**FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF ALIAH UNIVERSITY**

Submit fourteen (14) copies of the Research Project along with Covering letter and ‘soft copy’ on CD with the following information to the Member Secretary, Institution Ethics Committee, Department of Biological Sciences, Aliah University, Kolkata 700160.

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 **Institution 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/Regional Language, **in a simple layman’s language, in a narrative form, directed to Participant,** 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 days. Proposals received till two weeks before the scheduled Institution Ethics Committee meeting will be processed therein. Meetings of Institution Ethics Committee will be held once in two months or as the need may be.

While submitting replies raised by the Institution 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 Ethics Committee. Moreover, if the approval is required in a particular format, the same may be submitted in a CD.

**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.

**Format for Submission of Research projects/ Proposal**

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| --- | --- | --- |
| 1 | Full title of the Study |  |
| 2 | Name of Investigators / co- investigators with designation and departments |  |
| 3 | Objectives of the study |  |
| 4 | Justification for conduct of this study |  |
| 5 | Methodology | 5.1. Number of Patients:  5.2. Inclusion criteria a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ d)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5.3. Exclusion criteria a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ d)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  5.4. Control(s)  5.5. Study design  5.6. Dosages of drug  5.7. Duration of treatment  5.8. Investigation specifically related to projects 5.9 Permission to use copyrighted Questionnaire/proforma  5.10 Others |
| 6 | Permission from Drug Controller General of India (DCGI)  (Tick the Appropriate one) | Required  Not required  Received  Application pending |
| 7 | Permission from DGFT if applicable  (Tick the Appropriate one) | Required  Not required  Received  Application pending |
| 8 | a) Safety measures for proposed interventions  b) Results of relevant laboratory tests  c) Result of studies in human |  |

|  |  |  |
| --- | --- | --- |
| 9 | Plans to withdraw standard therapy during conduct of research |  |
| 10 | Plan for provision of coverage for medical risk (s) during the study period |  |
| 11 | How you will maintain confidentiality of subject? |  |
| 12 | Total Budget (Approx. in Rs.)  Who will bear the cost of investigation / implants drugs / contrasts? | 1. Patient  2. Project  3. Exempted  4. Other Agencies (Name)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 13 | Participant Information Sheet  (Tick the Appropriate one) | Hindi  English  Bengali |
| 14 | Participant Informed Consent Form  (Tick the Appropriate one) | Hindi  English  Bengali |
| 15 | Conflict of interest for any other investigator(s) (if yes, please explain in brief |  |
| 16 | Whether any work on this project has started or not? |  |
| 17 |  | 17.1 Covering letter, through proper channel. 17.2 Copy of the detailed protocol is mandatory.  17.3 Brief CV of Investigators (including No. of projects with Principal Investigator)  17.4 Investigator’s Brochure  17.5 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines  17.6 In case of multicentric study, IEC clearance of other centres must be provided  17.7 Definite undertaking as to who will bear the expenditure of injury related to the project 17.8 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)  17.9 Permission as mentioned in column 5.9 17.10 Certificate/undertaking as mentioned in column 16  17.11 Investigator should provide undertaking what they will do with the leftover sample tissue 17.12 Others |
| 18 | In case of clinical trials CTRI status |  |