**Title: - XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX**

**PLAN OF THESIS**

# FOR APPROVAL OF THE SUBJECT OF THESIS

**TO BE SUBMITTED IN PARTIAL FULFILMENT OF REQUIREMENTS FOR THE DEGREE OF**

**MASTER OF Name of the DEPARTMENT**



**Student Name: XXXXX**

**Batch: 202X-202Y**

**Course: MD/MS/MSc/PhD**

**Email:**

**Phone no:**

**Name of the Guide: XXXX**

**Name of the DEPARTMENT**

**HAMDARD INSTITUTE OF MEDICAL SCIENCES & RESEARCH**

**NEW DELHI**

Department of XXXXX

Hamdard Institute of Medical Sciences & Research

New Delhi-110062

Research Protocol for submission of thesis for the award Of

**MASTER OF Name of the DEPARTMENT**

Batch **202X-202Y**

Title: - XXXXX

Submitted by: **Student Name (Sign)**

Email: xxxx

Phone no:

**SUPERVISOR**

 **Name of the Guide: (Sign)**

Designation

Department

HIMSR, New Delhi, India

Email: xxxx

Phone no

# CO-SUPERVISOR CO-SUPERVISOR

# Name of the Guide: (Sign) Name of the Guide: (Sign)

Designation Designation

Department Department

HIMSR, New Delhi, India HIMSR, New Delhi, India

APPLICATION FORM FOR APPROVAL OF SUBJECT OF THESIS FOR M.D.

COMMUNITY MEDICINE

HAMDARD INSTITUTE OF MEDICAL SCIENCES & RESEARCH

|  |  |  |
| --- | --- | --- |
| 1. | Name of candidate | XXXXX |
| 2. | Father’s Name. | XXXXX |
| 3. | Mother’s Name | XXXXX |
| 4. | Correspondence address of thecandidate | XXXXX |
| 5. | Month and year of passingM.B.B.S. examination. | XXXXX |
| 6. | Name of the University fromwhich graduated | XXXXX |
| 7. | Present designation/posting | XXXXX |
| 8. | Date of joining PG course. | XXXXX |
| 9. | Likely date of appearing for PGexamination | XXXXX |
| 10. | Proposed subject of thesis. | XXXXX |
| 11. | Facilities for the subject of thesis | Available |
| 12. | Name and designation of the supervisor. | XXXXX |
| 13. | Name and designation of the Co- supervisor | XXXXX |

Date:

Place: Signature of the candidate

# CERTIFICATE OF CONSENT OF SUPERVISOR & CO-SUPERVISORS AND AVAILABILITY OF FACILITIES FOR WORK

It is certified that facilities for the work on the subject of the thesis entitled “XXXXXXXX XXXXXXXXXXXXXXXXX” do exist in the Department of xxxxxx Hamdard Institute of Medical Sciences & Research and will be provided to the candidate. I/We will see that the data being included in the thesis are genuine and is collected by the candidate himself/ herself under our supervision and guidance.

It is further certified that the research work on the subject of thesis has not been carried out earlier in this institution.

Name and designation of the supervisor:

**Name (Sign)**

Designation

Department

# Certificate from Head of the Department

To

The Coordinator,

P.G. Academics

Hamdard Institute of Medical Sciences & Research, New Delhi

Respected Sir,

The thesis plan submitted by XXXXXXX titled “XXXXXXXXXXXXXXXXXXXXXX” has been discussed and approved in the meeting held in Department of XXXXXX, Hamdard Institute of Medical Sciences & Research, New Delhi.

Facilities for the subject of thesis exist in the department and will be provided to the candidate. It is further certified that the research work on the subject of thesis has not been carried out earlier in this institution.

I forward this plan of thesis for your kind approval and necessary action Thanking you.

