JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION & RESEARCH, PUDUCHERRY-605006
(Institute of National Importance under Govt. of India)

NEW COMBINED FORMAT

(FOR SUBMITTING RESEARCH PROPOSAL FOR CONSIDERATION BY JIPMER SCIENTIFIC ADVISORY COMMITTEE (JSAC), INSTITUTE ETHICS COMMITTEE (HUMAN STUDIES) and INTRAMURAL RESEARCH FUND COMMITTEE)

SECTION – 1

(For JSAC)

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 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 source(s) of extramural funding :

8. Details of amount of extramural funding :

PART B – TECHNICAL DETAILS

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 (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 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 :
(Maximum 20) (in Vancouver style, to be cited sequentially in the text of project)

15 .Enclosures :

A. For Part – A – No. 6 :

B. For Part – B – No.13 .B. :

C. Data collection proforma

D. Questionnaires :

E. Others :

16. Undertakings for :

A. DCGI approval

B. HMSC approval :

C. MoU signing :

A. Signature of the Investigator
(Name & Designation)

Signature of Head of the Department
of the Investigator
(Name & Designation)

B. Signature(s) of the Co-Investigator(s)
(Name & Designation)

Signature(s) of Head(s) of the Department
of the co-investigator(s)
(Name & Designation)

SECTION – 2

(For Institute Ethics Committee (IEC)-Human Studies)

Proforma to be submitted to the Institute Ethics Committee (Human Studies) for faculty projects

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 *(for guidance please consult ICMR guidelines for biomedical research in human participants, 2006 – at JIPMER website)*

   [Along with level of risk, the risks should be written in detail. If you feel there will be no risk, give justification]
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 JIPMER
   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 (2006)

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 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 Tamil which can be understood by the participant. (Do not copy & paste from the study protocol submitted to JSAC).

- 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)

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 JSAC / PGRMC/ UGRMC	
2	Date of JSAC / PGRMC/ UGRMC 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)	
6a	Permission from DCGI (**if applicable)**.	
6b	DCGI approval for the mentioned indication in the study (for drugs, devices, cosmetics etc)	
7	Adequate justification for exemption from obtaining informed consent given **(if applicable).**	
8	Informed Consent Document **in both English and Tamil** attached as per JIPMER SOP format.	
9	**Information to the participant/ parent/guardian** in layman (simple) language.	
10	Validated questionnaire both in Tamil and English attached **(if study involves interview/ questioning)**	
11	Signature of all investigators (Principal & Co-investigator) and Head of corresponding department obtained with date	
12	Compensation mentioned as per JIPMER guidelines in consent form part 1	
13	Confidentiality mentioned as per JIPMER guidelines in consent form part 1	
14a	Separate consent form for subjects < 7 yrs attached **(if applicable)**	
14b	Separate assent form for subjects > 7 yrs < 18 yrs attached **(if applicable)**	
15	Separate consent form for cases and controls attached **(if applicable)**	
16	Ethical issues explained in detail with **level of risk**	
17	**No discrepancy** between tamil and English consent form	
18a	Declaration form from Guide (for all UG/PG/PhD/DM,MCh projects) regarding overall responsibility for the research	
18b	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)	

Date: Signature of principal investigator

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

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:
7. 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

Co-Investigator (S)

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