

**Hamdard Institute of Medical Sciences and Research and HAHC Hospital, New Delhi, India**

**Title: - …………………………………………………**

**Principal Investigator:**

**Name (Sign)**

Designation

Department

Hamdard Institute of Medical Sciences and Research (HIMSR),

New Delhi, India

Email: xxxx

Phone no:

**Co-Investigators:**

1. **Name (Sign)**

Designation

Department

Hamdard Institute of Medical Sciences and Research (HIMSR),

New Delhi, India

Email: xxxx

Phone no:

1. **Name (Sign)**

Designation

Department

Hamdard Institute of Medical Sciences and Research (HIMSR),

New Delhi, India

Email: xxxx

Phone no:

# Summary / Abstract

# Title : …………………………………………………………

**Background:**

**Problem and rationale**

**Objective:**

**Methods:**

**Implications:**

# Title : xxxxxx xxxxxxxx xxxxxxxxx

# INTRODUCTION

# 1.1 Introduction:

# 1.2 Review of literature:

# 1.3 Background:

# 1.4 Problem:

# 1.5 Rationale:

# Objectives

**1.**

**2.**

**3.**

# 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:

**Procedures**

# 3.10 Operational Definitions:

# 3.11 Data management:

**Data Quality – Validation, Monitoring**

**Data entry & Cleaning**

**Data Storage & Security**

**Data Sharing:** Open access / Restricted access / Classified / No access data

**Data Archiving**

# 3.11 Statistical analysis

**Statistical Methods**

**Data Analysis Software**

**3.12 Ethical considerations**

**Privacy and data confidentiality**

**Risks & Benefits**

**Dissemination**

**Conflict of interest**

# 3.12 Implications

# 3.13 Limitations

# 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](mailto:iec-himsr@himsr.co.in)

(Signature of the investigator)

Date:

**Part II - Certificate of Consent**

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

**Title: ……………………………**

**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**

# 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:

## Annex 2.

## Study questionnaire / Tool

**Check List for Protocol Submission**

**Check List of Documents for Protocol Submission to Institutional Ethics Committee to be filled in by study team.**

\* Compulsory documents

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SN** | **Document** | **Yes** | **No** | **NA** | **Comments** |
|  | \*Cover Letter to Member Secretary/ Chairperson. |  |  |  |  |
| 1 | \*Project Protocol in prescribed format |  |  |  |  |
| 2 | \*Summary/Abstract of protocol (in not more than 500 words). |  |  |  |  |
| 3 | \*Ethical Consideration & justification (Benefits, risk, Confidentiality) |  |  |  |  |
| 4 | \*Data management |  |  |  |  |
| 5 | \*Informed consent Part 1 (Patient information sheet) in English, |  |  |  |  |
| 6 | \*Informed consent Part 1 (Patient information sheet) in Regional languages (Hindi and/or Urdu) |  |  |  |  |
| 7. | \*Informed consent document Part 2 in English,  Child assent form if study participant age is >7 yrs and <18 yrs |  |  |  |  |
| 8. | \*Informed consent documents Part 2 in Regional languages (Hindi and/or Urdu)  Child assent form |  |  |  |  |
| 9. | \*Research participants Questionnaire/s |  |  |  |  |
| 10. | Current Status of Ongoing Studies approved by IEC and conducted by PI (title, no of participant, SAE at the site ) |  |  |  |  |
| 11 | Ethics Committee clearance of other centers |  |  |  |  |
| 12 | Brief current curriculum vitae of PI and Co PI. (Compulsory for regulatory studies) |  |  |  |  |
| 13 | Case Record Form (Compulsory for Clinical trials) |  |  |  |  |
| 14 | Research participants recruitment procedures: advertisement, notices |  |  |  |  |
| 15 | GCP training certificates of all PI and Co-PI (last 3years, (Compulsory for Clinical trials, highly suggested for all studies) |  |  |  |  |
| 16 | Log of delegation of responsibility of the study team members (Compulsory for regulatory studies) |  |  |  |  |
|  | **In case of Clinical Trial / interventional studies** | | | | |
| 17 | Information on Clinical Trials |  |  |  |  |
| 18 | Contact Address of Sponsor |  |  |  |  |
| 19 | Total Budget |  |  |  |  |
| 20 | Research participants selection |  |  |  |  |
| 21 | Privacy and confidentiality |  |  |  |  |
| 22 | Use of biological/ hazardous materials |  |  |  |  |
| 23 | Risks & Benefits |  |  |  |  |
| 24 | Data Monitoring |  |  |  |  |
| 25 | Consent |  |  |  |  |
| 26 | Compensation for participation |  |  |  |  |
| 27 | Undertaking by Principal Investigator regarding compensation for study related injury |  |  |  |  |
| 28 | Statement on conflict of interest |  |  |  |  |
| 29 | Insurance |  |  |  |  |
| 30 | Clinical Trial Agreement for drug trial / Memorandum of Understanding, as applicable, for collaborator & Govt sponsored trials |  |  |  |  |