Place: New Delhi

**(Sign)**

XXXXXXX

HOD of the Department

HIMSR

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# TITLE: XXXXXXXXXX

# INTRODUCTION

# 1.1 Introduction:

# 1.2 Review of literature:

# 1.3 Background:

# 1.4 Problem:

# Rationale:

# PROTOCOL REQUIREMENTS

The thesis protocol should be restricted to the following word limits:

Title : 120 characters (with spacing)

Introduction : 300-500

Review of literature : 800-1000

# Objectives:

# PROTOCOL REQUIREMENTS

The thesis protocol should be restricted to the following word limits:

Aim and Objectives : Up to 200 words

Should be explicit and self-explanatory

Ideally SMART: Specific, Measurable, Achievable, Relevant, and Time-bound

Material and Methods : 1200-1600

References : 10-25 **[Vancouver or ICMJE style]**

# METHODOLOGY

# 3.1 Study design:

# 3.2 Study setting:

# 3.3 Study population:

**Inclusion criteria:**

**Exclusion criteria:**

# 3.4 Sample Size:

# 3.5 Sampling technique:

# 3.6 Study duration:

# 3.7 Study Tools:

# 3.8 Study Variables:

**Outcome (dependent) variable:**

**Exposure (independent) Variables:**

# 3.9 Data collection:

# 3.10 Operational Definitions:

# 3.11 Statistical analysis

# 3.12 Implications

# 3.13 Limitations

# 3.14 Data Management

* **Data Entry:** including double-entry or data validation procedures
* **Data Cleaning:** identifying and correcting errors in the data
* **Data Validation:**  data accuracy and completeness
* **Data Storage & Security:**  e.g., secure server, cloud storage, access controls, encryption, and backup procedures
* **Data Sharing:** Open access / Restricted access / Classified / No access data
* **Data Dissemination:**  publications, presentations
* **Data Retention & Archiving:** No of years (2-10 years) or long-term preservation

# ETHICAL CONSIDERATIONS

The study will be conducted following the principles outlined in the Declaration of Helsinki and National Ethical Guidelines for Biomedical and Health Research Involving Human Participants given by the Indian Council of Medical Research. The following points will be taken into consideration and will be adhered to:

* The study shall be conducted on -----. The study plans to investigate --.
* Description of intervention planned in the study (if any): -----
* Each patient will be adequately informed of the aims, methods, the anticipated benefits and the potential risks of the study and discomfort it may entail to him/her and the remedies thereof.
* Every precaution will be taken to respect the privacy of the patient, the confidentiality of the patient’s information and to minimize the impact of the study on his/her physical and mental integrity and his/her personality.
* Written informed consent will be taken from all the patients/participants included in the study. The patient will be given the right to abstain from participation in the study or to withdraw consent to participate at any time of the study.
* Due care and precaution will be taken at all stages of the research to ensure that the patient is put to the minimum risk, suffer from no irreversible adverse effects and generally benefit from and by the research. Standard treatment will not be withheld from the study participants. If any adverse events are noted, these will be notified to the IEC as per national guidelines.
* **The study participant will not bear any extra cost for participation in the study.**
* The participants would be informed in their local language (Hindi/English) about the study and will be assured that all details will be kept confidential.
* Purpose of the research will be explained to the person in lay terms avoiding words which are overly scientific or are professional jargon.
* If the participant is illiterate, the thumb-print of the participant will be taken in the presence of the witness.
* A copy of the participant information sheet and informed consent will be handed over to the participant.
* Good Clinical Practices will be followed.
* Ethical approval will be obtained from the Institutional Ethics Committee of Hamdard Institute of Medical Sciences and Research before the start of the study.

# REFERENCES:

* APA

Or

* Vancouver
* It is suggested to use reference management software – Mendeley, Zotero, endnote, etc.

# Annexure I

# Part I - Participant Information Sheet

## Introduction with Title of the project

xxx

## Name of the student and department

xxx

## Name of guide and co-guides and their and departments

xxx

## Purpose of this study

xxx

## Procedure/methods of the study

xxx

## Expected duration of the subject participation

xxx

## The benefits to be expected from the research to the participant or to others

xxx

## Any risks expected from the study to the participant

xxx

## Maintenance of confidentiality of records

xxx

## Provision of free treatment for research related injury

xxx

## Compensation for participating in the study

xxx

## 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

xxx

## 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

xxx

## Address and mobile number of the investigator

xxx

## Contact details of IEC

In case of any query, you can contact member secretary IEC, B-16, Department of Community Medicine. Email: iec-himsr@himsr.co.in

(Signature of the investigator)

Date:

# Annexure II

**Part II - Certificate of Consent**

**Title of the project**:

**Unique Case ID: HIM/** \_\_\_ \_\_\_ \_\_\_ **/** \_\_\_\_\_\_

 I have read the foregoing information, or it has been read to me and **understand** the contents. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent **voluntarily** to participate as a participant in this research. I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

**Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** S/W/D/O**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Resident of**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Day/month/year

**Statement by the person taking consent**

**If illiterate**

A literate witness must sign. Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

**Name of witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of participant**

**Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**



**Date** Day/month/year **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the study procedure.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Inform consent form has been provided to the participant.

**Name of Researcher/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Researcher /person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Day/month/year

**Part I - Participant Information Sheet in HINDI to be attached**

**Part II - Certificate of Consent in – HINDI to be attached**

## **Annex III. Study questionnaire / Tool**

# Checklist for Student Protocol Submission

(only for thesis protocols, not for faculty/other research projects)

All the following requirements are fulfilled:

 Signed by all the guides and co-guides

 Signed by the candidate

 Ethical justification on a separate page immediately after methods. Should mention the following:

 Will follow the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants given by ICMR in 2017

 Benefits and risks of participation in the study

 How the risks will be minimized

 How adverse events will be monitored and reported to IEC

 The study participant will not bear any extra cost for participation in the study

* Patient information sheet (or Parent information sheet if study participant is minor)

 English, Hindi

 In IEC format (English format given below)

 Hindi translations - fonts and write-up should be legible. Do check the font in hard copy

 In simple language with no use of medical terms

 Should clearly explain the study procedure to the study participant including amount and frequency of sampling, follow-up visits etc.

 Should mention that “You will not bear any extra cost for participation in the study”

 Patient Informed consent form

 English

 Hindi formats - fonts and write-up should be legible

 Child assent form if study participant age is >7 years and <18 years (format given)

 Questionnaire

# DRAFT Part I - Participant Information Sheet

**Hamdard Institute of Medical Sciences and Research and HAH Centenary Hospital**

**Title: XXXXXXXXXXXXXXX XXXXXXXXX**

# Introduction

I, xxxxxxxxxx, working at Hamdard Institute of Medical Sciences and Research, would like to inform you that we are conducting a study on “**XXXXXXXXXXXXX”**. You are invited to take part in this research. Before you decide, it is important for you to understand why this research is being done and what participation in the study will involve. Please take your time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Thank you for reading this.

# Purpose & Duration

I am trying to assess -state objective here in local language.

The research will be conducted for a period of xxxxxxxxxx

# Selection of Participants

I am selecting people xxxxxxxxxx

# Procedure

# xxxxxxxxxx xxxxxxxxxx xxxxxxxxxx xxxxxxxxxx

# Benefits

Once the interview and examination are over, appropriate advice will be offered to you. I will counsel you in case there is a scope for improvement or steps to take for the better health of your child.

# Confidentiality & Sharing of Research Findings:

The information that we collect from this research project will be kept strictly confidential. All the information collected will be stored in a secure place during the study period and after the period of 3 years, it will be destroyed. In case you are interested in the result of the study, please contact the investigator. At the end of the study, we will publish the results in order that other interested people may learn from this research. You will not be identified individually in any report or publication.

# Right to refuse or withdraw:

You may choose not to participate in this study if you do not wish to do so. You may stop participating in the discussion/interview at any time that you wish.

In case you have complaints regarding your treatment by the researchers, you may contact the guide for the research, i.e., XXXXXXX . However, if you still feel that your complaint has not been handled to your satisfaction, you can contact the Chair of the Internal Ethics Committee of HIMSR, New Delhi.

You will be given a copy of this information sheet and a consent form that you will sign, provided you decide to take part in the study. A copy of the signed consent form will be given for you to keep.

Thank you for your participation and time.

# Whom to Contact

If you have any questions, you may contact me : xxxxx Name of PI

Department,

Phone number: 9999999999

Email ID: yyyyyyyy@gmail.com

# DRAFT ASSENT FORM

### (for children above 7 years and below 18 years of age)

**Title of the project:**

Child Participant’s name: Date of birth/Age:

Parent/LAR’ 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 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: