Standard Operating Procedures (SOP)

for

Institutional Ethics Committee (IEC)

Dr Shyama Prasad Mukherjee University

Ranchi, Jharkhand - 834008

SOP is prepared according to the following Guide lines of ICMR India

NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS

INDIAN COUNCIL OF MEDICAL RESEARCH
ANNEXURE 1 (Page no. 160)
STANDARD OPERATING PROCEDURES (SOPs)

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Content

IEC-DSPMU
Standard Operating Procedure (SOP)

1. Title: Establishing and Constituting the Institutional Ethics Committee (IEC)

1. **Purpose:** To establish and constitute the Institutional Ethics Committee for DSPMU.

2. SCOPE: Applicable to DSPMU

3. Responsibility: Vice Chancellor of DSPMU is responsible for implementing this SOP.

4. PROCEDURE:

4.1 Committee will be called Institutional Ethics Committee - DSPMU (IEC-DSPMU).

4.2 Vice Chancellor will select and nominate the Chairman and Member Secretary.

4.3 The IEC will be constituted by the VC in consultation with the Chairman & Member Secretary in accordance with the requirement specified in Appendix VIII of schedule Y, & Good research practices for Biological & Social Sciences research in India.

4.4 VC will invite the members to join ethics committee by sending the official request letter.

4.5 Members will confirm their acceptance to the VC by providing all the required information for membership.

4.6The VC will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve.

4.7 VC will designate and instruct Member Secretary / Chairman of IEC or his/her representative to conduct the regular proceedings of IEC for the institute

4.8 At regular intervals, VC will review the functioning of IEC.

4.9 Arrangement should be made for the documentation and maintenance of records of IEC. Details of IEC-DSPMU will be maintained in University's web site.

2. Title: Procedure for convening and conducting IEC meetings

1. Purpose: To hold regular Ethics Committee meetings.

2. SCOPE: Applicable to DSPMU

3. Responsibility: The Chairman and Member Secretary are responsible for implementing this SOP.

4. PROCEDURE:

4.1 Meetings will be planned in accordance with the need of the work load & the Member Secretary in consultation with Chairman may convene the IEC meeting.

4.2 Additional review meetings can also be held with short notice as and when required.

4.3 All the IEC meetings will be held regularly on scheduled dates that are announced and notified in advance.

4.4 All the proposals will be received at least two weeks before the meeting, checked for completeness as per the check list (IEC-05) initially by the IEC-DSPMU office, subsequently by the member secretary.

4.5 Members will be given not less than 7 days time in advance to review study proposals and the relevant documents.

4.6 Minutes of the IEC meetings, all the proceedings and deliberation will be documented.

4.7 Signatures of the Chairman and the Member Secretary will be obtained on the minutes of the meeting document.

4.8 Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.

4.9 Independent experts may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement. They will not have a role in decision making

3. Title: Procedure for submission of research project for review by Ethics Committee

1. Purpose: To submit a research proposal for review by IEC-DSPMU.

2. SCOPE: Applicable to Principal Investigators (PIs) from DSPMU and PIs from Collaborating Institutions where DSPMU faculty is Co-Investigators (CoIs).

3. Responsibility: All investigators are responsible for implementing this SOP. Every protocol or amendment submitted for review to IEC must contain number, version and date. All the research proposals must be submitted in the prescribed application form, duly filled, along with all necessary documents for the review.

4. PROCEDURE:

4.1 The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IEC-DSPMU (Form No: IEC-01, 02, 03, 04 and 05).

4.2 Application can be submitted to the office of the IEC-DSPMU on any working day.

4.3 All the proposals and documents must be submitted at least two weeks in advance from the scheduled date of IEC-DSPMU meeting.

4.4 Ten print (10) copies and a soft copy to iecdspmu@dspmuranchi.ac.in of Research proposal (IEC – 02) must be submitted for Ethic Committee review along with application form duly signed and dated by the investigator (s) to IEC-DSPMU office.

4.5 Receipt of the application will be acknowledged by the IEC-DSPMU office.

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

4.7 All amendments/ changes (if any) to the approved research proposal must be submitted to the IEC immediately for its review. No changes in the protocol, and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the subject, or when the change(s) involve only logistical or administrative aspects of the study. A covering letter should be submitted mentioning reason/s for amendments and summary

of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents.

4.8 Submission of Report of Serious Adverse Events (SAEs): In case of studies involving medical intervention (e.g. blood samples etc.) all Serious Adverse Events (SAEs) at field site occurring during the study should be submitted to the IEC within seven working days of their occurrence. If the SAE is ‘death’, it should be reported to the IEC within 24 hours of its occurrence.

4. Title: Procedure for initial scrutiny of proposals

1. Purpose: To check the research proposals submitted by the investigators for completeness.

2. SCOPE: Applicable to IEC-DSPMU Office

3. Responsibility: The office of Member Secretary is responsible for implementing this SOP

4. PROCEDURE:

4.1 Every proposal will be collected and compiled by the Institute Ethics Committee office.

4.2 An office staff / member nominated by the Member Secretary / VC will verify the proposals for completeness.

4.3 In case of incomplete data, the investigators will be informed by the office after consulting the Member Secretary to make the necessary corrections and to resubmit.

5. Title: Procedure for reviewing the research proposals

1. Purpose: To review the research proposals submitted by the investigators both scientifically and ethically.

2. SCOPE: Applicable to IEC-DSPMU Office

3. Responsibility: All members of IEC are responsible for implementing this SOP.

4. PROCEDURE:

4.1 Every proposal will be sent not less than 7 days before the meeting to all members of IEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC review.

4.2 All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.

4.3 Generally, the IEC review will be done through formal meetings but if required IEC can also decide through electronic circulation of proposal.

4.4 Expert opinion of additional members would be obtained if necessary. Every proposal will be collected and compiled by the Institute Ethics Committee office.

6. Title: Procedure for expedited review of research project by Ethics Sub-Committee

1. Purpose: To provide expedited review and approval of a research proposal.

2. SCOPE: Applicable to the members of IEC-DSPMU.

3. Responsibility: All members of Sub-committee are responsible for the implementing this SOP.

4. PROCEDURE:

4.1 IEC will receive and consider the proposals for expedited review and approval for the studies having/involving:

a. No or minimum risk to the study participants.

b. Re examination of a proposal already examined by the IEC.

c. Study based only on secondary data involving no fieldwork.

e. Similar study proposal for which IEC had already given approvals earlier.

f. When urgent studies are required.

All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.

4.2 All expedited approvals will be given in a meeting of the Sub-Committee of three members **(nominated by the Chairman and VC)**. All three members including the Member Secretary should be present for the meeting.

4.3 Decision taken by the Sub-Committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the IEC.

7. Title: Procedure for decision making regarding the research project

1. Purpose: To make a decision regarding approval of the submitted research proposal.

2. SCOPE: Applicable to IEC-DSPMU.

3. Responsibility: All members of are responsible for the implementing this SOP.

4. PROCEDURE:

4.1. In making decision on application for the ethical review of any research proposal, IEC will consider the following:

4.1 Member having a conflict of interest will indicate to the Chairman prior to the review of application and same will be recorded in the minutes.

4.2 Where there is a conflict of interest, member will withdraw from the decision making procedure.

4.3 A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non members (e.g. Investigator) from the meeting.

4.4 Decision will only be taken at meetings where a quorum is complete.

4.5 Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.

4.6 Only IEC members who participated in review and discussion will participate in decision making.

4.7 Wherever possible, the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.

4.8 Decision will specify the conditional decision if any, with clear suggestions and re-review procedure.

4.9 Rejection of proposal will be supported by clearly stated reasons.

8. Title: Procedure for decision making regarding the research project involving vulnerable population *

1. Purpose: To make a decision regarding approval of the submitted research proposal.

2. SCOPE: Applicable to IEC-DSPMU.

3. Responsibility: All members of are responsible for the implementing this SOP.

4. PROCEDURE:

In making decision on application for the ethical review of research proposal involving vulnerable population, IEC will consider the following:

4.1 A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non members (e.g. PI and CoIs) from the meeting.

4.2 Decision will only be taken at meetings where a quorum is complete.

4.3Decision will be taken only after reviewing a complete application with all the required documents necessary

4.4 Decision will specify the conditional decision if any, with clear suggestions and re-review procedure.

4.5 Rejection of proposal will be supported by clearly stated reasons.

*** Pregnant women / children / elderly / fetus / illiterate/ handicapped/ terminally ill / seriously ill / mentally challenged /more than 85 year's age.**

9. Title: Procedure for the non-funded & funded project budget

1. Purpose: To harmonize fund utilization and strengthening of the infrastructure for research.

2. SCOPE: Applicable to DSPMU.

3. Responsibility: Vice chancellor & Project PI or Mentors are responsible for implementing this SOP.

4. PROCEDURE:

4.1 There would not be any processing fees or any other fees for consideration of dissertation/thesis, non-funded/ self funded project by the faculty of DSPMU.

