Pacific Medical College & Hospital Udaipur

FORMAT FOR HUMAN STUDIES

(Submitting research proposal for consideration by institute ethics committee PMCH Udaipur to be submitted in soft and hard copies)

SECTION – 1

PART A – GENERAL INFORMATION

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 whether consent has been obtained from collaborating institutions. Enclose copies of the same. :

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

E. State the responsibilities of each collaborating Institution. :

7. **Details of foreign collaboration with supporting evidence :**

8. **Details of funding with supportive evidence (If any):**

A. Details of source(s) of finding :

B. Details of overall funding :

C. Details of funding to PMCH with breakup :

PART B – TECHNICAL DETAILS

1. **Title of the project :**

2. **Background :**

   A. **Rationale :**

   B. **Expected outcome & Application :**

3. **Research question(s) :**

4. **Research hypothesis (es), if any :**

5. **Aim and objectives :**

6. **Brief review of literature :**

7. **Study participants (humans, animals or both) :**

8. **Study design / type :**

9. **For participants, mention :**

   A. **Inclusion criteria :**

   B. **Exclusion criteria :**

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

11. **Sampling :**

   A. **Population :**

   B. **Sampling method:**

   C. **Sample size in each group :**

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. Data collection methods including settings &periodicity :

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

14. Relevant references for the project (Maximum 20) :

15. Enclosures :

A. Data collection proforma :

B. Questionnaire(s) :

C. Copy of signed original protocol in multicentre Studies :

D. Copy of signed consent letter from coordinator in multicentre studies :

E. 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 IEC.

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

C. The principal investigator hereby gives undertaking to get the required MoU signed and submit its copies to IEC.

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

For Institute Ethics Committee (IEC)-Human Studies

Ethical Considerations

1. **Title of the project:**

2. **Ethical issues involved in the study:**
   less than minimal risk / minimal risk / more than minimal risk to the study subjects [Along with level of risk, the risks should be written in detail. If you feel there will be no risk, give justification] As per ICMR guidelines for research in human participants.:

3. **Benefit of the study:**

4. **Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications.**

5. **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)

6. **Documents attached**
   a. **Brief CV of investigators (including no. of projects with him/her) - Needed only for Investigator/s from outside PMCH**

   b. **Investigator's Brochure**

   c. **Others**

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

8. **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.**

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 Performa must be accompanied by Informed Consent Document (ICD) in English and Hindi. 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 7 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 Hindi which can be understood by the participant.

- **Title of the project**
- **Name of the investigator/guide**
- **Purpose of this project/study**
- **Procedure/methods of the study**
- **Expected duration of the subject participation**
- **The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator**
- **Any risks expected from the study to the participant**
- **Maintenance of confidentiality of records**
- **Provision of free treatment for research related injury**
- **Compensation for participating in the study**
- **Compensation to the participants for foreseeable risks and unforeseeable risks related to research study leading to disability or death.**
- **Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled**
- **Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned**
- **Address and mobile number of the Principal investigator (PI) and Co- PI, if any :**

Signature of the investigator:

Signature of the participant:

Place:
Date :

CONSENT FORM

Title of the project:

Participant's name & Address :

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

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

Signature of the participant: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____ Date: _____

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. I fully consent for the participation of my child/ward in the above study.

Assent of child/ward obtained (for participants 7 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 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 7 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. 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 7-18 years; Language used should be simpler for children in the age group 7-12 years compared to children in the age group >12-18 years)