**FORM M. 09**

**INDIAN INSTITUTE OF TECHNOLOGY GUWAHATI**

**FORMAT FOR SUBMISSION OF RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS**

(To be submitted by the PI)

**Application No.­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

(To be filled by IHEC Office)

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| --- | --- |
| 1. Title of the Project/Study |  |
| 1. Is the project/study funded? | [ ] No [ ] Yes [ ] Applied for funding  (tick the appropriate option)  If Yes/Applied for funding, provide the  Name of the funding agency: |
| 1. Name of PI of the project/study |  |
| 1. Affiliation and Address of the PI |  |
| 1. Names of Co-PIs, Co-Is, and their affiliations | 1. [Enter name, affiliation and address] 2. [Enter name, affiliation and address] 3. [Enter name, affiliation and address] |
| 1. Is the project/study protocol been cleared by IBSC, IITG? | [ ] No [ ] Yes [ ] Not required  (tick the appropriate option)  If yes, enclose IBSC clearance certificate |
| 1. Is the project/study protocol cleared by IAEC, IITG? | [ ] No [ ] Yes [ ] Not required  (tick the appropriate option)  If yes, enclose IAEC clearance certificate |
| 1. Has the Human Ethics Clearance been obtained from the collaborating centers/institutes? | [ ] No [ ] Yes [ ] Not required  (tick the appropriate option) |
| 1. Has the proposed project/study protocol been cleared by IHEC, IITG before? | [ ] No [ ] Yes  (tick the appropriate option)  If yes, enclose a copy of IHEC clearance certificate |
| 1. Whether any work on this project/study has started? | [ ] No [ ] Yes  (tick the appropriate option)  If yes, did it involve human subjects? [ ] No [ ] Yes |
| 1. Name and Signature of PI with Seal |  |
| 1. Point wise objectives of the project/study |  |
| 1. Significance/importance of the project/study |  |
| 1. Justification of the project/study stating possible application of the results. |  |
| 1. Description of the project/study protocol enclosed | [ ] No [ ] Yes  (tick the appropriate option) |
| 1. Selection of Human subjects. (Inclusion and Exclusion Criteria |  |
| 1. Is the Information to participants and consent form enclosed? | [ ] No [ ] Yes  (tick the appropriate option) |
| 1. Will the project/study recruit healthy volunteers? | [ ] No [ ] Yes  (tick the appropriate option)  If yes, please enclose information and consent form for healthy volunteers. |
| 1. Any therapeutic/medical advantage to participants recruited in the project/study | [ ] No [ ] Yes  (tick the appropriate option)  If yes, give a very brief comment |
| 1. Any predictable medical advantage for subjects in the future | [ ] No [ ] Yes [ ] Cannot predict  (tick the appropriate option) |
| 1. Risk to participants in any form |  |
| 1. Method of data collection, documentation, storage and anonymity. |  |
| 1. How will the confidentiality of the data maintained? |  |
| 1. Participant consent form includes the participant’s consent that his/her data can be published subject to maintenance of anonymity | [ ] No [ ] Yes  (tick the appropriate option) |
| 1. Arrangement for risk management |  |
| 1. Criteria for withdrawing a participant from the study |  |
| 1. Number, age and gender of participants |  |
| 1. Is there any provision for reimbursement of travel expenses incurred by subjects for participation? | [ ] No [ ] Yes [ ] Not applicable  (tick the appropriate option)  If yes, briefly state the amount earmarked per participant. |
| 1. Arrangements for food and hospitality for the participants | [ ] No [ ] Yes [ ] Not applicable  (tick the appropriate option) |
| 1. Are there incentives for participants in any other form? | [ ] No [ ] Yes  (tick the appropriate option)  If yes, briefly state the nature of incentives |
| 1. Declaration   I, ………………………………………., the PI of the project for which the IHEC clearance is being sought declare that the information provided in this application form is correct to the best of my knowledge. Should the IHEC have any further queries, I will be happy to provide the responses.  Date: Signature:  Place: | |