Appendix 1

Title Page

For submission of Research proposal to Institutional Ethics Committee of MIMER MEDICAL COLLEGE

1. **Full Name of UG/PG Student/ Faculty (Start with Surname):**
2. **Department:**
3. **Candidate admitted in the year:**
4. **Course and subject:**
5. **College Name & Address:**
6. **Title of Research Project topic:**
7. **Full name of Guide:**
8. **Contact phone number of UG/PG Student/Faculty**

Soft copy to be mailed to: research@mitmimer.com

"**Subject**: Research Proposal & Name of PI"

Check-List Enclosures

1. Title Page (Appendix 1)

2. Research Proposal

    2.1 General information (Appendix 2)

    2.2 One-page summary (Appendix 2 A)

    2.3 Detailed plan (Appendix 3)

3. Participant related information (Appendix 4)

4. Informed Consent form (Appendix 5)

    4. a English

    4. b Hindi

    4. c Marathi

5. Participant Information sheet (Appendix 6)

6. Certificate from HOD (Appendix 7)

Appendix 2

For submission of Research proposal to Institutional Ethics Committee of MIMER MEDICAL COLLEGE

GENERAL INFORMATION

1. Title of the Project:
2. Name of UG/PG Student/ Faculty:
3. Name, Designation & Department of Guide:
4. Name, Designation & Department of Co-Guide:
5. Duration of the Project:

a) Period that may be required for data collection :

b) Deadline for collecting data :

c) Period that may be required for analysis of data :

d) Deadline for analysis of data :

6. SIGNATURES:

a. UG/PGSTUDENT/FACULTY:

b. GUIDE:

c. CO-GUIDE:

d. HEAD OF DEPARTMENT (PARENT/CONCERNED):

e. HEAD OF DEPARTMENT (OTHER INVOLVED):

Appendix 2A

One-page summary

1. Title
2. Introduction
3. Aims and objectives
4. Materials and methods
5. Study implications

(Total word limit 250 words)

Appendix 3

Details of Research Project

1. **Title**
2. **Introduction** (including need of the study, purpose & background justification)
3. **Aims and Objectives**

   3.1 Overall Aim

   3.2 Specific objectives

4. **Materials and Methods**

   4.1 Study setting:

   4.2 Study design:

   4.3 Sample size, sample type and sampling procedure:

   4.3.1 Justification of the sample size

   4.4 Subject selection

   4.4.1 Inclusion criteria:

   4.4.2 Exclusion criteria:

   4.5 Materials:

   4.5.1. Variables studied

   4.5.2. Primary outcome variable

   4.5.3 Secondary outcome variable

   4.5.4 Instruments/questionnaires used for data collection

   4.6 Detailed research plan:

   4.6.1 Data collection procedure:

   4.6.2 Cost involved

   4.6.3 Who is going to bear the cost?

   1. Patient. 2. Investigator(s). 3. Exempted. 4. Other Agencies (Name)

5. **Statistical analysis**
6. **Study implications**
7. **References**

Appendix 4

Participant related information

(write - YES/NO or TICK ✓ OR X wherever applicable)

1. Type of participants in the study:

Healthy volunteer		Patient		Vulnerable persons/ Special groups	

Others (Specify) .....

2. Who will do the recruitment?

……

3. Participant recruitment methods used:

Posters		leaflets/Letter		TV/ Radio advts		Phone	
Social media/ Institution website		Patients / Family/ Friends:		Visiting hospitals:		Others (Specify)	

4. Will there be vulnerable persons / special groups involved?

YES		NO		N/A	

5. If yes, type of vulnerable persons / special groups

Children under 18 yrs.:		Pregnant or lactating women:	
Differently abled (Mental/Physical):		Employees/Students/Nurses/Staff:	
Elderly:		Institutionalized:	
Economically and socially disadvantaged		Terminally ill, stigmatized or rare diseases	
Refugees/Migrants/Homeless		Any other (Specify) :	

6. Are there any anticipated physical/social/psychological discomforts/ risk to participants?

YES		NO		N/A	

7. Are adverse events expected in the study?

YES		NO		N/A	

8. Is there any reimbursement to the participants?

YES		NO		N/A	
Monetary		Details :			
Non-monetary					

9. Are there any incentives to the participants?

YES		NO		N/A	
Monetary		Details :			
Non-monetary					

10. Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

YES		NO		N/A	
Monetary		Details :			
Non-monetary					

Appendix 5

INFORMED CONSENT FORMS

A. INFORMED CONSENT FORM (English)

I, Mr. /Mrs. _____, age _____ years residing at_____
hereby give my informed consent to participate in the
"……..' project.

1. There is no compulsion on me to participate in this project and I am giving my free consent for it.

2. I am ready and willing to undergo all tests and treatments in the present project.

3. I have read and I have been explained the general information and purpose of the present project.

4. I have been informed / I have read the probable complications while participating in

the present project.

5. I know that I can withdraw from the present project at any time.

6. Any data or analysis of this project will be purely used for scientific purpose and my

name will be kept confidential except when required for any legal purpose.

7. I can read English / I can understand data read out to me in English.

Date:

Signature of subject Signature of Principal Investigator

- **Please note these are sample consent forms please customize according to your proposal also prepare customised patient information sheet**.

B. INFORMED CONSENT FORM (Hindi)

स्वीकृति प्रपत्र मैं डॉ _____ हूं| हम आपसे निवेदन करते है की आप इस अध्ययन मैं भाग ले|

इस अध्ययन में शामिल लोगों के अलावा आपकी सभी जानकारी गोपनीय रखी जाएगी |

इस अध्ययन में आपको किसी भी मूल्यांकन और उपचार प्रक्रिया के दौरान कोई नुकसान नहीं होगा।

आपको यह पता होना चाहिए:

- अगर आप नहीं चाहते हो तो आपको इस संशोधन में शामिल नहीं होना चाहिए।
- आप किसी भी समय इस अध्ययन में होने से रुक सकते है।
- अगर आपको बाद में कोई सवाल पूछना है, तो आप मुझे इस नंबर पर संपर्क कर सकते हैं। (संपर्क नंबर :_____)
  इस फॉर्म पे हस्ताक्षर करें :
- अगर आप समझ गए हो के आपको इस अध्ययन के लिए क्या करना होगा।
- अगर आपको आपके सभी सवालों के जवाब मिल गए है।
- अगर आप इस अध्ययन में सहभागी होने के लिए अपनी सहमति देते हो ।

तारीख :

नाम : हस्ताक्षर:

शोधकर्ता का नाम:

- **Please note these are sample consent forms please customize according to your proposal also prepare customised patient information sheet**

C. INFORMED CONSENT FORM (Marathi)

संमती पत्र

मी डॉ . ……. .मी तुम्हाला विनंती करते की, तुम्ही ह्या संशोधनात सहभागी व्हावे. .तुमची माहिती गुप्त ठेवण्यात येईल .ह्या संशोधनामध्ये काम करणारे फक्त हि माहिती बघू शकतात . संशोधनाच्या तपासणी आणि उपचार दरम्यान तुम्हाला कोणत्याही प्रकारची इजा होणार नाही. ह्या संशोधनात तुम्ही सहकार्य केल्याने तुम्हाला चांगले वाटेल

तुम्हाला हे माहिती असायला हवे –

- तुमची इच्छा नसल्यास तुम्ही ह्या संशोधनात सहभागी होऊ शकत नाही.
- तुम्ही ह्या संशोधनातून केव्हाही बाहेर पडू शकता
- तुम्हाला कोणतेही प्रश्न पडल्यास तुम्ही आता किंवा नंतर विचारू शकता .
- हे पत्रक तुम्ही सही करा ,जर –
- ह्या संशोधनात तुम्हाला काय करायचे आहे हे समजले आहे
- तुमच्या सगळ्या प्रश्नांची उत्तरे तुम्हाला मिळाली आहेत

ह्या संशोधनामध्ये भाग घेण्यासाठी तुम्ही तयार आहेत

दिनांक

संशोधकाचे नाव ,सही

सही

❖ **Please note these are sample consent forms please customize according to your proposal also prepare customised patient information sheet.**

Appendix 6

PARTICIPANT INFORMATION SHEET (PIS)

GUIDELINES FOR DESIGNING PARTICIPANT INFORMATION SHEET

1*. Study Title.*

2. Aim and methods of the research study.

3. Expected duration of participation.

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

5. Description of Diagnostic Test/ Procedure that the participant will be subjected to in layman's language

6. Any risk or discomfort to the participant associated with the study.

7. Your records will be strictly confidential

8. Provision of free treatment for research related injury.

9. Compensation of subjects for disability or death resulting from such injury.

10. Amount of blood sample (quantity in tea spoon full) to be taken.

11. Costs and source of investigations, disposables, implants and drugs/ contrast media.

12. In case of a drug trial: a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned.

13. You are free to withdraw from research at any time without penalty or loss of benefits to which the you would be entitled otherwise.

Telephone number/ contact number of Principal investigator and Co-Investigator

Contact number of the head of the institute (in case of complaints)

Appendix 7

CERTIFICATE from HOD

For submission of Research proposal to Institutional Ethics Committee of MIMER MEDICAL COLLEGE

Date:

This is to certify that Research Proposal titled

……

……

Principal Investigator:

……

was submitted to the department for review.

Discussions on the various technical considerations pertaining to the specialty was made and necessary inputs were given wherever necessary.

There are no major ethical violations in the proposal, to the best of my knowledge.

Signature :

Name of Head of Department :

Department :

Institute :