Institutional Ethics Committee (IEC)

Jamia Millia Islamia

Guidelines for submission of projects involving research on human participants to Institutional Ethics Committee (IEC), JamiaMilliaIslamia for ethical clearance.

All the proposals for ethical clearance should be submitted to the Member Secretary, IEC along with the following documents.

1. **One original set of IEC annexures (hard copy) consisting of**
   - i. Research proposal.(photocopy)
   - ii. Cover Letter duly forwarded by Head of the Department
   - iii. The Summary Performa (Annexure II).
   - iv. Subject Information Sheet and Consent Form (SISCF) for patients in English and Hindi/local language (Annexure III). Please ensure that Hindi translation is in language for the common person.
   - v. The Hindi translation must be certified as accurate by appropriate authority.
   - vi. Subject Information Sheet and Consent Form (SISCF) for controls in English and Hindi/local language (Annexure IV). Please ensure that Hindi translation is in language for the common person.
   - vii. Self-certification that a certified Hindi/local language translation of Subject Information Sheet and Consent Form is being submitted.
   - viii. Clinical Performa.
   - ix. Self-certification that no work has started.
   - x. Self-certification that work will be done according to ICMR/GCP guidelines.
   - xi. Brief Curriculum Vitae (1-2 pages) of the Principal Investigator and Co-Investigators.
   - xii. Any other information relevant to the study
   - xiii. Signed checklist of the submitted documents

2. Soft copy of the documents i, iii, iv, vi, viii, xii of Point No 1 above to be mailed to ksircar@jmi.ac.in
3. **Nine sets (photocopies) of** iii, iv, vi, viii, xii of Point No 1 above

Please note the following:

1. **All documents must be signed by the Principal Investigator**
2. **All applications to the IEC must be forwarded through the Head of the Department/ Centre.**
3. **The registration letter of the student should be attached to all applications submitted to IEC.**

   All student applications like the ICMR STS or SRF must have student names and signatures
4. **The hard copies as required may be submitted in Room No 302 , Faculty of Dentistry. The soft copes as required should be sent by email to ksircar@jmi.ac.in**

5. **A short Powerpoint presentation of 10-15 slides (6-8 minutes) of the research proposal will have to be made by PI/ research scholar/ student researcher on the day of the meeting. The date for submission of the PPT will be intimated later.**

Institutional Ethics Committee (IEC)

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Annexure II (Summary Performa)

Performa for submission of projects involving research on human participants for ethical clearance.

Title of the project:
Name, designation & address of the Principle Investigator:
Name, designation & address of the Co- Investigator 1:
Name, designation & address of the Co- Investigator 2:
Collaborating Institute /University/Hospital:
Objectives of the study:
Funding agency:
Duration of the project:
Nature of disease:
Place of sample collection for patients:
Place of sample collection for controls:
Type of clinical sample:
Number of patients:
Age and gender of patients:
Inclusion and exclusion criteria for enrolment of patients:
Number of controls:
Age and gender of controls:
Inclusion and exclusion criteria for enrolment of controls:
Volume/quantity of clinical samples:
Frequency of sample collection:
Duration of sample collection:
Safety measures forproposed study:
Confidentiality of study subjects:
Consent form in English and Hindi/local language:
Has the project been submitted to other Committee/Institution for ethical clearance:
If yes give the status of ethical clearance:
Other remarks:

Signature of the Principal Investigator: Date:

Note: 1) Submit 9 copies of the Summary Performa duly signed by the Principal Investigator.

2) Use additional sheets if needed.

Institutional Ethics Committee (IEC)
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Annexure III (Subject Information Sheet and Consent Form for <u>patients</u>)

Title of the project:
Site of the investigation:
Name and address of the Principal Investigator:
Contact number of Principal Investigator:

1. Aims and methods of the research (A brief introduction about the investigation along with purpose of the study and procedure of investigation involving human subjects in simplified manner (10-15 lines).
2. Expected duration of the subject participation.
3. The benefits to be expected from the research to the subject or to others.
4. Alternative treatment/procedure options.
5. Right to prevent use of biological samples (DNA, cell line etc.) at any time during the research.
6. Any risk to the subject associated with the study.
7. Maintenance of confidentiality of records.
8. Provision of free treatment for research related injury.
9. Compensation of subjects for disability or death resulting from such injury.
10. Freedom of individual to participate or to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
11. Amount of clinical sample in quantity, to be taken should be mentioned.
12. Source of funding for the Investigation.
13. In case of drug trials:
    a) The chemical name of drug, date of its manufacturing and batch number must be mentioned.
    b) Initial bio equivalent study of the drug/references should be provided
14. Foreseeable extent for information on possible current and future usage 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, clear mention of the same.
15. Risk of discovery of biologically sensitive information.
16. Publication, if any, including photographs and pedigree charts.
17. Responsibility of Investigators.

