**Guidelines for submission of research proposal to IRC/ IEC**

1. **IRC submission –**

* Covering letter addressed to the Member secretary along with one hardcopy of the research proposal in the IRC/IEC format (with original signatures and all relevant annexures as mentioned in the checklist).
* The scanned copy of the same should be mailed to [ircigmcripdy@gmail.com](mailto:ircigmcripdy@gmail.com).
* Proposals can be submitted to the IRC anytime.
* Only those proposals which are received atleast a week before the IRC meeting will be reviewed and others would be reviewed in the next meeting.
* Comments / suggestions provided by IRC should be rectified and the proposal must be resubmitted with all relevant documents within a week of receiving the comments.
* After approval from the IRC, it would be submitted to the IEC for further review.

1. **Institute Biosafety committee (IBSC) review**-

Any project that involves micro-organisms or gene manipulation requires a Notification of Intention to Perform Research in Microorganism/ Genetic Manipulation in the format attached as annexure. For such projects after IRC review, the projects will be sent to IBSC review and if approved, forwarded to IEC for review.

1. **IEC submission –**

* Covering letter addressing Member secretary with 6 hardcopies (one copy with original signatures) and scanned copy (as one pdf file with all necessary details with original signatures in the Research proposal submission format) should be mailed to [iecigmcri@gmail.com](mailto:iecigmcri@gmail.com)
* Submission date: Proposals submitted beyond the stipulated time for each meeting will not be considered for that meeting and will be included for review in the next meeting.
* Proposals submitted by fulfilling the checklist alone will be considered for review by IEC
* Comments / suggestions provided by IEC should be rectified and resubmitted within a week of receiving the comments
* IEC Approval certificate should be collected from the IEC member secretary within a month of meeting
* Study completion certificate should be submitted to IEC member secretary within a year of project approval. In case of non-completion of the study, extension of approval should be obtained from the IEC.

1. **Participant Information Sheet (PIS)** - written in dialogue format (not as question and answer) addressing the patient/participant with all the questions answered in complete sentence and in simple understandable language. Abbreviations to be avoided. (Format enclosed)
2. **Informed consent form** - Complete address and phone number of the investigator/guide provided in the appropriate place. Consent form is appropriately worded for adults and children (less than 18 years) e.g. Instead of ‘my participation’, ‘my child’s/ward’s participation’ to be replaced. (format enclosed)
3. **Questionnaire:** It should be validated and pretested before submission to IRC
4. **Necessary approval letters from the concerned for data collection is mandatory for research proposal submission**

**Participants information sheet**

**Instructions** - This is the patient / participants information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Tamil which can be understood by the participant. **It should be written in dialogue format addressing the patient/participant**

- Title of the project

- Name of the investigator/guide

- Purpose of this project/study

- Procedure/methods of the study

- Expected duration of the subject participation

- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator

- Any risks expected from the study to the participant

- Maintenance of confidentiality of records

- Provision of free treatment for research related injury

- Compensation of the participants not only for disability or death resulting from such injury but also for unforeseeable risks.

- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled

- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned

- Address and telephone number of the investigator and co-investigator/guide

- The patient information sheet must be duly signed by the investigator

**CONSENT FORM**

Participant’s name: Address:

**Title of the project**:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Signature of the participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Principal investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_

Note: Consent form should be appropriately worded for adults and children (less than 18 years) e.g. If the participant is less than 18 years of age, instead of ‘my participation’, ‘my child’s/ward’s participation’ needs to be replaced. In case of child > 7 yrs, assent form should be attached

**Checklist: Requirements for research involving children**

Name of Principal Investigator: Study Title:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sl. No. | Questions | Yes | No | NA |
| 1. | Does the research pose greater than minimal risk to children? |  |  |  |
| 2. | If yes: Are convincing scientific and ethical justifications given? |  |  |  |
| 3. | If yes: Are adequate safeguards in place to minimize these risks? |  |  |  |
| 4. | Does the study involve healthy children? |  |  |  |
| 5. | If yes: Is the inclusion of healthy children justified? |  |  |  |
| 6. | Are the studies conducted on animals and adults appropriate and justified? |  |  |  |
| 7. | If No: Is the lack of studies conducted on animals and adults justified? |  |  |  |
| 8. | Will older children be enrolled before younger ones? |  |  |  |
| 9. | Is permission of both parents necessary? |  |  |  |
| 10. | If Yes: Are conditions under which one of the parents may be considered: “not reasonably available” described? |  |  |  |
| 11. | If Yes: Are the conditions acceptable? |  |  |  |
| 12. | Will efforts be made to ensure that parents’ permission to involve  their child in research studies is free from coercion, exploitation, and/or unrealistic promises? |  |  |  |
| 13. | Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent? |  |  |  |
| 14. | Are provisions made to protect participants’ privacy and the confidentiality of information regarding procedures? |  |  |  |
| 15. | Are there special problems that call for the presence of a monitor or IEC member during consent procedures? |  |  |  |
| 16. | Are special needs of adolescents such as counseling and confidentiality accounted for in the research design? |  |  |  |
| 17. | Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers? |  |  |  |
| 18. | Does the research involve possibility of findings which may have implications for other family member? (for eg. Genetic risk. HIV infection, Hepatitis C) |  |  |  |
| 19. | If yes: Are there adequate mechanisms in place to deal with other members of the family? |  |  |  |
| 20. | Are parents required to be present during the conduct of the research? (Are proposed participants’ very young?) |  |  |  |

Signature of Principal Investigator: Date

**IEC Office use only**

Comments of Primary Reviewer: Primary Reviewer’s Signature:

**Checklist: Requirements for research involving pregnant women**

Name of Principal Investigator: Study Title:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sl. No. | Questions | Yes | No | NA |
| 1. | Where scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women have been conducted and provide data for assessing potential risks, pregnant women and fetuses? |  |  |  |
| 2. | Is the risk to the fetus not greater than minimal, or any risk to the fetus which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus? |  |  |  |
| 3. | Any risk that is the least possible for achieving the objectives of the research? |  |  |  |
| 4. | Is the woman’s consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions, unless altered or waived? |  |  |  |
| 5. | Is the woman or her legally authorized representative, as appropriate, fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child? |  |  |  |
| 6. | Will any inducements, monetary or otherwise, be offered to terminate a pregnancy? |  |  |  |
| 7. | Do individuals engaged in the research have a part in any decisions as to the timing, method, or procedures used a terminate a pregnancy? |  |  |  |
| 8. | Do individuals engaged in the research have a part in determining the viability of a fetus? |  |  |  |

If the response to any of the above is NO, the research should not be approved by the IEC.

Signature of Principal Investigator: Date:

**IEC Office use only**

Comments of Primary Reviewer:

Primary Reviewer’s Signature and Date:

**Checklist: Requirements for research involving foetuses**

Name of Principal Investigator: Study Title:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sl. No. | Questions | Yes | No | NA |
| 1. | Are scientifically appropriate, preclinical and clinical studies, conducted and provide data for assessing potential risks to neonates? |  |  |  |
| 2. | Is the individual providing consent, fully informed regarding the reasonably foreseeable impact of the research on neonate? |  |  |  |
| 3. | Will any inducements, monetary or otherwise, be offered to terminate a pregnancy? |  |  |  |
| 4. | Do individuals engaged in the research have a part in any decisions as to the timing, method or procedures used to terminate pregnancy? |  |  |  |
| 5. | Do individuals engaged in the research have a part in determining the viability of a fetus? |  |  |  |
| 6. | **In research involving fetuses of uncertain viability,** |  |  |  |
| 6a. | Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and is any risk least possible for achieving the objectives of the research? |  |  |  |
| 6b. | Or The purpose of the research is development of important biomedical knowledge which cannot be obtained by other means. |  |  |  |
| 7. | Will there be a risk to the fetus from the research? |  |  |  |
| 8. | Is the legally effective informed consent of either parent of neonate or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, legally effective informed consent of either parent’s legally authorized representative obtained? |  |  |  |
| **9.** | **In research involving nonviable fetuses** |  |  |  |
| 9a. | Will vital functions of the neonate be artificially maintained? |  |  |  |
| 9b. | Is there any risk to the neonate resulting from the research? |  |  |  |
| 9c. | The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. |  |  |  |
| 9d. | The legally effective informed consent of both parents of the neonate will be obtained except that the waiver and alteration provisions do not apply. However, if either parent ;is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a noviable fetus will suffice to meet the requirements of this paragraph.) |  |  |  |

If the response to any above is NO, the research should not be approved by the IEC.

This type of research can be conducted only after the IEC finds that

1. The research presents a reasonable opportunity to further the understanding, prevention or alleviation of serious problem affecting the health or welfare of pregnant women and/or fetus
2. The research will be conducted in accordance with applicable regulatory and ethical guidelines

Signature of Principal Investigator:----------------------- Date -----------

**IEC Office use only**

Comments of Primary Reviewer:

Primary Reviewer’s Signature and Date

**Checklist: Research involving students, employees or residents**

Name of Principal Investigator:

Study Title:

Research involving participants who are students, employees or residents require special considerations (All items must be “Yes”)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sl. No.** | **Items** | **Yes** | **No** | **NA** |
| A. | Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not? |  |  |  |
| B. | Have the risks to participants been minimized? |  |  |  |
| C. | Have participants been assured that participation is voluntary (no signs of coercion)? |  |  |  |
| D. | Have participants been assured that privacy and confidentiality will be protected? |  |  |  |

**Signature of Principal Investigator: Date:**

**IEC Office use only**

Comments of Primary Reviewer:

Primary Reviewer’s Signature and Date:

**Checklist: Research involving cognitively impaired adults**

Name of Principal Investigator:

Study Title:

1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the participant (All items must be “Yes”)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sl. No.** | **Items** | **Yes** | **No** | **NA** |
| A. | Is the recruitment of participants justified considering rationale and objectives of study? |  |  |  |
| B. | Is the risk justified by anticipated benefit to the participants? |  |  |  |
| C. | The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches. |  |  |  |
| D. | Will the participants be withdrawn if they appear to be unduly distressed? |  |  |  |
| E. | The proposed plan for the assessment of the capacity to consent is adequate. |  |  |  |

**2.** Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant (All items must be “Yes”)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sl. No.** | **Items** | **Yes** | **No** | **NA** |
| A. | Is the recruitment of participants justified considering rationale and objectives of study? |  |  |  |
| B. | Are the foreseeable risks to the participants low? |  |  |  |
| C. | Is the negative impact on the participant’s well-being minimized and low? |  |  |  |
| D. | Will the participants be particularly closely monitored? |  |  |  |
| E. | Will the participants be withdrawn if they appear to be unduly distressed? |  |  |  |
| F. | The proposed plan for the assessment of the capacity to consent is adequate. |  |  |  |
| G. | Consent will be taken from participants capable of being consulted. |  |  |  |
| H. | Does consent document include provision for legally acceptable representative in case the participants are not capable of being consulted? |  |  |  |

Signature of Principal Investigator: Date:

**IEC Office use only**

Comments of Primary Reviewer:

Primary Reviewer’s Signature and Date

**Application for Biosafety Review**

*(Notification of Intention to Perform Research in Microorganism/ Genetic Manipulation)*

|  |
| --- |
| Section I (ADMINISTRATIVE)  Application No. ; Date of Receipt:  Final Status : |

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1. Project Details :

|  |
| --- |
| * 1. New / Ongoing: |
| * 1. If ongoing: Briefly state whether applied to IBSC earlier and purpose for which permission granted: |
| * 1. Does your study involve any Microorganism -- Yes [ ] No [ ]   If yes   1. Indicate the Microorganism which is going to be used in this study (as per Regulations & Guidelines for Recombinant DNA Research & Biocontainment 2017): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_; & Risk Groups: [ ] 1/ [ ] 2/ [ ] 3/ [ ] 4. 2. Type of work to be carried out: [ ] Microscopy / [ ] Microbial Culture other than Cell Culture / [ ] AST/ [ ] Gene Detection by PCR or Sequencing/ [ ] Cell Culture/ [ ] Virus neutralization assay/ [ ] Recombinant DNA Technology/ [ ] Transfection into eukaryotic cells/ [ ] others (including Serology) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. 3. Proposed work will be conducted at (Biosafety Level):   [ ] BSL 1/ [ ] BSL 2/ [ ] BSL 2+/ [ ] BSL 3/ [ ] BSL 3+/ [ ] BSL 4 Laboratory . |
| * 1. Duration of the study: |
| * 1. Clinical Samples/ Cultures/ DNA, RNA, Mitochondrial DNA, etc., retention period): \_\_\_\_.   2. Storage Temperature: 🖵2-6ºC/ 🖵-20ºC/ 🖵-80ºC/ 🖵 \_\_\_\_\_ ºC and Location: |
| * 1. Containment facility present with the investigator: |
| * 1. Details of disposal of waste generated commensurate with risk as per biomedical waste management regulations Act, 2016. |

1. Declaration

|  |
| --- |
| The information provided in this form is to the best of my knowledge accurate. I have ensured that all persons nominated in the initial submission or their successors are fully aware of and are in agreement with the proposal  Sign(Proposer) Date |