4.2 All externally funded projects should have budget provision of IEC processing fee of 5000/-. IEC processing fee will be utilized for organizing IEC meetings and related incidental expenses.

4.3 Processing fee may be deducted after the actual realization of grant for PI serving DSPMU.

10. Title: Procedure for communicating the decision of IEC to the Investigator

1. Purpose: To communicate the decision of IEC to the applicant.

2. SCOPE: Applicable to IEC-DSPMU.

3. Responsibility: Member secretary is responsible for implementing this SOP.

4. PROCEDURE:

4.1. A decision of the IEC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken. All the approvals will be valid for only five years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after five years if necessary.

4.2. An investigator is expected to submit **reply** to the letter of recommended modifications / queries sent by the IEC, within 30 days of date of receipt of the letter. If the investigator fails to reply within this period, the file will be considered closed by the IEC and ethics clearance certificate will not be issued by IEC. The investigator will have to re-apply for the ethics committee approval.

4.3. Applicant needs to collect a certificate of approval from the IEC – DSPMU office / Member Secretary.

4.4. The communication of the decision will include:

4.4.1. Name and address of IEC-DSPMU.

4.4.2. The date of decision.

4.4.3. The name and designation of the applicant.

4.4.4. Title of the research proposal reviewed.

4.4.5. The clear identification of proposal no., version no., date, amendment no., date.

4.4.6. A clear statement of decision reached.

4.4.7. Any advice by the IEC to the applicant.

4.4.8. In case of conditional decision, any requirement by IEC-DSPMU, including suggestions for revision, and the procedure for having the application re reviewed.

4.4.9. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated. Signature of the member secretary with date.

11. Title: Procedure for follow-up of research projects by Ethics Committee

1. PURPOSE: To carry out follow-up of the research proposals.

2. SCOPE: Applicable to IEC-DSPMU.

3. RESPONSIBILITY: All members of the IEC and the investigators are responsible for implementing this SOP.

4. **PROCEDURE:**

4.1 IEC-DSPMU will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
4.2 Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC-DSPMU will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
4.3 Following instances and events will require the follow-up review:
4.4.1. Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.
4.4.2. Serious or unexpected adverse effect, action taken by Investigator, Sponsor and Regulatory Authority.
4.4.3. Any event or information that may affect the benefit/risk ratio of the study.
4.5. A decision of a follow up review will be issued and communicated to the applicant indicating modification/suspension/termination /continuation of the project.
4.6. In case of premature suspension / termination, the applicant must notify the IEC of the reasons for suspension / termination with a summary of results.
4.7. Applicant (non-thesis project) must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

12. Title: Procedure for documentation and archiving of documents and communications of IEC

1. PURPOSE: To archive the study related documents, proceedings and communications.

2. SCOPE: Applicable to IEC DSPMU.

3. RESPONSIBILITY: The Member Secretary is responsible for implementing this SOP.

4. PROCEDURE:

4.1 All the documents and communications of IEC will be dated, filed and archived in IEC office.

4.2 Only persons, who are authorized by the Chairman of IEC, will have the access to the various documents.

4.3 All the documents related to research proposals will be archived for a minimum period of 2 years in the Institute, following the completion / termination of the study.

4.4 No document (except agenda) will be retained by any IEC member.

4.5 At the end of each meeting, every member must return all the research proposals and documents to IEC office staff / member secretary. They will archive one copy in IEC office and other copies will be destroyed after two years.

4.6 Following documents will be filed and archived with proper label in on the top of file.

4.6.1 The constitution, written standard operating procedures of the IEC, and regular (annual) reports.

4.6.2 The curriculum vitae of all IEC members.

4.6.3 A record of all income and expenses if any, of the IEC, including allowances and reimbursements made to the secretariat and IEC members.

4.6.4 The published guidelines for submission established by the IEC.

4.7 Following documents will be filed and archived for easy identification of proposal.

4.7.1 The agenda of the IEC meetings.

4.7.2 The minutes of the IEC meetings.

4.7.3 One copy of all material submitted by an applicant.

4.7.4 A copy of the decision and any advice or requirements sent to an applicant.

4.7.5 All written documentation received during the follow-up.

4.7.6 The notification of completion, premature suspension, or premature termination of study.

13. Title: Constitution of the IEC of DSPMU

The following experts will constitute the Institutional Ethics Committee (40-50 %. of Committee members should be outside the DSPMU)

1 Chairman, IEC-DSPMU;
2 Member (Subject Expert);
3 Member (Subject Expert);
4 Member (Medical Expert);
5 Member (Legal Expert);
6 Member (Philosopher/Psychologist)
7 Member (Theologist / Social Worker);
8 Member Secretary Faculty (Member of the DSPMU);

From the year 2020, the following is the composition of the IEC-DSPMU Committee.

Sl. No.	Designation	Details	Qualifications
1.	Chairman	Dr. Firoz Ahmad, Ex-VC of N.P. University and Retired Prof. & Ex- HOD Zoology, RU, Ph. 9534088000, ahmadfiroz14@gmail.com	Ph. D

2.	Member (Philosophy)	Dr. Pankaj Kumar, Ex-HOD of Philosophy, DSPMU, dr.pankaj11@gmail.com Ph. 9431587424	Ph. D
3.	Member (Subject Expert)	Dr. Syed Mubarak Abbas, HOD, Anthropology, DSPMU, Ph. 9430115680 smabbas@dspmuranchi.ac.in	Ph. D
4.	Member (Subject Expert)	Dr. Ajay Kr Choudhary, HOD Zoology, DSPMU, Ph. 9955526132, choudharyajaykumar1969@gmail.com	Ph. D
5.	Member (Subject Expert)	Dr. Shalini Lal, Coordinator Microbiology, Asst. Professor of Botany, DSPMU, Ph. 7759901121, slal@dspmuranchi.ac.in	Ph. D
6.	Member (Medical Expert)	Dr. Shishir Kumar Mahato RIMS, Ranchi. Ph. 9570133474, dr.shishir.rims@gmail.com	MD
7.	Member (Medical Expert)	Dr. Vivek Goswami, (Plastic Surgery), Vivekananda Hospital, Lucknow, vivek.dr@gmail.com, Ph. 8795918050	M.Ch
8.	Member (Legal Expert)	Mr. Subhasis Rasik Soren Jharkhand High Court, Ranchi Ph. 9990666073, joharsoren@gmail.com	LLB
9.	Social Worker	Dr. Soma Singh Munda, Ex Asst. Director, Ramdayal Munda Tribal Research Institute. Ranchi, Ph. 8969728208	Ph. D
10.	Member Secretary	Dr. Sajalendu Ghosh, Asst Professor of Zoology, DSPMU, 7979006650 ghosh.sajal@gmail.com	Ph. D

14. Title: Form (IEC - 01) to be filled for submission to IEC-DSPMU 1 copy

Tick Appropriately:

Sponsor Information : 1. Indian: a) Research Councils: DBT ☐ DST ☐ UGC ☐ Other ☐ a) Government: Central ☐ State ☐ Local ☐ b) Private: Foundation Corporate	
2. International: Government Private UN agencies	
Contact Address of Sponsor: Total Budget :	

Proposal Title:		
Name, Designation & Qualifications	Address, Tel. No. Email ID	Signature
Principal Investigator (Includes Ph. D students and Post Docs)		
Co Investigator (Includes Guide/Supervisor)		
1.		
2.		
Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years). Email it to iecdspmu@dspmuranchi.ac.in		

1.Type of Study : Field based ☐ Secondary Data based ☐ Both ☐

Involved Clinical text (e.g. blood test) ☐

2. Status of Review: New ☐ Revised ☐

3. Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies :
Does the study involve use of : Drug ☐ Devices ☐ Vaccines ☐

Indian /Alternate System of Medicine ☐ Any other ☐ NA ☐

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and rationale (Attach sheet with maximum 500 words):

5. Subject selection: (Sample Size)
i. Number of Subjects :

ii. Duration of study :

iii. Will subjects from both sexes be recruited	YES	NO
iv. Inclusion / exclusion criteria given: Briefly mention:	YES	NO

Vulnerable subjects	YES	NO
Tick the appropriate boxes: pregnant women ☐ children ☐ elderly ☐ fetus ☐ illiterate ☐ handicapped ☐ Terminally ill ☐ seriously ill ☐ mentally challenged STs ☐ SCs ☐ Backward (OBCs) ☐		
6. Privacy and confidentiality: i. Study involves – Direct Identifiers: ☐ Indirect Identifiers/coded: ☐ Completely delinked: ☐		
ii. Confidential handling of data by staff	YES	NO
7. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	YES	NO
8. Is there compensation for participation? If Yes, Monetary ☐ In kind ☐ Specify amount and type:	YES	NO

9. Consent: Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	Alternatives to participation
Statement that study involves research	Confidentiality of records
Sponsor of study	Contact information
Purpose and procedures	Statement that consent is voluntary
Risks & Discomforts	Right to withdraw
Benefits	Consent for future use of biological material
Compensation for participation	Benefits if any on future commercialization

ii. Who will obtain consent? PI/Co-PI: ☐ Nurse/Counselor: ☐

Research staff: ☐ Any other: ☐

10. Risks & Benefits: i. Is the risk reasonable compared anticipated benefits to subjects /community /country?	YES	NO
ii. Is there physical / social / psychological risk / discomfort? If Yes -	YES	NO
Minimal or **no risk:** ☐		

More than minimum risk: **High risk:** ☐		
iii. Is there a benefit **a)** to the subject? Direct ☐ Indirect ☐ **b)** Benefit to society ☐		
11. Data Monitoring:		
i. Is there a plan for reporting of adverse events? If Yes, reporting is done to : Sponsor ☐ Ethics Committee ☐	YES	NO
ii. Is there a plan for interim analysis of data?	YES	NO
iii. Are there plans for storage and maintenance of study database? If Yes, for how long ?	YES	NO
12. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	YES	NO
Checklist for documents: Project proposal Curriculum Vitae of Investigators Brief description of proposal Respondent information sheet Informed Consent form Copy of advertisements/Information brochures ☐		

Place: Signature of PI/PG Student &:

Date: CO-PI/PG Guide:

15. Title: Protocol for research proposal (IEC - 2)

Prepare the proposal using MS world, Times New Roman 12 font size, with 1.0 line spacing for A4 size paper with 1 inch margin on all side. Submit the proposal to Gen. Secretary IEC-DSPMU.

1. **Title of the Project:** Indicate the appropriate title for the proposed study
2. **Principal Investigator / Ph. D Student:** Bold letters only
3. **Ph. D Guide / Co-investigator/s:** Bold letters only
4. **Subject key words:** 3-5 words
5. **Introduction:** Explain the scientific background and rationale for the investigation being proposed (100- 300 words). Mention justification for study.
6. **Research question:** Mention Study problem, Need of the study, Usefulness of the project. Will the study lead to improvements in human wellbeing and/or increase knowledge?

7. **Aims & Objective:** Mention Aims & Objectives (State specific objectives, including any pre-specified hypotheses)
8. **Sponsor details:** Source of funding & financial allocation for the project
9. **Study type:** Field based/Secondary data etc.
10. **Methodology:** Mention details methodology describing the duration of the project, setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection, potential risks & benefits, method of subject/patient accrual for study, provide Performa / questionnaire. Also provide inclusion & exclusion criteria
11. **Ethical issues:** Mention Plan / Process of obtaining informed consent / confidentiality of information / risks involved minimal? More than minimal ? - high risk? [Explain all anticipated 'risks' (adverse events, injury, and discomfort) of the project & efforts taken to minimize the 'risks'] / Report of adverse event/ Policy regarding treatment of study related injury/ Policy regarding dissemination of data, presentation of data, publication.
12. **Statistical methods to be applied:** Use of SPSS / R / other statistical method etc.
13. **Expected results & Conclusion:** Brief about results of similar studies, benefits of study, analysis and whether it is of national significance with rationale
14. **Reference:** Provide as per standard journal requirement

16. Title: RESPONDENT INFORMATION SHEET (RIS, IEC - 3)

Investigator must provide the subjects/respondents with the following information in simple **understandable layman's language in English / Hindi /** Other regional language which can be understood by them:

1. Title of the study / project.
2. Aims and methods of the research.
3. Expected duration of the subject participation.

4. The benefits to be expected from the research to the subject or to others.

5. Any risk to the subject associated with the study.

6. Maintenance of confidentiality of records.

7. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.