Consent

1. I agree voluntarily to take part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I am free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.

6. I agree that I will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if I am harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use.

I willingly agree to take part in the above study.

Signature of the participant/guardian Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.

Signature page for research involving children ages birth to 6 years of age or unable to provide assent for other reasons

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child's medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use

I willingly agree that my child will take part in the above study.

Allow Do not allow

Signature of the parent/guardian Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Waiver of assent

The assent of ---------- (name of child/minor) was waived because of:

Age:
Maturity:
Psychological state of the child:

Signature of the Parent/Legally authorized representative: Date:

Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.

Signature page for research involving children ages 7 through 17 years of age and able to provide assent

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child's medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use

I willingly agree that my child will take part in the above study.

Signature of the parent/guardian Date:

Assent of child
---------- (name of child/minor) has agreed to participate in above study

Signature of the child Date:

Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.

Institutional Ethics Committee (IEC)

Jamia Millia Islamia
Annexure IV (Subject Information Sheet and Consent Form for <u>controls</u>)

Title of the project:
Site of the investigation:
Name and address of the Principal Investigator:
Contact number of Principal Investigator:

1. Aims and methods of the research (A brief introduction about the investigation along with purpose of the study and procedure of investigation involving human subjects in simplified manner (10-15 lines).
2. Expected duration of the subject participation.
3. The benefits to be expected from the research to the subject or to others.
4. Alternative treatment/procedure options.
5. Right to prevent use of biological samples (DNA, cell line etc.) at any time during the research.
6. Any risk to the subject associated with the study.
7. Maintenance of confidentiality of records.
8. Provision of free treatment for research related injury.
9. Compensation of subjects for disability or death resulting from such injury.
10. Freedom of individual to participate or to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
11. Amount of clinical sample in quantity, to be taken should be mentioned.
12. Source of funding for the Investigation.
13. Foreseeable extent for information on possible current and future usage 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, clear mention of the same.
14. Risk of discovery of biologically sensitive information.
15. Publication, if any, including photographs and pedigree charts.
16. Responsibility of Investigators.

Consent

1. I agree voluntarily to take part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I am free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that I will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.

8. I agree that if I am harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use.
10. I have been explained that I am being enrolled in the present study as a **control**.

I willingly agree to take part in the above study.

Signature of the participant/guardian Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.

Signature page for research involving children ages birth to 6 years of age or unable to provide assent for other reasons

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child's medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use

I willingly agree that my child will take part in the above study

Signature of the parent/guardian Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Waiver of assent

The assent of ---------- (name of child/minor) was waived because of:

Age:
Maturity:
Psychological state of the child:

Signature of the Parent/Legally authorized representative: Date:

Signature page for research involving children ages 7 through 17 years of age and able to provide assent

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child's medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree / do not agree that the biological samples collected during this study may be stored for future use

I willingly agree that my child will take part in the above study.

Signature of the parent/guardian Date:

Assent of child
---------- (name of child/minor) has agreed to participate in above study

Signature of the child Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.

Proposal No .....(to be filled by office)

Checklist of submissions to the Institutional Ethics Committee, JMI

Date of submission:

Title of proposal:

Name and Institute of Principal Investigator:

Names of Co investigators with institute

(i)

(ii)

S. No	Document	Submitted	Not submitted
1.	Covering letter forwarded by HOD		
2.	Student registration letter		
3.	ICMR JRF/ SRF applications with student names		
4.	Research proposal (hard copy)		
5.	Research proposal (soft copy)		
6.	Summary proforma (soft copy)		
7.	Summary proforma (7 copies)		
8.	Subject information sheet for patients (soft copy)		
9.	Subject information sheet for patients(7 copies)		
10.	Subject information sheet for controls (soft copy)		
11.	Subject information sheet for controls (7 copies)		
12.	Consent from parent/guardian in case of persons below birth to 6 yearsyears. (7 copies where applicable)		
13.	Assent form from parent/guardian in case of persons below 7 to 17 years. (7 copies where applicable)		
14.	Certified Hindi translation of subject information sheet for patients (7 copies)		
15.	Certified Hindi translation of subject information sheet for controls (7 copies)		
16.	Self-certification that Hindi/local language translation of Subject Information Sheet and Consent Form is true version of the corresponding English form. (7 copies)		
17.	Self-certification that no work has started. (7 copies)		
18.	Self-certification that work will be done according to ICMR/GCP guidelines. (7 copies)		
19.	Brief Curriculum Vitae (1-2 pages) of the Principal Investigator and Co-Investigators. (1 copy)		
20.	Signed checklist of the submitted documents		