Institutional Review Board Proposal Form (Checklist)

University of Public Health, Yangon

Ministry of Health, The Republic of the Union of Myanmar

Application number (for office use): Date: |__|__||__|__||__|__|__|__|

Title of research study:

Supporting Agency: Project Status: New study |__|
Continuation |__|
Secondary data analysis |__|

Please circle the relevant response
(NA=Not-applicable)

1. **Study population**
   - (a) Ill subjects Yes No
   - (b) Non ill subjects Yes No
   - (c) Minors or persons under guardianship Yes No
   - (d) National groups Yes No

2. **Does the study involve**
   - (a) physical risks to the subjects? Yes No
   - (b) social risks? Yes No
   - (c) psychological risks to subjects? Yes No
   - (d) discomfort to subjects? Yes No
   - (e) invasion of privacy of subjects? Yes No
   - (f) disclosure of information damaging to subject or others? Yes No

3. **Does the study involve**
   - (a) use of record? (hospital, medical, death, birth or others) Yes No
   - (b) use of fetal tissues or abortuses? Yes No
   - (c) use of organs or body fluids? Yes No
   - (d) use of left-over specimens? Yes No

4. **Are subjects clearly informed about**
   - (a) nature and purpose of study? Yes No NA
   - (b) procedures to be followed including alternatives used? Yes No NA
   - (c) physical risks? Yes No NA
   - (d) intrusive questions? Yes No NA
   - (e) invasive procedures? Yes No NA
   - (f) benefits to be obtained? Yes No NA
   - (g) right to refuse to participate or withdraw from study? Yes No NA
   - (h) Confidential handling of data? Yes No
   - (i) Compensation where there are risks or loss of working time? Yes No NA

5. **Will consent be required**
   - (a) from participants? Yes No
   - (b) from parent or guardian (if) participants are minors? Yes No

6. **Will precautions be taken to protect anonymity of subjects?** Yes No

7. **The following documents (circled) are submitted**
   1. Application Proposal Form (Checklist)
   2. Covering letter
   3. Proposal summary
   4. Full research proposal
   5. Agreement to carry out according to guidelines
   6. Investigator's curriculum vitae

   The following documents (circled) are submitted if applicable

   7. *Informed consent form*
   8. *Assent form*
   9. *Permission form*
   10. *Consent/Assent document for taking biological samples*
   11. *Information to be provided to participant concerning biological samples*
   12. *Forms and questionnaires for participants*
   13. *Materials for recruitment of participants*
   14. Relevant documents/tools/products
   15. Material Transfer Agreement
   16. Any previous decision(s) made by other Ethical Committees(s)/IRB(s)
   17. Copy of MOU/LOA

NB *No. 7,8,9,10,11,12 and 13* must be submitted in both English and Myanmar language.

If there are two Principal Investigators, both shall sign the proposal.

Signature
Name :
Designation:

Signature
Name:
Designation: