Institutional Review Board Proposal Form (Checklist)

University of Public Health, Yangon

Ministry of Health and Sports, 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/Data 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: