Instructions for Filling the Form

(Read the instructions/ Pre-requisite carefully before filling the form)

I. Application procedures

a. Research proposals can be submitted on any working day, at least one month in advance. The applications can be downloaded from the following link https://sites.google.com/iccons.co.in/icconsintranet/home, Filled in applications prescribed for the specific purposes, with the signatures of the researchers, along with the relevant documents can be uploaded in relevant forms in the above mentioned site.

b. All research proposals must be submitted in English language only

c. All fresh proposals should be submitted in the prescribed format (Application for Initial Review).

d. The application form, in prescribed format should be duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators, and forwarded by the Head of the Department.

e. The forms given as Annexure 1-12 may be used in addition to the General form, as per the specific need of the participant.

f. The Principal Investigator should also submit signed Curriculum Vitae in the prescribed form given as Annexure13 at the time of submitting application for ethical review.

g. All relevant documents should be enclosed with the application form, as given in the checklist in the link.

h. The Informed consent form along with the Patient information system should be submitted along with the application including all the relevant elements as detailed in the checklist given in website via link.

i. The application receipt will be acknowledged by the Member Secretary upon receipt and will be forwarded to the Chairperson of the IEC, after scrutiny. If there are any more clarifications needed in scrutiny it will be intimated via e-mail and the researchers can send back the document(s) after making suggested changes.

j. Every application will be allotted an IEC registration number to be used for all future correspondence and reference

k. The date of IEC meeting will be informed to the IEC members and to the PI at least 2 weeks in advance to make a brief presentation of the proposal and to clarify the points raised by the members. IEC can suggest for online meetings and virtual presentations of the investigators in special situations such as COVID-19 pandemic, etc.

l. If revision is to be made, the revised proposal in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

m. In case any clarifications are required in the application process or for any updates regarding the application the Member Secretary can be contacted.

1. Dr. Nandini Jayachandran, Lecturer in Clinical Psychology-Grade 1, ICCONS, Thiruvananthapuram.
   Email: nandinijayachandran@iccons.co.in

2. Dr. Anitha Aiyyappan Pillai, Associate Professor, Dept. of Neuro Genetics ICCONS, Shoranur
   Email: anitha@iccons.co.in

II. Details of the documents to be submitted for EC Review.

1. Covering letter to the Member Secretary
2. Type of review requested
3. Application form for initial review.
4. Brief CV of all investigators.
5. Approval of Scientific committee.
6. The correct version of the Informed Consent Document (ICD) in English and local language(s). Translation and Back translation certificates if applicable.
7. Case record form/questionnaire
8. Recruitment procedures: advertisement, notices, if applicable.
9. Patient instruction card, diary, etc. (if applicable)
10. Investigator's brochure (as applicable for drug/biologicals/device trials)
11. Details of funding agency/sponsor and fund allocation (if possible)
12. Brief curriculum vitae of all the study researchers
13. A statement on Conflict of Interest, if any.
14. GCP training certificate (preferably within 5 years) of investigators (clinical trials)
15. Any other research ethics/other training if applicable, as per EC SOP.
16. List of ongoing research studies undertaken by the Principal Investigator (if applicable).
17. Undertaking with signatures of Investigators
18. Regulatory permissions as applicable.
19. Relevant administrative approvals (such as HSME approvals for International Trials)
20. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
21. MoU in case of studies involving collaboration with other institutions (if applicable)

22. Clinical trial agreement between the sponsors, Investigators and the Head of the Institution. studies involving fund allocation (if applicable)
23. Documentation of clinical trial registration (preferable)
24. Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
25. Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
26. Any additional document(s), as required by the EC (such as other EC clearances for Multicentric studies)
27. Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol.
28. Assent form for minors (12-18 years) (English and Translated).
29. Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)
30. Protocol

III. Details to be included in the Protocol:

The protocol should including the following:

1. The face page carrying the title of the proposal with signatures of the Investigators.

   i. Brief summary/ lay summary;
   ii. Background with rationale of why a human study is needed to answer the research question;
   iii. Justification of inclusion/exclusion of vulnerable populations;
   iv. Clear research objectives and end points (if applicable);
   v. Eligibility criteria and participant recruitment procedures;
   vi. Detailed description of the methodology of the proposed research, including sample size (with justification),type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
   vii. Duration of the study;

viii. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, for the same;

2. Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Audio/Visual recording if applicable; informed consent for stored samples;
    i. Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated).
    ii. Plan for statistical analysis of the study;
    iii. Plan to maintain the privacy and confidentiality of the study participants;
3. For research involving more than minimal risk, an account of management of risk or injury;
4. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
    i. Provision of ancillary care for unrelated illness during the duration of research;
    ii. An account of storage and maintenance of all data collected during the trial; and
5. Plans for publication of results –positive or negative – while maintaining confidentiality of personal information/identity.
    i. Ethical considerations and safeguards for protection of participants.

IV. Informed Consent Form & Patient Information Sheet:

Details to be included

- The ICD has two parts – patient/participant information sheet (PIS) and the informed consent form (ICF).
- Information on known facts about the research, which has relevance to participation, is included in the PIS.
- This is followed by the ICF in which the participant acknowledges that she/he has understood the information given in the PIS and is volunteering to be included in that research.

An informed consent form must include the following:

i. Statement mentioning that it is research
ii. Purpose and methods of the research in simple language
iii. Expected duration of the participation and frequency of contact with estimated number of participants to be enrolled, types of data collection and methods.
iv. Benefits to the participant, community or others that might reasonably be expected as an outcome of research
v. Any foreseeable risks, discomfort or inconvenience to the participant resulting from participation in the study
vi. Extent to which confidentiality of records could be maintained, such as the limits to which the researcher would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality.
vii. Payment/reimbursement for participation and incidental expenses depending on the type of study
viii. Free treatment and/or compensation of participants for research-related injury and/ or harm
ix. Freedom of the individual to participate and/or withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled
x. The identity of the research team and contact persons with addresses and phone numbers(for example, PI/Co PI for queries related to the research an Chairperson/ Member Secretary/ or helpline for appeal against violations of ethical principles and human rights)

5. In addition, the following elements may also be required, depending on the type of study:

i. Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected
ii. If there is a possibility that the research could lead to any stigmatizing condition, for example HIV, provision for pre test and post-test counseling.
iii. Insurance coverage if any, for research-relate or other adverse events
iv. Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research. Other specifics are as follows:
    a. period of storage of the sample/data and probability of the material being used for secondary purposes.
    b. whether material is to be shared with others, this should be clearly mentioned.
    c. right to prevent use of her/his biological sample, such as DNA, cell-line, etc., and related data at any time during or after the conduct of the research.

d. risk of discovery of biologically sensitive information and provisions to safeguard confidentiality.

V. post research plan/benefit sharing, if research on biological material and/or data leads to commercialization.

VI. Publication plan, if any, including photographs and pedigree charts.