**Annexure 4B**

**Procedure for submission of projects**

**Involving research in human subjects for clearance**

**By Ananya IEC**

Submit ten (10) copies of the Research Project along with Covering letter and ‘soft copy’ on email iec.acmr@kirc.ac.in

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 Institution Ethics Committee.

All submissions should be made in the prescribed Format of the **Ananya Institutional Ethics Committee** with signatures of all the investigators **(Annexure 4A)**. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Gujarati/Concerned local Language, **in a simple layman’s language, in a narrative form, directed to Participant /LAR,** before it can be considered for placing before the Ethics Committee.

While submitting replies raised by the Ethics Committee, the candidates are advised to mention the Institution Ethics Committee reference number/s and also attach a copy of the comments of the Institution Ethic Committee.

**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.