

### Annexure 3B

#### FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF NSMCH

Submit three (3) copies of the Research Project along with Covering letter and 'soft copy' on email [crecnsrch@gmail.com](mailto:crecnsrch@gmail.com) ~~or crecnsrch@nsmch.in~~ along with a soft copy with the following information to the Member Secretary, Institution Ethics Committee at Room No. \_\_\_\_, \_\_\_\_\_ NSMCH, Tel No. \_\_\_\_ . The Principle Investigator must submit protocol forwarded through the Head of Department.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Clinical Research Ethics Committee.

All submissions should be made in the prescribed Format of the **Clinical Research Ethics Committee** with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points given on the website**, before it can be considered for placing before the Institution Ethics Committee. Also ensure that all the pages are numbered.

**Project Submission Time:** Submissions will be received on all working days. Proposals received till 15th of preceding month will be processed in the coming Clinical Research Ethics Committee meeting and those received after 15th will be processed in the next Clinical Research Ethics Committee meeting. All meetings of Clinical Research Ethics Committee will be held as far as possible on first Monday of Jan, April, July & October. The frequency will change depending upon the Load and will be updated on the website: [www.nsmch.com](http://www.nsmch.com)

While submitting replies raised by the Clinical Research Ethics Committee, the candidates are advised to mention the Clinical Research Ethics Committee reference number/s and also attach a copy of the comments of the Clinical Research Ethic Committee. Moreover if the approval is required in a particular format, the same may be submitted in a soft copy.

**Amendment Submission:** While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.