Title: Management of Submission of Research Study Protocol and Study Related Documents, MGMCRI

SOP Code: SOP 06/V2

Effective Date: 21-10-2019

SOP Constitution and Approval:

Prepared by:	Signature and Date:
Dr. Lokesh. S, IHEC Member	21/10/19
Dr. Siva Ranganathan Green, Member Secretary, IHEC	21/10/19
Dr. Uma Narayanamurthy, Additional Member Secretary, IHEC	Uma. N 21/10/19
Reviewed by:	**Signature and Date:**
Dr. Ananthakrishnan. N, IHEC Member	21/10/19
Dr. Sivagnanam G, IHEC Co-Chairperson	
Approved by:	**Signature and Date:**
Dr. Jambulingam, P IHEC Chairperson	21.10.19
Dr. Adithan C, Dean Research, SBV	21/10/19
Dr. Ravishankar M, Dean, MGMCRI	21/10

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Institutional Human Ethics Committee (IHEC), manages a submitted Research protocol and/or other documents.

2. Scope

The scope of this SOP includes:

- Submission of Research Project and related documents for initial review
- Resubmission of Protocols or Research Projects with corrections
- Submission of Protocol Amendment
- Submissions of written communications related to continuing review of approved protocols
- Protocol completion/Termination of Protocol deviations/violation
- SAE initial/ follow up/ final reports
- Submission of Protocol deviations, Protocol violations

3. Responsibility

It is the responsibility of the IHEC Secretariat to receive & record all the protocol. The member secretary/Additional Member Secretary will distribute the received Research Proposal and any other documents for review to the Members of IHEC, act on the instructions given by the appropriate member of the IHEC and ensure that the communication reaches the concerned recipient.

4. Detailed Instructions

4.1 Receive study protocols/ documents

Principal Investigator (PI) will submit a research proposal to the IHEC office for review and decision under any of the following sections within the specified time period:

- New Proposals for Initial Review
- Re-submission of corrected Protocols
- Amended Protocols and related documents

Submission of SAE (On-Site) (As per the timelines stated in **SOP12/V2**for initial and detailed reporting of SAE)

Projects should be submitted 4 weeks Prior for consideration of research proposal in the next upcoming meeting of IHEC. All other documents for consideration at the full board meeting (except those related to participant safety, which may be submitted any time) must be submitted at least 72 hours in advance of the meeting to be considered in next meeting agenda.

4.2 Initial Review Application

Check for submission items: The Secretariat will check the hard and soft copies of the following items: in AX 01/SOP 06/V2 (A, B or C Depending on the Protocol submitted)

a) 2 sets of research proposals duly signed by PI/Guide/Co-PI/Co-Guide in the hardcopies (1 original and 1 sets of Xerox copies) and softcopy (in PDF format) to be uploaded in the IHEC OFFICE system
b) Completely filled IHEC Project Submission Application Form for Initial Review
c) The marked checklist in AX 01/SOP 06/V2 (A,B or C Depending on the Protocol submitted)
d) Duty Delegation Log of the Study team
e) Document Receipt Form (AX 02/SOP 06/V2)

- **Verification of the contents of Submitted Documents:**

  The Secretariat will:

  Use the checklist (AX 01 /SOP 06/V2) to confirm whether all the ticked documents are there in the application and ensure that the application is complete in terms of required documents (if any essential document is not available an explanation must be sought in writing for the IHEC to review). All the following documents must be in the file

  1) Project submission application form for initial review
  2) Covering letter to Chairperson
  3) Approval Certificate from Institutional Research Committee/PG research Committee/ RAC (Research Advisory Committee), Institutional Stem Cell Research Committee
  4) Protocol
  5) Amendments to protocol (if any)
  6) Informed consent document (ICD) in English and Tamil OR Waiver of Consent form
  7) Back translations of ICDs and Back translation certificates (if applicable)
  8) Amendments to the ICD (if any)
  9) Case Record Form (If applicable)
  10) Recruitment procedures: advertisement, notices and other related document if any

11) Patient instruction card, identity card, diary etc. (if applicable)
12) Regulatory permissions (DCGI approval, FDA marketing/manufacturing license for herbal drugs, Health Ministry Screening Committee (HMSC) approval, Bhabha Atomic Research Centre (BARC) approval) (if applicable)
13) Investigator's Undertaking to DCGI (if applicable)
14) Administrative sanction from the Head of the Institution or Memorandum of Understanding in case of studies involving collaboration with other institutions. (if applicable)
15) A copy of Administration sanction from the Head of the Institution or Memorandum of Understanding for sending the samples to laboratories outside the Institution. (if applicable)
16) Brief Curriculum Vitae of all the study team members
17) GCP training certificate (within 5 years) of principal investigator, co-investigator/s and study coordinator/s. (applicable for Regulatory Clinical Trial)
18) Research Methodology training certificate (within 5 years) of principal investigator, co-investigator/s and study coordinator/s (if applicable)
19) List of ongoing research studies undertaken by principal investigator
20) Investigator's Brochure (as applicable for Drug/Device trials)
21) Agreement to comply with national and international ethical guidelines and GCP protocols
22) Details of Funding agency / Sponsor and fund allocation
23) Clinical Trial Agreement between sponsors, investigators and head of the institution(s)
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) Memorandum Of Understanding (MOU)for collaborative studies (if applicable)
27) Ethics Committee clearance of other centers (if applicable)
28) Institutional Stem cell Research Committee approval (if applicable)
29) Documentation of clinical trial registration (if available)

30) Any additional document(s), as required by IHEC

- **Complete the submission process:** The Secretariat will:
  - Complete the checklist of submission AX 01/SOP 06/V2 (A, B or C Depending on the Protocol submitted)
  - Stamp the receiving date on the first page/last page of the covering letter and initial it.
  - Make a photocopy of the completed document receipt form and return the original copy of the form to the applicants for their records.
  - Keep the copies of the submitted documents with original signatures in the protocol "Submission" files.
  - Number the project file as RES/MGMCRI/0X/year /XX/IHEC/YY
  - 0X will represent
    - 01- PG Research
    - 02- PhD Research
    - 03- ICMR STS/SBV STS
    - 04- Faculty Research
    - 05- CIDRF/CMTER/CYTER/AHS/CHPE
    - 06- SBV Funded/ M.Phil./ PG diploma
  - The secretariat of IHEC will maintain a database of all the research details including the Name, designation, department, type of proposal, title, and dates (details of first proposal submission, initial review date, decision letter, final submission and approval certificate, Periodic Review date of Approved Protocol, SAEs if any reported, Annual Report submission, Study completion report), Archiving
- **Dispatch and Storage of the received Documents:** The Secretariat will
  - Prepare 2 sets of a protocol package containing completed and duly signed application form, protocol related documents along with checklist (AX 01/SOP 06/V2) and send 1 set to the IHEC members along with a copy of Project Assessment Form for Initial Review after the last day of submission is over, ensuring at least 14 days for review before the next meeting.
  - Store the appropriately labeled original protocol documents in the designated storage area in the IHEC office.

- If the IHEC members prefer to receive and review soft copies, these are sent in pen drive/ email along with a copy of Project Assessment Form for Initial Review after the last day of submission is over, ensuring at least 14days for review before the next meeting.

4.3 Resubmission of Protocols with corrections and Amendments of protocol/ related documents

- For resubmitted protocol, the PI will submit duly signed one soft copy and one hard copy of the amended Protocol and related documents.
- The Secretariat will verify the completeness of the documents and confirm that the copy contains the modifications highlighted with respect to the earlier protocol submitted mentioning the justification for the amendment & renaming it as Protocol Version 2.
- The protocol related documents which do not require to be changed and are already submitted for the IHEC office during initial review are not required to be submitted again.
- The Secretariat will present the file to the Member Secretary/Additional Member Secretary.

The Member Secretary/Additional Member Secretary will decide if a resubmitted protocol

- will follow all steps of initial review
- handle it as decided in the meeting (e.g. Carry out review by one or more member(s) selected by the Chairperson. The selected members are normally those who reviewed and recommended the previous version of that protocol) or keep on full board agenda.

4.4 . Annual Continuing Reviews of Approved Protocols, Amended Protocols and related documents, Study completion/ termination, SAE report, Protocol deviations

The IHEC will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents, study completion/ termination, SAE report, protocol deviations in the prescribed format as given in the applicable SOPs.

4.5 . Processing fees for IHEC review:

The fees for reviewing various categories of research study proposals in Indian Rupees (INR); non – refundable are as given in the following table:

S.No	Fee Structure for New study Protocol Review	Amount
1.	Pharma industry sponsored Research Protocol Review	Rs. 50,000/- or10% of the project budget whichever is higher, from the industry conducting sponsored clinical trials
2.	Govt Sponsored	NIL
3.	NGO Research Protocol Review	5% of the project Budget or Rs.25,000/- whichever is lower
4.	Academic/ Faculty/ Investigator initiated Research / Post Graduate / Ph.D. New Study Protocol Review	Rs. 2000/- for approval and Rs. 1000/- for annual renewal
5.	Under Graduate study Protocol Review	NIL

5. Glossary

Clinical Trial	In relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its, clinical or; pharmacological including pharmacodynamics, pharmacokinetics or; adverse effects, with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug.

6. Annexures

Annexure 1A: AX 01-A/SOP 06/V2 - Project submission application form for initial review for academic (non-regulatory) studies of students along with checklist of protocol submission

Annexure 1B: AX 01-B/SOP 06/V2–Project submission application form for initial review for academic (non-regulatory) studies of faculty along with checklist of protocol submission

Annexure 1C: AX 01-C/SOP 06/V2 - Project submission application form for initial review for drug trials and other regulatory studies (Industry sponsored studies).

Annexure 2: AX 02/SOP 06/V2 - Document Receipt Form

Annexure 3: AX 03/SOP 06/V2 - Curriculum Vital for the Principal Investigator/ Co – Investigator/ Guide

Annexure 4: AX 04/SOP 06/V2 – Cover letter

Annexure 1A: AX 01-A/ SOP 06/V2

Project submission application form for initial review for academic (non-regulatory) studies of students along with checklist of protocol submission

MAHATMA GANDHI MEDICAL COLLEGE AND RESEARCH INSTITUTE, PILLAIYARKUPPAM, PUDUCHERRY 607402

NEW COMBINED FORMAT FOR SUBMITTING RESEARCH

PROPOSAL FOR CONSIDERATION BY

INSTITUTE RESEARCH COUNCIL (IRC), POSTGRADUATE RESEARCH MONITORING COMMITTEE (PGRMC), INSTITUTIONAL HUMAN ETHICS COMMITTEE (IHEC)

Version 2.0 dated 21st October 2019

MAHATMA GANDHI MEDICAL COLLEGE AND RESEARCH INSTITUTE, PILLAIYARKUPPAM, PUDUCHERRY, 607402

Format

FOR SUBMITTING PG DISSERTATION PROPOSAL FOR CONSIDERATION BY PG RESEARCH MONITORING COMMITTEE

SECTION- 1

PART A – GENERAL INFORMATION

1. Title of the dissertation

2. Name of the candidate with mobile numbers and email ID

3. Name of the course studying

4. Year of admission

5. Month and year of appearing for final examination

6. Month and year of submitting dissertation

7. Name (s), Designation (s) & Addresses of the guide and co-guide (s) with mobile numbers and email ID
8. A. State whether it is intradepartmental or interdepartmental

   B. If the study is interdepartmental

   I. State the names of collaborating departments
   II. State whether consent has been obtained from them

9. Total funds required for the study (in rupees)

10. Source of funding

PART B – TECHNICAL DETAILS

1. Title of the dissertation
2. Introduction
    A. Problem statement
    B. Rationale
    C. Novelty
    D. Expected outcome and application
3. Research question(s)
4. Research hypothesis (es), if any
5. Aim and objectives: Primary objective(s) & secondary objective(s)
6. Review of literature
7. Methodology
    A. Study design
    B. Study participants (human, animals or both)
        a. Inclusion criteria
        b. Exclusion criteria
        c. Withdrawal criteria, if any
        (Trial-related therapy, follow-up and documentation are terminated prematurely as it is indicated to ensure safety of the participants)
        d. Rescue criteria, if applicable
        (starting symptomatic therapy either to control symptoms of disease or to overcome lack of adequate efficacy of the study drug or placebo)
        e. Number of groups to be studied, identify groups with definition
    C. Sampling
        a. Sampling population
        b. Sample size calculation
        c. Sampling technique
    D. Randomization details (for interventional studies)- Intervention details with standardization techniques (drugs / devices / invasive procedures / noninvasive procedures / others)

E. Study procedure

F. Data collection methods including settings and periodicity

G. Registration with CTRI in case of Clinical trial will be done

H. Are the drugs/devices to be used approved for these indications by Drug Controller General of India (DCG-I)? (Enclose the approval letter for the drug/device from DCG-I for trial on humans or give undertaking to get the approval from DCGI; For all drugs and devices submit documents showing DCGI approval for the proposed indication of the study)

I. List of variables and their measurement methods with standardization techniques

   a. Independent variables
   b. Outcome variables
   c. Confounding and interacting variables

J. List variable wise statistical tests to be used for data analysis

8. List risks and benefits of the study
9. Relevant references for the project(Minimum 10, Maximum 20) (in Vancouver style)
10. Enclosures
    A. Brief CV of guide and co-guides
    B. Data collection proforma
    C. Questionnaires
    D. Consent form (English version and local language)
    E. Other relevant papers
11. Undertaking for DCGI approval
12. Declarations by guide

A. Signature of the candidate

(Name & Designation)

Signature of the guide

(Name & Designation)

Signature (s) of the co-guide

(Name & Designation)

Signature of Head of the Department

of the candidate

(Name & Designation)

STATEMENT BY POSTGRADUATE/ PRINCIPAL INVESTIGATOR ON RESEARCH INTERGRITY

I, _____ do hereby declare that this study will be carried out by me under supervision of my guide _____ upholding enshrined in the Declaration of Helsinki , and simultaneously abiding by the ICMR`s National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017).

Signature & Name of the PG/PI

Date:

Place:

STATEMENT BY PG GUIDE ON RESEARCH INTEGRITY

I, _____ the guide of the Postgraduate, department of _____, do hereby declare that this study will be carried out by my student, under my direct supervision upholding the principles enshrined in the Declaration of Helsinki, and simultaneously abiding by the ICMR`s National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017).*"I take full responsibility and accountability for planning, executing and adverse events occurring during the study. the data collected and records received will be retained for a period of three years"*

Signature and Name of the Guide

Date

Place:

SECTION – 2

[For Institutional Human Ethics Committee (IHEC)]

Proforma to be submitted to the Institutional Human Ethics Committee (IHEC), MGMCRI, for MD/MS/MSc/DM/M. Ch/Fellowship/MPH Students (for Thesis or Dissertation)

1. Title of the project:
2. Name and department/address of the investigator:
3. Name of Faculty (Guide/Co-guide) with designation & department:
4. Date of approval by PG research monitoring committee:
5. Ethical issues involved in the study: *less than minimal risk/ minimal risk/ minor increased over minimal risk/more than minimal risk to the study subjects (for guidance please consult ICMR 2017 guidelines - at MGMCRI website)* [Along with the level of risk, the risks should be discussed in detail]
6. Benefit of the study:
7. Details of Informed Consent Process (Who/When/How/Where):
8. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications?
9. Whether Consent forms in English and in local language are enclosed? *(if the consent form in local language is not applicable, appropriate explanations must be provided)*
10. Documents attached

    a. Waiver Application Form (Annexure-1)
    b. Review Exemption Application Form (Annexure-2)
    c. Brief CV of investigators (including no. of projects with him/her) - Needed for all Investigators for each project separately
    d. For student projects, the guide should give a signed statement on a separate sheet with details of the project proposal that "I take full responsibility and accountability for planning, execution and adverse events occurring during the study. The data collected and records received will be retained for a period of three years".

e. Investigator's brochure

f. Advertisements if applicable

g. Others

11. Conflict of interest for any other investigator(s) (if yes, please explain in brief)

12. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2017)

Signature of the Investigator: Date:

Signature of the Guide: Date:

Signature of the Head of the Department Date:

Signature of the Co- Guides: Date:

Signature of the Heads of the Department of Co- Guides: Date:

(Note: The proforma must be accompanied by Informed Consent Document (ICD) in English and Tamil. Informed Consent Document should comprise Patient Information Sheet and the consent form. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format. Studies involving children below 7 years should include parent / LAR consent form while studies involving children above 12 years and below 18 years of age should include assent form in addition to parent / LAR consent form. Refer to Annexure 1 /SOP 06/V2 – relevant documents attached)

INFORMED CONSENT DOCUMENT (ICD)

Patient / Participant information sheet(PIS)

Information for Participants of the Study

Instructions – *This is the patient 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. (This need to be deleted after reading)*

We welcome you and thank you for having accepted our request to consider whether you can participate in our study. This sheet contains the details of the study, the possible risks, discomfort and benefits for the participants are also given. You can read and understand by yourself; if you wish, we are ready to read and explain the same to you.

If you do not understand anything or if you want any more details we are ready to provide the details.

1. **What is the title of the Research Project?**
2. **Who /where is this study being conducted?**

   This study is being conducted by ---------- a Post graduate medical student belonging to …… Department under the guidance of …… Designation …….

3. **What is the purpose of the study?**

4. **Procedure/Methods of the study (in brief, simple non-technical terms)**

   Note: Do not copy paste from the protocol

5. **How long you are expected to participate in this study?**
   (including the number of visits required)

6. Why I am being considered as one of the participant?

Describe in simple understandable terms.

7. Should I definitely have to take part in this study?

No. If you do not wish to participate you will not be included in this study. Also you will continue to get the medical treatment without any prejudice.

8. If I am participating in this study, what are my responsibilities? (Responsibility of the individual as a participants)

Being a participants in this study your responsibility are : _____

9. Are there any benefits for me/Public?

Yes, you will benefit by ……. Or you will not benefit but the results of the study may benefit future patients by …….

10. Will there be any discomfort / risks to me?

You may suffer some discomforts like giving few ml of blood for investigation, undergoing some medical examinations or any other risks (to be enumerated if any) expected from the study to the participant.

11. Will my participating in this study, my personal details will be kept confidentially?

Your participation in the study and the study records relating to you will be kept confidential throughout the study and thereafter. Your personal identity will not be revealed in case of publication in any journal or analysis of your results, nor will it be shared with anyone. The study records relating to you will be preserved for a period of three (if academic Research)/ five years (if clinical trial) for analysis and follow up.

12. Will I be paid for participating in the Study?

You will be paid/ not paid compensation for participation in the research (appropriate responses depending upon the nature if the study)

13. Can I withdraw from this study at any time during the study period?

Your participation in the study is purely voluntary. You are free to withdraw from the study at any time without assigning any reason. Your withdrawal from the study would in no way affect the medical care or other benefits which you are otherwise entitled to receive from the Institute

14. Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?

The biological materials collected from you may be utilized for further analysis in future, if needed. All the biological materials obtained from you will be used only for research purposes in this study and will not be used for any secondary purpose nor will it be shared with others.

15. Possible current and futures uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?

The data collected from you may be utilized for further analysis in future, if needed. All the data obtained from you will be used only for research purposes. It will not be used for any secondary purpose nor will it be shared with others. In case of analysis of your data in any publication in any journal, your identification will not be revealed.

16. Will I be informed of this study's results and the findings?

Yes, on your request the results of the study and its findings you will be informed.

17. Provision of free treatment for research related injury.

Although no study related injury to you is expected, in case anything happens appropriate treatment for the same will be provided free of cost as per the Institutional policy.

18. Compensation to the participant for death or disability arising out of foreseeable and unforeseeable risks attributable to the study.

Compensation as per the Institutional Policy will be provided to you in case of death or disability arising out of the foreseeable and unforeseeable risks attributable to the study.

Address and mobile number of the Principal Investigator (PI) and Co-PI, if any:

Address and telephone number of the IHEC office, MGMCRI

Office of Institutional Human Ethics Committee, 1st floor college block (Adjacent to dept. of Pathology), MGMCRI, Puducherry 607 402. Phone No.: 0413- 2616700 (Extn No.: 754)

Signature of the Participant

Signature of the Investigators

CONSENT FORM

Name of the Research Project _____

_____

_____

I (Name of the Participant/ LAR) have been informed about the details of the study in own Language.

I have understood the details about the study.

I know the possible risks and benefits for me, by taking part in the study.

I understand that I can withdraw from the study at any point of time without assigning any reason, and even then I will continue to get the medical treatment as usual.

I understand that I will not get any payment for taking part in this study.

I will not object if the results of this study is getting published in any medical journals, provided my personal identity is not revealed.

I know what I am supposed to do by taking part in this study and I assure that I will give my full co-operation for this study.

Date:

Signature/Thumb impression of the participant/ LAR

_____

_____

_____

Name, Address and Signature/Thumb impression of the witness

_____ _____

_____

Name & Signature of the investigator

_____

_____

CONSENT FORM (for participants less than18 years of age)

Parent/Legally acceptable representative (LAR)

Title of the project:

Participant's name: Address:

Parent/LAR's name:

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 child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward 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. **Risk and benefit of this project has been explained to me.** I fully consent for the participation of my child/ward in the above study.

Assent of child/ward obtained (for participants 12 to 18 years of age)

(I also consent / do not consent to use my child/ward's stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature/ thumb impression of the parent/ LAR: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____ Date: _____

ASSENT FORM

(For children above 12 years and below 18 years of age)

Assent form to participate in a clinical research

Child Participant's name: Date of birth/Age:

Parent/LAR'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 understand that following completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully assent to participate in the above study.

(I also assent / do not assent to use my stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature of the child participant : Date:
(If child knows to sign/Thumb impression)
Signature of the parent or guardian : Date:
Name and address of the witness :
Signature of the witness : Date:
Signature of the Investigator : Date:

(Assent form should be accompanied by patient / participant information sheet for children in a simple language comprehensible to a child of 12-18 years; Language used should be simpler for children in the age group >12-18 years)

CHECK LIST

(To be filled and duly signed by the principal investigator)

Title of the study:

Name of the Investigator:

Designation & Department:

S. No	Items	Yes/No
1	Exact title as approved by PGRC	
2	Date of PGRC approval mentioned in proper format (dd/mm/yyyy)	
2	Source of funding mentioned	
3	Adequate literature review with justification for the study mentioned	
4	Detailed description about methodology (Study design, number of groups, sample size etc)	
5	No mirror statement in Inclusion/Exclusion criteria (Ex: Age <18 in inclusion & Age>18 in exclusion)	
6. For Randomized Trial:		
a.	Method that will be used to generate the random allocation sequence	
b.	Type of randomization; details of any restriction (such as blocking and block size)	
c.	Mechanism that will be used to implement the random allocation sequence (such as sequentially numbered containers0, describing any steps taken to conceal the sequence until interventions were assigned	
7. For Analytical/Observational Studies (STROBE Guidelines)		
a.	• Cohort study – the eligibility criteria, sources and methods of selection of participants • Methods of follow-up	
b.	• Case-Control Study – eligibility criteria, sources and methods of case ascertainment and control selection • The rationale for the choice of cases and controls	

c.	• Cross-sectional study – eligibility criteria, sources and methods of selection of participants	
d.	• Cohort study – for matched studies, matching criteria and number of exposed and unexposed	
e.	• Case-control study – for matched studies, matching criteria and number of controls per case	
8.	Outcomes – completely defined primary and secondary outcome measures, including how and when they will be assessed	
9.Statistical methods		
	Statistical methods that will be used to compare groups for primary and secondary outcomes	
	Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
10. Ethical issues explained in detail with **level of risk as per ICMR 2017**		
11. Signature of all investigators (Principal & Co-investigator) and Head of corresponding department obtained with date		
12. Confidentiality mentioned as per IHEC MGMCRI guidelines in consent form part 1		
13. Information to the participant/ parent/guardian in layman (simple) language.		
14. Informed Consent Document **in both English and Tamil** attached as per IHEC, MGMCRI SOP format		
• Separate assent form for subjects >12yrs< 18 yrs attached **(if applicable)** • Separate consent form for cases and controls attached **(if applicable)** • **No discrepancy** between Tamil and English consent form		
15. Validated questionnaire both in Tamil and English attached		
16. Adequate justification for exemption from obtaining informed consent given **(if applicable).**		
17a	Permission from DCGI (**if applicable**).	
17b	DCGI approval for the mentioned indication in the study (for drugs, devices,	

	cosmetics etc)	
18a	Declaration form from principal investigators / Guide stating that all procedures used in the study are standard and professionally acceptable (for faculty projects / for all UG/PG/PhD/DM,MCh)	
18b	Declaration form from Guide (for all UG/PG/PhD/DM,MCh projects) regarding overall responsibility for the research	

Date: Signature of principal investigator

(It is mandatory to submit this form along with proforma)

Annexure-1

Application form for requesting waiver of consent

1. *Principal Investigator's name:*
2. *Department:*
3. *Title of project:*
4. *Names of co-investigators and Department/s:*
5. *Request for waiver of informed consent:*

☐ *Please tick the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).*

[1] Research involves 'not more than minimal risk'

[2] There is no direct contact between the researcher and participant

[3] Emergency situations as described in ICMR Guidelines

[4] Any other (please specify)

☐ *Statement assuring that the rights of the participants are not violated:*

☐

☐ *State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant:*

Principal Investigator's signature with date:

_____

Final decision at full board meeting held on:

_____

Waiver granted: Yes ……. No……..

If not granted, reasons, _____

Signature of the Chairperson with Date:

_____

Annexure-2

REVIEW EXEMPTION APPLICATION FORM

1 Principal Investigator's Name:

2 Department:

3 Title of Project:

4 Names of other participating staff and students:

5 Brief description of the project:

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project: -

6 State reasons why exemption from ethics review is requested?

- ☐ Audits of educational practices
- ☐ Research on microbes cultured in the laboratory
- ☐ Research on immortalized cell lines
- ☐ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ☐ Analysis of data freely available in public domain
- ☐ Any other

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Principal Investigator's signature: _____

Date _____

Forwarded by the Head of the department:

Name: _____ Signature: _____

Date_____

Recommendations by the IHEC Member Secretary/Additional Member Secretary:

Exemption

Cannot be exempted

Reasons_____

Discussion at full board

Signature of the Member Secretary/Additional Member Secretary:

_____

Date _____

Final Decision:

Exemption

Cannot be exempted

Reasons_____

Discussion at full board

Signature of the Chairperson: _____

Date _____

Final Decision at Full Board meeting held on _____

Signature of the Chairperson: _____

Date _____

No research can be counted as low risk if it involves:

(i) Invasive physical procedures or potential for physical harm

(ii) Procedures which might cause mental/emotional stress or distress, moral or cultural offence

(iii) Personal or sensitive issues

(iv) Vulnerable groups

(v) Cross cultural research

(vi) Investigation of illegal behavior(s)

(vii) Invasion of privacy

(viii) Collection of information that might be disadvantageous to the participant

(ix) Use of information already collected that is not in the public arena which might be disadvantageous to the participant

(x) Use of information already collected which was collected under agreement of confidentiality

(xi) Participants who are unable to give informed consent

(xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.

(xiii) Deception

(xiv) Audio or visual recording without consent

(xv) With holding benefits from "control" groups

(xvi) Inducements

(xvii) Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.

Please check that your application / summary had discussed:

- ☐ Procedures for voluntary, informed consent
- ☐ Privacy & confidentiality

- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IHEC. This might be because of requirements of:

- The publisher of the research
- An organization which is providing funding resources, existing data, access to participants etc.

SECTION – 3

FOR INTRAMURAL RESEARCH FUND COMMITTEE

BUDGET DETAILS

1. Title of the Project:
2. Total amount required:
3. Year wise break-up of the amount:
4. Budget requirement:
    A. Consumable (Provide the list of items required with all relevant details)
    B. Non-consumable (Detailed justification required)
    C. Travel (Not for attending conference) – field work etc.
5. Justification for the budget:
6. For projects where faculty as a guide:
    A. Name of the Candidate:
    B. Study course:
    C. Year of the study:
    D. No. of previous intramural grant received:
    E. Enclose order copy of last intramural grant:
    F. Year of receiving the last intramural grant:
    G. Amount of receiving the last intramural grant
    H. Enclose copy of UC, SOE and progress report of last intramural grant:

Declaration:

A) I/we declare that the infrastructure necessary for carrying out the above-mentioned research scheme are available with me/us.

B) I/we agree to submit within, one month of termination of the scheme a final report on the work and an annual report within one month of expiry of a year if the project goes for more than one year. Extension of the project will be subject to approval of the report by the expert committee.

C) The faculty members those who have not submitted the final reports in respect of earlier projects granted by the Institute, are not entitled for the Institute Grant in future till they submit the report.

Principal Investigator (Guide)

Co-Investigator (S)

Forwarded with remarks from Head of the Department
(in which The Principal Investigator is working)

Annexure 1B: AX 01-B/SOP 06/V2

Project submission application form for initial review for academic (non-regulatory) studies of faculty along with checklist of protocol submission

MAHATMA GANDHI MEDICAL COLLEGE AND RESEARCH INSTITUTE, PILLAIYARKUPPAM, PUDUCHERRY - 607402

NEW COMBINED FORMATFORSUBMITTINGRESEARCHPROPOSALFORCONSIDERATIONBY INSTITUTE RESEARCH COMMITTEE (IRC), INSTITUTIONAL HUMAN ETHICS COMMITTEE (IHEC)

Version 2.0 dated 21st October 2019

SECTION – 1

(For IRC)

PART A–GENERALINFORMATION

1. Title of the Project :
2. Name, Designation & Address of the Principal Investigator with mobile number, e-mail ID& Number of ongoing projects as Principal Investigator :
3. Name(s), Designation(s) & Address(es) of the Co-: Investigator(s)with mobile numbers & e-mail IDs
4. Duration of study :

5. A. If the study is institutional, state whether it is intra- departmental or inter-departmental. :

   B. If the study is inter-departmental :

   (i) State the names of collaborating departments :

   (ii) State whether consent has been Obtained from them :

6. A. If the study is inter-institutional, state whether it Is national or international :

   B. State the name of coordinating institution :

   C. State the names of collaborating institutions:

D. State whether consent has been obtained from Collaborating institutions Enclose copies of the same. :

E. State whether you have enclosed a copy of The original research protocol submitted by the coordinating institution :

F. State the responsibilities of each collaborating Institution :

7. Details of foreign collaboration with supporting evidence :

8. Details of foreign extramural funding with supporting evidence:

A. Details of source(s) of finding

B. Details of overall funding

C. Details of funding to MGMCRI with breakup

9. Details of Indian extramural funding with supportive evidence:

A. Details of source(s) of finding

B. Details of overall funding

C. Details of funding to MGMCRI with breakup

PARTB–TECHNICALDETAILS

1. Title of the project :

2. Background :
   A. Rationale :
   B. Novelty
   C. Expected outcome & application :
3. Research question(s) :

4. Research hypothesis(es), if any :

5. Aim and objectives: Primary objective(s)&:
   Secondary objective(s)

6. Brief review of literature

7. Study participants

8. Study design/type :
9. For participants, mention :
   A. Inclusion criteria :
   B. Exclusion criteria :
   C. Withdrawal criteria, if any (trial-related therapy, follow-up and documentation are terminated prematurely as it is indicated to ensure safety of the participants) :
   D. Rescue criteria, if applicable (starting symptomatic therapy either to control symptoms of disease or to overcome lack of adequate efficacy of the study drug or placebo) :

10. Number of groups to be studied, their names and definitions :

11. Sampling :

A. Population :

B. Sampling method :

C. Sample size in each group and sample size : Calculation method(s)

12. Randomization details :

A. Selection of participants :

B. Allocation to groups :

13. Methods: :

A. Intervention details with standardization techniques (drugs/devices/invasive procedures/noninvasive procedures/others) :

B. Are the drugs/devices to be used approved for these indications by Drug Controller General Of India(DCGI)? (Enclose the approval letter: from DCGI for trial on humans or give undertaking to get the approval from DCGI; For all drugs and devices submit documents showing DCGI approval for the proposed indication of the study)

C. Are all procedures to be used professionally: acceptable?

D. List of variables and their measurement methods with standardization techniques

(i) Independent variables :

(ii) Dependent variables :

(iii)Confounding & interacting variables :

E. Data collection methods including settings & periodicity:

F. List variable-wise statistical tests to be used for data analysis:

14. Relevant references for the project (Maximum20) (in Vancouver style, to be cited Sequentially in the textof project):

15. Enclosures :

A. Brief CV of all investigators :

B. Data collection proforma :

C. Questionnaire(s) :

D. Copy of signed original protocol in multicentric: Studies

E. Copy of signed consent letter from coordinator : In multicentric studies

F. Others :

16. Undertakings (please retain what is applicable)

A. The principal investigator hereby gives undertaking to obtain required DCG-I approval and submit its copies to IRC and IHEC.

B. The principal investigator hereby gives undertaking to obtain HMSC approval and submit its copies to IRC and IHEC.

C. The principal investigator hereby gives undertaking to follow official guidelines for exchange of human biological material.

D. The principal investigator hereby gives undertaking to get the required MOU signed and submit its copies to IRC and IHEC.

A. Signature of the Investigator
(Name, Designation, Department,
Seal and Date)

Signature of Head of the Department
of the Investigator
(Name, Designation, Department, Seal
and Date)

B. Signature(s) of the Co-Investigator(s)
(Name, Designation, Department,
Seal and Date)

Signature(s) of Head(s) of the Department
of the co-investigator(s)
(Name, Designation, Department, Seal and Date)

SECTION – 2

[For Institutional Human Ethics Committee (IHEC)]

Proforma to be submitted to the Institutional Human Ethics Committee (IHEC) for faculty projects

- Title of the project:
- Ethical issues involved in the study: *less than minimal risk/ minimal risk/ minor increased over minimal risk/more than minimal risk to the study subjects (for guidance please consult ICMR 2017 guidelines - at MGMCRI website)* [Along with the level of risk, the risks should be discussed in detail]
- Benefit of the study:
- Details of Informed Consent Process (Who/When/How/Where):
- Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications?
- Whether Consent forms in English and in local language are enclosed? *(if the consent form in local language is not applicable, appropriate explanations must be provided)*
- Documents attached
  - Waiver Application Form (AX 01/SOP 06/V2)
  - Review Exemption Application Form (AX 02/SOP 06/ V2)
  - Brief CV of investigators (including no. of projects with him/her) - Needed for all Investigators for each project separately
  - Investigator's brochure
  - Advertisements (if applicable)
  - Others

- Conflict of interest for any other investigator(s) (if yes, please explain in brief)
- We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2017)

Signature of the Investigators: Date:

Signature of the Head of the Department Date:

Signature of the Co- Investigators: Date:

Signature of the Heads of the Department of Co- Investigators Date:

(Note: The proforma must be accompanied by Informed Consent Document (ICD) in English and Tamil. Informed Consent Document should comprise Patient Information Sheet and the consent form. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format. Studies involving children below 7 years should include parent / LAR consent form while studies involving children above 12 years and below 18 years of age should include assent form in addition to parent / LAR consent form)

INFORMED CONSENT DOCUMENT (ICD)

Patient / Participant information sheet

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions – *This is the patient 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. (This need to be deleted after reading)*

We welcome you and thank you for having accepted our request to consider whether you can participate in our study. This sheet contains the details of the study, the possible risks, discomfort and benefits for the participants are also given. You can read and understand by yourself; if you wish, we are ready to read and explain the same to you.

If you do not understand anything or if you want any more details we are ready to provide the details.

19. What is the title of the Research Project?

20. Who /where is this study being conducted?

This study is being conducted by ---------- a Post graduate medical student belonging to …… Department under the guidance of …… Designation …….

21. What is the purpose of the study?

22. Procedure/Methods of the study (in brief, simple non-technical terms)

Note: Do not copy paste from the protocol

23. How long you are expected to participate in this study?

(including the number of visits required)

24. Why I am being considered as one of the participant?

Describe in simple understandable terms.

25. Should I definitely have to take part in this study?

No. If you do not wish to participate you will not be included in this study. Also you will continue to get the medical treatment without any prejudice.

26. If I am participating in this study, what are my responsibilities? (Responsibility of the individual as a participants)

Being a participants in this study your responsibility are : _____

27. Are there any benefits for me/Public?

Yes, you will benefit by …….

Or you will not benefit but the results of the study may benefit future patients by …….

28. Will there be any discomfort / risks to me?

You may suffer some discomforts like giving few ml of blood for investigation, undergoing some medical examinations or any other risks (to be enumerated if any) expected from the study to the participant.

29. Will my participating in this study, my personal details will be kept confidentially?

Your participation in the study and the study records relating to you will be kept confidential throughout the study and thereafter. Your personal identity will not be revealed in case of publication in any journal or analysis of your results, nor will it be shared with anyone. The study records relating to you will be preserved for a period of three (if academic Research)/ five years (if clinical trial) for analysis and follow up.

30. Will I be paid for participating in the Study?

You will be paid/ not paid compensation for participation in the research (appropriate responses depending upon the nature if the study)

31. Can I withdraw from this study at any time during the study period?

Your participation in the study is purely voluntary. You are free to withdraw from the study at any time without assigning any reason. Your withdrawal from the study would in no way affect the medical care or other benefits which you are otherwise entitled to receive from the Institute

32. Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?

The biological materials collected from you may be utilized for further analysis in future, if needed. All the biological materials obtained from you will be used only for research purposes in this study and will not be used for any secondary purpose nor will it be shared with others.

33. Possible current and futures uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?

The data collected from you may be utilized for further analysis in future, if needed. All the data obtained from you will be used only for research purposes. It will not be used for any secondary purpose nor will it be shared with others. In case of analysis of your data in any publication in any journal, your identification will not be revealed.

34. Will I be informed of this study's results and the findings?

Yes, on your request the results of the study and its findings you will be informed.

35. Provision of free treatment for research related injury.

Although no study related injury to you is expected, in case anything happens appropriate treatment for the same will be provided free of cost as per the Institutional policy.

36. Compensation to the participant for death or disability arising out of foreseeable and unforeseeable risks attributable to the study.

Compensation as per the Institutional Policy will be provided to you in case of death or disability arising out of the foreseeable and unforeseeable risks attributable to the study.

Address and mobile number of the Principal Investigator (PI) and Co-PI, if any:

Address and telephone number of the IHEC office, MGMCRI

Office of Institutional Human Ethics Committee, 1st floor college block (Adjacent to dept. of Pathology), MGMCRI, Puducherry 607 402. Phone No.: 0413- 2616700 (Extn No.: 754)

Signature of the Participant Signature of the Investigators

CONSENT FORM

Name of the Research Project _____

_____

_____

I (Name of the Participant/ LAR) have been informed about the details of the study in own Language.

I have understood the details about the study.

I know the possible risks and benefits for me, by taking part in the study.

I understand that I can withdraw from the study at any point of time without assigning any reason, and even then I will continue to get the medical treatment as usual.

I understand that I will not get any payment for taking part in this study.

I will not object if the results of this study is getting published in any medical journals, provided my personal identity is not revealed.

I know what I am supposed to do by taking part in this study and I assure that I will give my full co-operation for this study.

Date:

Signature/Thumb impression of the participant/ LAR

_____

_____

_____

Name, Address and Signature/Thumb impression of the witness

_____ _____

_____

Name & Signature of the investigator

_____

_____

CONSENT FORM (for participants less than18 years of age)

Parent/Legally acceptable representative (LAR)

Title of the project:

Participant's name: Address:

Parent/LAR' s name:

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 child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward 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. **Risk and benefit of this project has been explained to me.** I fully consent for the participation of my child/ward in the above study.

Assent of child/ward obtained (for participants 12 to 18 years of age)

(I also consent / do not consent to use my child/ward's stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature/ thumb impression of the parent/ LAR: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____ Date: _____

ASSENT FORM

(for children above 12 years and below 18 years of age)

Assent form to participate in a clinical research

Child Participant's name: Date of birth/Age:

Parent/LAR' 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 understand that following completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully assent to participate in the above study.

(I also assent / do not assent to use my stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature of the child participant : Date:

(If child knows to sign/Thumb impression)

Signature of the parent or guardian : Date:

Name and address of the witness : Date

Signature of the witness : Date:

Signature of the Investigator : Date:

(Assent form should be accompanied by patient / participant information sheet for children in a simple language comprehensible to a child of 12-18 years; Language used should be simpler for children in the age group >12-18 years)

CHECK LIST

(To be filled and duly signed by the principal investigator)

Title of the study:

Name of the Investigator:

Designation & Department:

S. No	Items	Yes/No
1	Exact title as approved by IRC	
2	Date of IRC approval mentioned in proper format (dd/mm/yyyy)	
2	Source of funding mentioned	
3	Adequate literature review with justification for the study mentioned	
4	Detailed description about methodology (Study design, number of groups, sample size etc)	
5	No mirror statement in Inclusion/Exclusion criteria (Ex: Age <18 in inclusion & Age>18 in exclusion)	
6. For Randomized Trial:		
a.	Method that will be used to generate the random allocation sequence	
b.	Type of randomization; details of any restriction (such as blocking and block size)	
c.	Mechanism that will be used to implement the random allocation sequence (such as sequentially numbered containers0, describing any steps taken to conceal the sequence until interventions were assigned	
7. For Analytical/Observational Studies (STROBE Guidelines)		
f.	• Cohort study – the eligibility criteria, sources and methods of selection of participants • Methods of follow-up	
g.	• Case-Control Study – eligibility criteria, sources and methods of case ascertainment and control selection • The rationale for the choice of cases and controls	
h.	• Cross-sectional study – eligibility criteria, sources and methods of selection of participants	

i.	• Cohort study – for matched studies, matching criteria and number of exposed and unexposed	
j.	• Case-control study – for matched studies, matching criteria and number of controls per case	
8.	Outcomes – completely defined primary and secondary outcome measures, including how and when they will be assessed	
9.Statistical methods		
	Statistical methods that will be used to compare groups for primary and secondary outcomes	
	Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
10. Ethical issues explained in detail with **level of risk as per ICMR 2017**		
11. Signature of all investigators (Principal & Co-investigator) and Head of corresponding department obtained with date		
12. Confidentiality mentioned as per IHEC MGMCRI guidelines in consent form part 1		
13. Information to the participant/ parent/guardian in layman (simple) language.		
14. Informed Consent Document **in both English and Tamil** attached as per IHEC, MGMCRI SOP format		
• Separate assent form for subjects >12yrs< 18 yrs. attached **(if applicable)** • Separate consent form for cases and controls attached **(if applicable)** • **No discrepancy** between Tamil and English consent form		
15. Validated questionnaire both in Tamil and English attached **(if study involves interview/ questioning)**		
16. Adequate justification for exemption from obtaining informed consent given **(if applicable).**		
17a	Permission from DCGI (**if applicable**).	
17b	DCGI approval for the mentioned indication in the study (for drugs, devices, cosmetics etc)	
18	Declaration form from principal investigators / Co-Investigator stating that all procedures used in the study are standard and professionally acceptable (for faculty projects / for all UG/PG/PhD/DM, MCh) and regarding overall responsibility for the Research.	

Date: Signature of principal investigator

(It is mandatory to submit this form along with proforma)

Annexure-1

Application form for requesting waiver of consent

1. *Principal Investigator's name:*
2. *Department:*
3. *Title of project:*
4. *Names of co-investigators and Department/s:*
5. *Request for waiver of informed consent:*

- *Please tick the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IHEC to consider waiver of consent).*

  [1] Research involves 'not more than minimal risk'

  [2] There is no direct contact between the researcher and participant

  [3] Emergency situations as described in ICMR 2017 Guidelines

  [4] Any other (please specify)

- *Statement assuring that the rights of the participants are not violated:*
- *State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant:*

Principal Investigator's signature with date:

_____

Final decision at full board meeting held on:

_____

Waiver granted: Yes …… No……..

If not granted, reasons,

_____

Signature of the Chairperson with Date:

_____

Annexure-2

REVIEW EXEMPTION APPLICATION FORM

1. **Principal Investigator's Name:**

_____

2. **Department:**

_____

3. **Title of Project:**

_____

_____

4. **Names of other participating staff and students:**

_____

5. **Brief description of the project:**

   Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project

6. **State reasons why exemption from ethics review is requested?**
   - Audits of educational practices
   - Research on microbes cultured in the laboratory
   - Research on immortalized cell lines
   - Research on cadavers or death certificates provided such research reveals no identifying personal data
   - Analysis of data freely available in public domain
   - Any other

     (This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Principal Investigator's signature: _____

Date _____

Forwarded by the Head of the department:

Name: _____ Signature: _____

Date_____

Recommendations by the IHEC Member Secretary/Additional Member Secretary:

Exemption

Cannot be exempted

Reasons_____

Discussion at full board

Signature of the Member Secretary/Additional Member Secretary:

_____

Date _____

Final Decision:

Exemption

Cannot be exempted

Reasons_____

Discussion at full board

Signature of the Chairperson: _____

Date _____

Final Decision at Full Board meeting held on _____

Signature of the Chairperson: _____

Date _____

No research can be counted as low risk if it involves:

(i) Invasive physical procedures or potential for physical harm

(ii) Procedures which might cause mental/emotional stress or distress, moral or cultural offence

(iii) Personal or sensitive issues

(iv) Vulnerable groups

(v) Cross cultural research

(vi) Investigation of illegal behavior (s)

(vii) Invasion of privacy

(viii) Collection of information that might be disadvantageous to the participant

(ix) Use of information already collected that is not in the public arena which might be disadvantageous to the participant

(x) Use of information already collected which was collected under agreement of confidentiality

(xi) Participants who are unable to give informed consent

(xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.

