**Ethics Review Proposal Form**

**Institutional Review Board (2)**

**Ministry of Health and Sports, Republic of The Union of Myanmar**

Application number (for office use): Date:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Title of research study: | | | | | | | |
| Funding Agency : | | | | Project Status: New study  Continuation | | | |
| **Please circle the relevant response,if not applicable, please write NA** | | | | | | | |
| 1.  2.  3.  4. | **Study population**  (a) Healthy subjects  (b) Unhealthy subjects  (c) Minors or persons under  guardianship  (d) National groups  **Does the study involve**  (a) physical risks to the subjects?  (b) social risks?  (c) psychological risks to subjects?  (d) discomfort to subjects?  (e) invasion of privacy of subjects?  (f) disclosure of information damaging to subject or others?  **Does the study involve**  (a) use of record? (hospital, medical, death, birth or others)  (b) use of fetal tissues or abortuses?  (c) use of organs or body fluids?  (d) use of left-over specimens?  **Are subjects clearly informed about**  (a) nature and purpose of study?  (b) procedures to be followed including alternatives used?  (c) physical risks?  (d) intrusive questions?  (e) invasive procedures?  (f) benefits to be obtained?  (g) right to refuse to participate or withdraw from study?  (h)confidential handling of data?  (i) compensation where there are risks or loss of working time? | Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes  Yes | No  No  No  No  No  No  No  No  No  No  No  No  No  No  No  No  No  No  No  No  No  No  No | 5.  6. | **Will consent/assent be required**  (a) from subjects?  (b) from parent or guardian (if)  subjects are minors?  **Will precautions be taken to protect anonymity of subjects?** | Yes  Yes  Yes | No  No  No |
| 7.  NB | **The following documents (circled) are submitted**   1. Ethics review proposal form 2. Agreement to carry out according to guidelines 3. Any previous decision made by other Ethical Committees\* 4. Proposal summary 5. Full proposal protocol 6. Informed consent form\*/Assent form\*/ Permission form\* 7. Investigator’s curriculum vitae with recent photo 8. Official letter from MOHS to pass IRB 9. Information to be provided to participant concerning research samples 10. Consent/assent document for taking/keeping biological samples\* 11. Forms and questionnaires for participants\* 12. Materials for recruitment of participants\* 13. Relevant documents and tools/products for the study\* 14. Material Transfer Agreement\*/ Data Transfer Agreement\* 15. Copy of MOU/LOA 16. Permission letter from relevant authorities 17. Research Team Composition   \* (If applicable)  No. 6, 9, 10 and 11 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 : | | | |