul style="list-style-type: none"> - To modify objectives section mentioning year before and after change of model - To remove group C <p><i>Methodology</i></p> <ul style="list-style-type: none"> - To revise group outcome variables into program outcomes and health workforce burden outcomes - To mention comparison of outcome variables between before and after change of model - To mention comparison of outcome variable among different phases of change of model (e.g., Phase I, II, III and IV etc.) - To add inclusion and exclusion criteria (e.g. exclusion subjects may be those who are enrolled less than 6 months of study end period or those whose outcomes cannot be identified) - To revise the reflection of workload and performance in Outcome section separately

Comments

- To describe the operational definition and the list of lost to follow-up, death and failure event
- To mention “census observation” for outcome observation
- To describe the data sharing and ownership in the protocol after ethical consideration
- To describe the central level dissemination plan
- To describe the budget breakdown

Ethical Issues

- There can be conflict of interest or bias.
- Therefore, it needs to mention that PI and Co PI are staff of MSF who are currently managing the program (OR) add third party co-investigator in conducting data analysis and interpretation

Notes

1. The received protocol resubmitted package should contain:
 - a. The cover letter mentioning updated version number (or) revised version of protocol and date of resubmission
 - b. The **communication letter with respective page numbers** revised/amended
 - c. Revised submission package should contain all the documents listed in the original application package
 - d. Three complete hard copies of revised submission package with updated version number and the **changes highlighted or underlined**
2. Please **attach this communication letter** in the revised package. **(3 Copies of communication letter and revised package)**
3. Please resubmit the old version-protocols with comments of the IRB members (if given back to you) together with revised package.
***Please resubmit the revised submission package within 14 days of receipt of this communication letter.**