(xiii) Deception

(xiv) Audio or visual recording without consent

(xv) Withholding benefits from "control" groups

(xvi) Inducements

(xvii) Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be

encountered in normal daily life.

Please check that your application / summary had discussed:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IHEC. This might be because of requirements of:

- The publisher of the research
- An organization which is providing funding resources, existing data, access to participants etc.

SECTION – 3

FOR INTRAMURAL RESEARCH FUND COMMITTEE

BUDGET DETAILS

1. Title of the Project:
2. Total amount required:
3. Year wise break-up of the amount:
4. Budget requirement:
    A. Consumable (Provide the list of items required with all relevant details)
    B. Non-consumable (Detailed justification required)
    C. Travel (Not for attending conference) – field work etc.
5. Justification for the budget :
6. For Faculty project:
    A. No. of intramural grants received in last five years:
    B. Enclose order copy of last intramural grant:
    C. Enclose copy of UC, SOE and progress report of last intramural grant:
    D. No. of extramural grants received in last five years:
    E. Enclose order copy of last extramural grant:
    F. Enclose copy of UC, SOE and progress report of last extramural grant:

Declaration:

A) I/we declare that the infrastructure necessary for carrying out the above-mentioned research scheme are available with me/us.

B) I/we agree to submit within, one month of termination of the scheme a final report on the work and an annual report within one month of expiry of a year if the project goes for more than one year. Extension of the project will be subject to approval of the report by the expert committee.

C) The faculty members those who have not submitted the final reports in respect of earlier projects granted by the Institute, are not entitled for the Institute Grant in future till they submit the report.

Principal Investigator

Co-Investigator (S)

Forwarded with remarks from Head of the Department

(in which The principal Investigator is working)

Annexure 1C: AX 01-C/SOP 06/V2

Project submission application form for initial review for drug trials and other regulatory studies (Industry sponsored studies).

SECTION – 1

(For Sponsored Clinical Trials)

Proforma for Submission of Proposal for Sponsored Clinical Trial Research, MGMCRI, Puducherry

1. Title (This should match the title registered with the CTRI and the DCGI wherever applicable)
2. Name of the Investigator/ Principal Investigator:
3. Department/Division:
4. Designation:
5. State:
    a. The number of ongoing research projects as principal investigator
    b. Source and amount of funds in each of his/her research project
6. Name of the Co-Investigator:

(Qualification, Designation & Department)

i)

ii)

iii)

iv)

7. CV of each investigator
8. Is the study Intradepartmental/Inter departmental?

If interdepartmental

a. State names of the collaborating departments:
b. Whether consent obtained from them:

If inter-institutional:

a. State the name of co-ordinating institution:
b. State the name of the collaborating institution:
c. State whether consent obtained from the collaborating institutions (Enclose copies):

9. State whether you have enclosed a copy of the original research protocol submitted by the co-ordinating institution:
10. Duration of Proposed Study.
11. Year of start of the study:
12. Year of Proposed Termination:
13. Is the study Inter-institutional (National/International)?
14. Is the study Interventional:
15. Have the investigator(s) received any special training for carrying out this study or intervention?
16. Investigators. (CV of each investigator) – To assess their ability to carry the study.
17. Name, address and tel/fax/email of (primary) sponsor with the name of contact person
18. Background information (What's already known) describe adequately.
    a. Drug(s), device(s) and/or biologics?
    b. Pharmacology of the drug.
    c. Is the drug already approved by the regulatory authorities and available in the market or are they new ones?
    d. Who has prepared and/or is manufacturing them?
    e. Who holds the patent or IND/IDE of the drug(s) or Device(s)?
    f. The results of previous trials.
    g. Information on the medical condition in which the study drug will be used.
    h. Treatment options available for the condition at present.
    i. Whether the non-drug interventions to be used professionally accepted?
    j. The need for the present study
19. Objectives
    a. Overall
    b. Specific

20. The study designs
21. Summary of methods
22. Methodology
23. The population studied: inclusion and exclusion criteria (explanation if vulnerable populations included deliberately)
24. Sample size and sampling method
25. The detailed methods
    a. How will the subjects be recruited?
    b. How will the study / intervention be carried out?
    c. What outcome will be measured and how.
    d. Specify if procedure involves banking of biological samples, HIV testing, genetic testing.
    e. Plan of data analysis – including by whom and how.
    f. Please mention whether data will be analysed to understand politically and socially sensitive group differentials- gender, caste, class, ethnicity, race.
26. Systems in place for reduction, management of anticipated (and unanticipated) risks, discomfort, adverse events/toxicity and their monitoring.
    a. Describe all possible risks and discomfort for subject/participant due to use of intervention and/or interaction procedures/data collection methods proposed.
    b. Risk reduction: Describe steps you have taken or propose to take to minimise such risk, discomfort or for early recognition of side effects and their management.
    c. Data and Safety Monitoring:
        i. Define adverse events in the study
        ii. How and to whom you propose to report them
        iii. Describe rules for stopping the study due to adverse events.
        iv. Describe Data and Safety Monitoring Plan of your project.
    d. Does the project require appointment of a Data Safety Monitoring Board (DSMB)?
27. Privacy and Confidentiality:

a. Measures to provide privacy to subjects/participants while conducting study
b. What level of confidentiality promised?
c. What are the likely consequences to the subject/participant in the event of violation of confidentiality?
d. The types of identifiable information on subject/participant collected.
e. How will they be masked/removed
f. How will this data be stored and its safe keeping ensured?

28. Benefits of the study:
    a. Benefits to the subjects in the study.
    b. Benefits, if any, to the society.
    c. Risk/Benefit analysis to be presented.
29. Informed consent
    a. Compliant with Schedule 'Y'?
    b. Must be in the local (Tamil) language translation and in English.
    c. Describe the process:
        i. How, Where, When and By Whom the Informed Consent will be obtained.
        ii. How will be video recorded.
        iii. How much time the subject/participant will be given to consider participation and decide.
        iv. Additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates, prisoners, etc.
        v. How you will assess that information is correctly understood by the participant.
    d. Content:
        i. A statement that consent is for a study/research/experiment,
        ii. An explanation of the purpose of research and nature of procedure,
        iii. All foreseeable risks/discomforts to participants due to research must be enumerated.

iv. Any benefits to be expected should be mentioned.

v. Alternative procedures or courses of treatment in case subject does not want to participate,

vi. The extent of confidentiality protection provided.

vii. Explanation on provision of compensation for injury caused to participant during the study.

viii. Whom to contact to know more about the study and participants' rights.

ix. A statement that participation is voluntary.

x. A statement that participant can withdraw consent and from the study at any time without any facing any penalty.

xi. The reimbursement of expenses and compensation provided to the trial subjects for participation.

xii. The post-trial benefits would be given to the trial subjects. Whether the investigational drug or device will be provided to the study participants/subjects if it is found to be effective.

30. Compliance with requirements of regulatory authorities (copies)-

a. DCGI approval.
b. CTRI registration
c. Permission for sending biological materials out of the country. (DCGI and DGFT or INI).
d. Copy of MOU on this.
e. HMSC for international collaborative trials.
f. From other Government department(s).

31. Financial:

a. Type of funding - Contract/Grant, Subcontract, Gift/donation of drugs/devices
b. Source of funding: Government: Central/ State/ local / Intramural
c. Private Foundation: Indian / Foreign
d. Industry: Private / Public / Other
e. Other / Unfunded / No funding required
f. Compensation to trial subjects – give details.

g. Are the study participants, investigators, member of IHEC and institution protected by insurance coverage to cover litigation costs and compensation?
h. If yes, specify the amount and conditions of coverage.
i. Provide a copy of the Insurance document.
j. Budget Details (show fund allocation to various heads- manpower, material, etc.)

S. No.	BUDGET HEADS	AMOUNT (LAKH Rs)
1.	Equipment	
2.	Equipment maintenance charges	
3.	Salaries	
4.	Hospital expenses (Investigation, hospital stay charges etc)	
5.	Subject compensation (transport, means etc)	
6.	Travel (investigator's meet, conferences, project work etc)	
7.	Contingencies (Xerox, stationary, postage, telephone, fax etc)	
8.	Consumables	
9.	Miscellaneous	
10.	Others	
11.	Insurance charges (for investigators, patients/volunteers)	
TOTAL COST OF STUDY CONDUCT		
12.	Institutional over heads (25%)	
GRAND TOTAL		

32. Legal – Copy of the draft CTA
    a. Are the institutions and investigator's rights and interests protected?
33. Statement on Conflict of Interests - The financial and other interests of any of the investigators and/or close relative(s), with the sponsor(s) and outcome of the study.
34. List of attachments:
    a. Full proposal, with protocols/instruments for data collection and budget in detail.

b. Informed consent in local language (and English).
c. Copy of the agreement signed by the Institute and the sponsor of the study (if applicable)
d. Copies of all permissions obtained from regulatory authorities.

35. Principal Investigator's Certification:
    a. I certify that the information provided in this application is complete and correct.
    b. I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
    c. I will comply with all policies and guidelines of MGMCRI, Puducherry (Web link) where this study will be conducted, as well as with all applicable laws regarding the research.
    d. I will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IHEC-MGMCRI, Puducherry approved protocol.
    e. I will not modify this IHEC certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.
36. Name and signature of investigator with date.
37. Name and signature of the head of the department of the principal investigator with date.
38. Name and signature of all co- investigators with date.
39. Name and signature of the head of the department of each of the co-investigator with date.

Checklist for enclosures

(To be filled by the Investigator):

1) Research proposal Registration form	Enclosed Yes/No
2) Application for project proposal approval	Enclosed Yes/No
3) Budget details of the project proposal	Enclosed Yes/No
4) Short summary (synopsis) of research proposal	Enclosed Yes/No
5) Request letter from sponsor (if applicable)	Enclosed Yes/No
6) Ethics committee approval	Enclosed Yes/No
7) DCGI approval (if applicable)	Enclosed Yes/No
8) Institute sponsor agreement (ISA)	Enclosed Yes/No
9) HMSC permission (if applicable)	Enclosed Yes/No
10) Clinical Trial Insurance document copy	Enclosed Yes/No
11) Undertaking by the investigator: This shall include all the details/ elements as mentioned in the Appendix VII of Schedule- Y	Enclosed Yes/No
12) Informed consent documents (Patient information sheet Informed consent form, etc) as per Appendix V of Schedule-Y	Enclosed Yes/No
13) Informed consent documents should mention the following: "In case of study related injury or death M/s. << NAME OF THE COMPANY>> will provide complete medical care along with compensation for the injury or death"	Enclosed Yes/No
14) Principal Investigator's Certification	Enclosed Yes/No
15) Any other documents enclosed (give details)	Enclosed Yes/No
16) Signature of the investigators:	Yes/No
17) Signature of all the co-investigators:	Yes/No
18) Signature of Head of the Department of the investigators:	Yes/No
19) Signature of Head of the Department of each of the co-investigators:	Yes/No

RESEARCH PROPOSAL REGISTRATION FORM, MGMCRI, PUDUCHERRY

(To be filled by the Investigator)

.....

1. Project Title:
2. Name of the Investigator with designation:
3. Department /Division:
4. Name of Co-Investigators:

(Qualification, Designation & Department)

5. Sponsor's Name:

(For Office use)

Sponsored Clinical Trial No: _____ Date of receiving the proposal: _____

6. Comments/suggestions:
7. Legal opinion on liabilities:
8. Decision of the Sponsored Clinical Trial: Approved/ Not Approved
9. Date decision taken by the Sponsored Clinical Trial:

Signature of Member-Secretary

(To be filled after ISA is signed)

10. Ethics Committee approval No and date:
11. Date of submission of copy of ISA submitted to Office of Dean (Research):
11. Year of start of the study:
12. Year of proposed termination of study:
13. Year actually finished:
14. Project completion report submission date:

General instruction to investigators regarding filling up of the proforma and points to take note of:

1. The submission of proposal shall be in the enclosed format. No section shall be left blank or filled by a '-' or 'N.A.' or 'Not applicable'. If a section is not applicable the section must be filled with the reason why that section is not applicable.

2. The 'Informed Consent' document should contain information to the study participant regarding the facts of the trial, possible side reactions due to trails on them etc.

3. Videography of informed consent process must be done as per CDSCO guidelines and other orders issued by the Government from time to time.
4. The investigator –sponsor agreement should include a clause that the sponsor takes responsibility for providing insurance to cover compensation and the entire legal costs of litigation related to the trial to investigators, institute, members of the Institutional Human Ethics Committee and other related committees as well as patients for not only trial related injury but also for professional liability of the health care providers involved in managing the trial patients and general liability of the institution in so far as the trial subjects are concerned and shall also compensate any injury to the subjects arising out of the trial as defined by the in the Drugs and Cosmetics (First Amendment) Rules, 2013 and any subsequent amendments including injury arising from violation of approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator or other healthcare providers involved in the care of the trial participant.
5. Sponsor should ensure post trial benefit to the participants, wherever medically relevant, by continuing to provide free of cost, and without interruption of treatment, the best drug available at that point in time to all trial participants for up to 1 year.
6. The sponsor must agree to bear the medical and travel expenses related to the treating of any trial related harm caused to trial participants including investigations performed and treatment given in hospitals outside MGMCRI for such purposes.

7. These responsibilities undertaken by the trial sponsor must be reflected in the 'informed consent'.
8. The informed consent document must mention the no compensation shall be provided in case of non-response or disease progression if no compensation is intended to be given.
9. In the declaration signed by the subject volunteering to participate in the trial there must be the following statement "I will not hold the institute (MGMCRI, Puducherry) in any way responsible for any injury or adverse event occurring to me due to participation in this clinical trial and shall not file a law suit against MGMCRI, Puducherry in this regard."
10. Whenever biological samples are sent to another laboratory outside MGMCRI on the grounds that facilities for performing the desired tests are not available in MGMCRI, an assurance must be provided by the laboratory and/ or sponsor that the biological samples submitted for testing will be used only for such tests as mentioned in the protocol and for no other purpose and that such samples will not be retained but be discarded after the study is over.
11. Institute overheads must be calculated as 5% of the overall project cost as worked out before inclusion of institute overheads and must be added at the end to arrive at the total project cost Institute overheads must not be less than at least Rs.30,000/-.
12. No liability on the Institution shall reflect on any the Clinical Trial Agreement (Investigator – Sponsor Agreement).
13. The jurisdiction of this above-mentioned agreement must be in the court of Puducherry or Chennai only.
14. Investigator, while submitting proposals, must suitably index and flag documents submitted for the easy access of appropriate documents by committee members.
15. The investigator while submitting the research proposal must understand that the drugs or device under investigation must be administered or implanted respectively, as the case may be, only by the investigator or co-investigator.
16. Accurate Tamil version of informed consent must be provided.
17. The sponsor must agree to pay the revised hospital charges in case hospital charges are revised in the future in course of the trial.

18. The sponsor or the investigator must agree to bear additional costs involved in archiving of the trial related documents including the Clinical Trial Agreement with its annexures for such period (currently 5 years from the date of completion of trial) and in such manner as is required by the regulations in force from time to time governing the conduct of such trials in case the archiving of such documents is outsourced by the institution in future.

SECTION – 2

[For Institutional Human Ethics Committee (IHEC)]

Proforma to be submitted to the Institutional Human Ethics Committee for faculty projects

- Title of the project:
- Ethical issues involved in the study: *less than minimal risk/ minimal risk/ minor increased over minimal risk/more than minimal risk to the study subjects (for guidance please consult ICMR 2017 guidelines - at MGMCRI website)* [Along with the level of risk, the risks should be discussed in detail]

- Benefit of the study:
- Details of Informed Consent Process (Who/When/How/Where):
- Whether Consent forms in English and in local language are enclosed? *(if the consent form in local language is not applicable, appropriate explanations must be provided)*
- Documents attached
  - Brief CV of investigators (including no. of projects with him/her) - Needed for all Investigators for each project separately
  - Investigator's brochure
  - Advertisements (if applicable)
  - Others

- Conflict of interest for any other investigator(s) (if yes, please explain in brief)
- We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2017)

Signature of the Investigators: Date:

Signature of the Head of the Department Date:

Signature of the Co- Investigators: Date:

Signature of the Heads of the Department of Co- Investigators Date:

(Note: The proforma must be accompanied by Informed Consent Document (ICD) in English and Tamil. Informed Consent Document should comprise Patient Information Sheet and the consent form. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format. Studies involving children below 12 years should include parent / LAR consent form while studies involving children above 12 years and below 18 years of age should include assent form in addition to parent / LAR consent form)

INFORMED CONSENT DOCUMENT (ICD)

Patient / Participant information sheet

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions – *This is the patient 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. (This need to be deleted after reading)*

We welcome you and thank you for having accepted our request to consider whether you can participate in our study. This sheet contains the details of the study, the possible risks, discomfort and benefits for the participants are also given. You can read and understand by yourself; if you wish, we are ready to read and explain the same to you.

If you do not understand anything or if you want any more details we are ready to provide the details.

37. What is the title of the Research Project?

38. Who /where is this study being conducted?

This study is being conducted by ---------- a Post graduate medical student belonging to …… Department under the guidance of …… Designation …….

39. What is the purpose of the study?

40. Procedure/Methods of the study (in brief, simple non-technical terms)

Note: Do not copy paste from the protocol

41. How long you are expected to participate in this study?

(including the number of visits required)

42. Why I am being considered as one of the participant?

Describe in simple understandable terms.

43. Should I definitely have to take part in this study?

No. If you do not wish to participate you will not be included in this study. Also you will continue to get the medical treatment without any prejudice.

44. If I am participating in this study, what are my responsibilities? (Responsibility of the individual as a participants)

Being a participants in this study your responsibility are : _____

45. Are there any benefits for me/Public?

Yes, you will benefit by …….

Or you will not benefit but the results of the study may benefit future patients by …….

46. Will there be any discomfort / risks to me?

You may suffer some discomforts like giving few ml of blood for investigation, undergoing some medical examinations or any other risks (to be enumerated if any) expected from the study to the participant.

47. Will my participating in this study, my personal details will be kept confidentially?

Your participation in the study and the study records relating to you will be kept confidential throughout the study and thereafter. Your personal identity will not be revealed in case of publication in any journal or analysis of your results, nor will it be shared with anyone. The

study records relating to you will be preserved for a period of three (if academic Research)/ five years (if clinical trial) for analysis and follow up.

48. Will I be paid for participating in the Study?

You will be paid/ not paid compensation for participation in the research (appropriate responses depending upon the nature if the study)

49. Can I withdraw from this study at any time during the study period?

Your participation in the study is purely voluntary. You are free to withdraw from the study at any time without assigning any reason. Your withdrawal from the study would in no way affect the medical care or other benefits which you are otherwise entitled to receive from the Institute

50. Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?

The biological materials collected from you may be utilized for further analysis in future, if needed. All the biological materials obtained from you will be used only for research purposes in this study and will not be used for any secondary purpose nor will it be shared with others.

51. Possible current and futures uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?

The data collected from you may be utilized for further analysis in future, if needed. All the data obtained from you will be used only for research purposes. It will not be used for

any secondary purpose nor will it be shared with others. In case of analysis of your data in any publication in any journal, your identification will not be revealed.

52. Will I be informed of this study's results and the findings?

Yes, on your request the results of the study and its findings you will be informed.

53. Provision of free treatment for research related injury.

Although no study related injury to you is expected, in case anything happens appropriate treatment for the same will be provided free of cost as per the Institutional policy.

54. Compensation to the participant for death or disability arising out of foreseeable and unforeseeable risks attributable to the study.

Compensation as per the Institutional Policy will be provided to you in case of death or disability arising out of the foreseeable and unforeseeable risks attributable to the study.

Address and mobile number of the Principal Investigator (PI) and Co-PI, if any:

Address and telephone number of the IHEC office, MGMCRI

Office of Institutional Human Ethics Committee, 1st floor college block (Adjacent to dept. of Pathology), MGMCRI, Puducherry 607 402. Phone No.: 0413- 2616700 (Extn No.: 754)

Signature of the Participant Signature of the Investigators

CONSENT FORM

Name of the Research Project _____

_____

_____

I (Name of the Participant/ LAR) have been informed about the details of the study in own Language.

I have understood the details about the study.

I know the possible risks and benefits for me, by taking part in the study.

I understand that I can withdraw from the study at any point of time without assigning any reason, and even then I will continue to get the medical treatment as usual.

I understand that I will not get any payment for taking part in this study.

I will not object if the result of this study is getting published in any medical journals, provided my personal identity is not revealed.

I know what I am supposed to do by taking part in this study and I assure that I will give my full co-operation for this study.

Date:

Signature/Thumb impression of the participant/ LAR

_____

_____

_____

Name, Address and Signature/Thumb impression of the witness

_____ _____

_____

Name & Signature of the investigator

_____

_____

CONSENT FORM (for participants less than18 years of age)

Parent/Legally acceptable representative (LAR)

Title of the project:

Participant's name: Address:

Parent/ LAR' s name:

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 child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward 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. **Risk and benefit of this project has been explained to me.** I fully consent for the participation of my child/ward in the above study.

Assent of child/ward obtained (for participants 12 to 18 years of age)

(I also consent / do not consent to use my child/ward's stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature/ thumb impression of the parent/ LAR: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____ Date: _____

ASSENT FORM

(for children above 12 years and below 18 years of age)

Assent form to participate in a clinical research

Child Participant's name: Date of birth/Age:

Parent/LAR' 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 understand that following completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully assent to participate in the above study.

(I also assent / do not assent to use my stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature of the child participant : Date:

(If child knows to sign/Thumb impression)

Signature of the parent or guardian : Date:

Name and address of the witness :

Signature of the witness : Date:

Signature of the Investigator : Date:

(Assent form should be accompanied by patient / participant information sheet for children in a simple language comprehensible to a child of 12-18 years; Language used should be simpler for children in the age group >12-18 years)

CHECK LIST

(To be filled and duly signed by the principal investigator)

S. No	Items	Yes/No
1	Exact title as approved by DCGI	
2	Date of CTRC approval mentioned in proper format (dd/mm/yyyy)	
2	Source of funding mentioned	
3	Adequate literature review with justification for the study mentioned	
4	Detailed description about methodology (Study design, number of groups, sample size etc)	
5	No mirror statement in Inclusion/Exclusion criteria (Ex: Age <18 in inclusion & Age>18 in exclusion)	
6. For Randomized Trial:		
a.	Method that will be used to generate the random allocation sequence	
b.	Type of randomization; details of any restriction (such as blocking and block size)	
c.	Mechanism that will be used to implement the random allocation sequence (such as sequentially numbered containers0, describing any steps taken to conceal the sequence until interventions were assigned	
7. For Analytical/Observational Studies (STROBE Guidelines)		
k.	• Cohort study – the eligibility criteria, sources and methods of selection of participants • Methods of follow-up	
l.	• Case-Control Study – eligibility criteria, sources and methods of case ascertainment and control selection • The rationale for the choice of cases and controls	

m.	• Cross-sectional study – eligibility criteria, sources and methods of selection of participants	
n.	• Cohort study – for matched studies, matching criteria and number of exposed and unexposed	
o.	• Case-control study – for matched studies, matching criteria and number of controls per case	
8.	Outcomes – completely defined primary and secondary outcome measures, including how and when they will be assessed	
9.Statistical methods		
a.	Statistical methods that will be used to compare groups for primary and secondary outcomes	
b.	Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
10. Ethical issues explained in detail with **level of risk as per ICMR 2017**		
11. Signature of all investigators (Principal & Co-investigator) and Head of corresponding department obtained with date		
12. Compensation mentioned as per IHEC, MGMCRI guidelines in consent form part I		
13. Confidentiality mentioned as per IHEC MGMCRI guidelines in consent form part 1		
14. Information to the participant/ parent/guardian in layman (simple) language.		
15. Informed Consent Document **in both English and Tamil** attached as per IHEC, MGMCRI SOP format		
• Separate assent form for subjects >12yrs< 18 yrs attached **(if applicable)** • Separate consent form for cases and controls attached **(if applicable)** • **No discrepancy** between Tamil and English consent form		
16. Validated questionnaire both in Tamil and English attached **(if study involves interview/ questioning)**		
17. Adequate justification for exemption from obtaining informed consent given **(if applicable).**		

18a	Permission from DCGI (**if applicable**).	
18b	DCGI approval for the mentioned indication in the study (for drugs, devices, cosmetics etc)	
19	Declaration form from principal investigators / Co-Investigator stating that all procedures used in the study are standard and professionally acceptable (for faculty projects / for all UG/PG/PhD/DM, MCh) and regarding overall responsibility for the research.	

Date: Signature of principal investigator

Annexure 2: AX 02/SOP 06/V2

Document Receipt Form

Protocol Number:

Received number:

Submitted date:

Protocol Title:

Principal Investigator:

Department:

Communication with the IHEC

- **E-mail address:** ihec@mgmcri.ac.in

- **Phone:**

Documents submitted:

- Complete
- Incomplete, will submit on……...

Documents to be submitted later:

- _____
- _____
- _____
- _____
- _____

AX 03/SOP 06/V2

Curriculum Vital for the Principal Investigator/ Co – Investigator/Guide

First Name	Middle Name	Last Name

Name to be entered in certificate (IN CAPITAL LETTER):	
Date of Birth (dd/mm/yy):	**Sex**
Study Site Affiliation (Institute):	
I am the (Principal Investigator/ Co-Investigator, Guide / Co-Guide)	
Present Designation:	
Medical Registration (Including State):	
Professional Mailing Address (Include institution name)	**Study Sited Address (Include Department in Institution)**
Telephone (Office/Department):	**Mobile Number:**
E-Mail:	
Academic Qualifications (Most current qualification first)	

Degree/Certificate	Year	Institution, Country

Provide Details

- **Training in Bioethics**
- **Training in Good Clinical Practice (GCP)**

Brief Summary of Relevant Clinical Research Experience:	
Signature: **(Signature Required)**	**Date:**

AX 04/SOP 06/V2

Cover letter

From,

To,

The Chairperson,

Office of Institutional Human Ethics Committee,

Mahatma Gandhi Medical College and Research Institute,

Puducherry, India.

(Through Proper Channel)

Subject: ETHICAL CLEARANCE FOR DISSERTATION/ RESEARCH PROTOCOL Reg.

Respected Sir,

I _____ am conducting a study as a part of my Postgraduate course requirement on "_____" under the guidance of _____ from the Department of _____, _____(College Name).

I am attaching a copy of my protocol along with this letter. I request you to kindly grant me the ethical Clearance for this study

Thanking You,

Your Sincerely.

Principal Investigator Sign

Date:

Place: Puducherry.

7. References:

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: http://www.ferci.org/sops/*