8. Where applicable, amount of blood sample to be taken should be mentioned.

9. Telephone number/contact number of the candidate and one of the investigators must be mentioned.

10. Self certification should be given that translation to vernacular is accurate.

17. Title: Respondent Informed Consent Form (RICF, IEC - 04)

Title of project: ……

Name of Principal Investigator: ……Tel.No(s)……..

The contents of the respondent information sheet (RIS) dated ……. that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions. The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

I understand that the information collected about me from my participation in this research may be looked at by responsible individuals from the institute. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

(Signatures / Left Thumb Impression)

Date:

Place:

Name of the Respondent: ……..

This is to certify that the above consent has been obtained in my presence

Witness:

Date:

Place:

18. Title: Checklist for the submission of project proposal (IEC-05)

Title of Project	
Principle Investigator	
Date of Submission	

Sl. No	**Document**	**YES/NO/NA**	**Submission date**
1.	Project submission application form duly filled IEC-01		
2.	Protocol as per the format IEC-02		

3.	IEC-01, 02, duly signed by the PhD-student/ investigator(s), guides, co-guides and Head of concerned departments, with date?		
4.	Information sheet & consent in English IEC-03		
5.	Information sheet & consent in Regional language/Hindi		
6.	Consent form appropriately worded for adults and children (less than 18 years) e.g. Instead of 'my participation', 'my child's/ward's participation' to be replaced		
7.	Complete address and phone number of the investigator/guide provided in the appropriate place in consent form		
8.	Case record form / Questionnaire/ Performa		
9.	Others as per requirement of project *** Administrative sanction** from the Head of the Institution should be sought by investigators for studies involving collaboration with other Indian or foreign institution / University.		

19. Title: Reviewer Form

Title of the Project				
Principle Investigator/ Ph. D Scholar/ Others				
IEC-DSPMU No. Date				
DETAILS		**YES**	**NO**	**NA**
Is all the documentation provided?				
Scientific importance and validity				

1. Will the study lead to improvements in human health or increase knowledge?			
2. If the study is a replication of a previous study, is it justified?			
3. Can the intervention studied be practically implemented?			
4. Are the objectives stated clearly?			
5. Is the study design appropriate in relation to the objectives?			
Assessment of Risks / Benefits			
1. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?			
2. Is the justification of predictable risks and inconveniences weighted against anticipated benefits for the participant adequately?			
Notes if any:			
3. Have adequate provisions been made for dealing with and reporting adverse effects?			
4. Have adequate provisions been made for safety monitoring and termination of the research project?			
Respect for the dignity of the research participants			
Informed consent			
1. Is the process for obtaining informed consent appropriate?			
2. Are the participants competent to give consent?			
3. Will dissent be respected?			
4. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?			
5. Is the consent given voluntarily and not due to deception, intimidation or inducement? (**Deception**: dishonesty/trick/fraud,			
Intimidation: pressure, **Inducement**: incentive/encouragement)			
Confidentiality			
1. Will the researcher collect only the minimum information/samples required to fulfill the study objectives?			
2. Is the privacy of the research participant safeguarded?			
3. Are data/sample storage and disposal procedures adequate?			
Rights of the participants			
1. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?			
2. Is there provision for participants to be informed about newly discovered risks or benefits during the study?			

3. Is there provision for the subjects to be informed of results of clinical research?			
Fair participant selection			
1. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?			
2. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized?			
3. Is the research conducted on vulnerable individuals or groups?			
4. Is the research a community research?			
5. Is the research a clinical trial?			
Responsibilities of the researcher			
1. Has the researcher obtained permission from the relevant authorities?			
2. Are there any conflicts of interest, including payments and other rewards?			
3. Are there any other ethical / legal/ social /financial issues in the study?			
4. Budget: Acceptable?			

Additional Comments:

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Recommendation: **Approve** [ ] **Reject** [ ] **Conditional Approval** [ ] (please state the conditions):

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Name of Reviewer:

Signature:

Date: