Title:

Name:
Designation (year of residency if applicable)
Department:
SSG Hospital & Govt. Medical College Baroda:
Contact No.:
Email id:

Name of Guide:
Designation:
Department:

INDEX

PERMISSION LETTER

Name
Designation
Department
SSG Hospital & Medical College Baroda.
Contact No:
Email:
Date:

To,
The Local Research Committee (LRC)
Medical College Baroda,
Vadodara.

Subject: Application for permission to carry out study/ thesis/ research for a dissertation.
Forwarded through the Head of the Department.

Respected sir/ma'am,

I, Dr. (**Name)** am studying as a (**Designation**) in the **(Department of)** at the Faculty of Medicine under The M. S. University of Baroda.

I want to carry out a study/ thesis/ research titled **(Title)** under the guidance of **(Guide name, designation, department)**

I am submitting a proposal for approval of the study/ thesis/ research in the prescribed format along with necessary reference papers and an assurance letter from the mentors.

This study will be conducted strictly as per ethical guidelines with due consideration to preventing plagiarism.

Thanking You.

Yours Sincerely,
(Signature)
Name

(Signature of HOD with stamp)

Enclosures:

1. Application Form
2. Assurance Letter
3. Permission of Dean, Medical College Baroda
4. Permission of Medical Superintendent, Medical College Baroda
5. Permission from other departments (if any)
6. Permission in special cases
7. Study Protocol with Study-Related Documents
8. Case report form, Patient information sheet, and informed consent form
9. Study tool/ questionnaire
10. Reference articles (At least three)

PERMISSION LETTER

Name:
Designation:
Department:
SSG Hospital & Medical College Baroda.
Contact No.
Email:
Date:

To,
The Institutional Ethics Committee for Biomedical and Health Research (IECBHR)- PG Research (IECBHR-PGR),
Medical College Baroda,
Vadodara.

Subject: Application for permission to carry out study/ thesis/ research for a dissertation.

Forwarded through the Head of the Department.

Respected sir/ma'am,

I, Dr. (**Name)** am studying as a (**Designation**) in the **(Department of)** at the Faculty of Medicine under The M. S. University of Baroda.

I want to carry out study/ thesis/ research titled **(Title)** under the guidance of **(Guide name, designation, department)**

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Yours Sincerely,
(Signature)
Name

(Signature of HOD with stamp)

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1. Application Form
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6. Permission in special cases
7. Study Protocol with Study-Related Documents
8. Case report form, Patient information sheet, and informed consent form
9. Study tool/ questionnaire
10. Reference articles (At least three)

APPLICATION FORM

Title of the study	
Name of the student Designation	
PG admission month and year Branch name	
Name of the guide & department	
Source of funding if any	
Type of Study	
Ethical issues involved in the study	
Proposal Enclosed in 3 copies	
Whether consent forms in English & vernacular language enclosed?	
Whether reference study articles are attached	
Is this special research?	**Animal Experiment:** **Clinical Trial:** **Research on Patented Products:** **Research on Herbal Extract:**

Signature of the PG Resident:

Name:
Designation:
Department:

Signature of the Guide:

Name of Guide:
Designation:
Department:

PERMISSION LETTER

Name:
Designation:
Department:
SSG Hospital & Medical College Baroda
Email Id:
Mobile No:
Date:

To,
The Dean,
Medical College Baroda

Subject: **Application for permission to carry out thesis/ study/ research work**
Forwarded through the Head of the Department.

Respected Sir,

I, the undersigned (**Name)** want to carry out thesis/study/research work in the (**Department of)**, Medical College Baroda, titled **"Title**" Under the guidance of (Name of guide, designation and department)

Kindly permit me to carry out above mentioned **thesis/ study/ research work**.
Thanking you.

Yours Sincerely,
(Signature)
Name

(Signature of HOD with stamp)

PERMISSION LETTER

Name:
Designation:
Department:
SSG Hospital & Medical College Baroda
Email Id:
Mobile No:
Date:

To,
The Medical Superintendent,
SSG Hospital & Medical College Baroda,

Subject: **Application for permission to carry out thesis/ study/ research work**
Forwarded through the Head of the Department.

Respected Sir,

I, the undersigned (**Name)** want to carry out thesis/study/research work in the (**Department of)**, Medical College Baroda, titled **"Title**" Under the guidance of (Name of guide, designation and department)

Kindly permit me to carry out above mentioned **thesis/ study/ research work**.

Thanking you.

Yours Sincerely,
(Signature)
Name

(Signature of HOD with stamp)

ASSURANCE LETTER

From:
Name of guide
Designation of guide,
Department,
SSG Hospital & Medical College, Baroda.
Date:

To,
The LRC/IECBHR-PGR,
Medical College, Baroda.
Subject: Assurance for mentoring of **(Name of researcher)** for research in the **(Department of)**
Respected sir/ma'am,

This is to inform you that the research work titled "**Title"** will be carried out for dissertation by **(Name of researcher, designation, department)**, Medical College, Baroda under my guidance and observation.

We assure you that the work will be done strictly as per the ethical guidelines with due consideration of the prevention of plagiarism.

Yours Truly

(Signature of guide)

Name of guide
Designation of guide,
Department,
Medical College, Baroda.

(Signature of HOD with stamp)

PERMISSION LETTER (Special case if any)

Name:
Designation:
Department:
SSG Hospital & Medical College Baroda
Email Id:
Mobile No:
Date:

(Concerned Authority
Concerned department/ organization)

Subject: Application for permission to conduct thesis/ study/ research work under the (Concerned department/ organization)
Forwarded through Head of Department.

Respected Sir/Madam,

I, the undersigned (**Name)** applying for a study in the (**Department of)**, Medical College Baroda. I want to carry out research titled **"Title**" Under the guidance of (Name of guide, designation and department)

Kindly permit me to carry out above mentioned **thesis/ study/ research work**.
Thanking you.

Yours Sincerely,
(Signature)
Name

(Signature of HOD with stamp)

UNDERTAKING

Name:
Designation:
Department:
SSG Hospital & Medical College Baroda
Email Id:
Mobile No:
Date:

To,
The LRC/ IECBHR-PGR,
Medical College Baroda,
Vadodara.

Subject: Undertaking for bearing cost incurred in the thesis/ study/ research work

Respected Sir,

I, the undersigned (**Name)** am applying for thesis/study/research work in the (**Department of)**, Medical College Baroda. I want to carry out research titled **"Title**" Under the guidance of (Name of guide, designation and department)

I hereby assure that I will be responsible for all expenses related to the study. The participants or their family members will not bear the expenses.
Thanking you.

Yours Sincerely,
(Signature)
Name

Signature of Guide

Signature of Head of Department

STUDY PROTOCOL

NAME OF THE RESEARCHER

Name
Designation (with year of residency, if applicable)
Department
SSG Hospital & Medical College Baroda

NAME OF THE GUIDE AND DEPARTMENT

Name of guide
Designation of guide,
Department,
SSG Hospital & Medical College, Baroda.

TITLE OF THE STUDY

INTRODUCTION

PURPOSE OF THE STUDY/ RATIONALE (Why is this study required?)

AIM

OBJECTIVES

METHODOLOGY

Study setting (Participant recruitment site)

Study design

Study duration

Study population

Inclusion criteria

Exclusion criteria

SAMPLE SIZE with calculation and justification

1. Case-control study: The sample size was calculated using open epi software to be (x) in each group (cases and control with ratio 1:1) based on the results of a reference study where the odds ratio was (), exposure rate among cases was (), exposure rates among controls was () at 95%CI, 80%power. (Cite the reference study)
2. Cohort study/RCT: The sample size was calculated using XXX software to be *(x)*in each group (Intervention and Control group) based on the results of a reference study where the mean and Sd of group 1 was (), mean and sd of group 2 was () at 95%CI, 80%power. (Cite the reference study)
3. Cross-sectional study: The sample size was calculated using XXX software to be (x) based on the results of a reference study where the proportion of .... (variable of interest) at 95%CI, 80%power.
4. If using formula to calculate then mention each parameter (i.e., CI, power, statistical significance, variable, proportions used etc.)

SAMPLING TECHNIQUE AND RANDOMISATION IF NEEDED

DATA COLLECTION QUESTIONAIRRE AND PLAN OF DATA COLLECTION

Intervention if needed

Investigations specifically related to the study protocol, cost of each investigation,if any that the PI will bear

Follow up plan, if any (number of visits the patients has to make for this study, number of follow ups etc, whether they are routinely done or will be done specifically in context of your study)

Recruitment plan considering the feasibility of the study in discussion

DATA VARIABLES

	Exposure variable	**Outcome variable**
Objective 1		
Objective 2		
Objective 3		

Can add the rows if there are additional objectives

DATA ANALYSIS

1. Identify Numerical Data (e.g. height, weight, BP, pulse, RR, temp, BMI, drug doses, serum drug levels, serum biochemistry levels, etc); Ordinal Data (e.g. Pain Score, Nausea Score, Satisfaction Score,

Difficulty Score, etc); and Nominal Data (e.g. Sex, ASA PS, counts of success, counts of failures, number of emetic episodes, counts of adverse events, etc).

2. Normally distributed Numerical Data between two INDEPENDENT groups should be compared using the unpaired t-test (independent samples t-test). Non-normally distributed data between the two INDEPENDENT groups should be compared using the Mann Whitney U test. Normally distributed Numerical Data between two DEPENDENT groups should be compared using the paired t-test (dependent samples t-test).
3. Normally distributed Numerical Data between more than two DEPENDENT groups should be compared using the One-way Repeated-Measures Analysis of Variance (ANOVA) test.
4. Nominal Data between two or more groups should be compared using the Chi-square test (large samples, two groups or more than two groups); or Fisher\'s exact test (small samples, two groups).

ETHICAL CONSIDERATION:

- The study will be conducted only after obtaining permission from the Local Research Advistory Committee (Scientific Committee) and the Institutional Ethics Committee for Biomedical and Health Research of Medical College, Baroda, Vadodara.
- Informed written consent of all the participants will be taken in offline mode (physical copy) before their involvement in the study.
- How will you maintain privacy and confidentiality of the participant?
- Participants' identities and data will remain anonymous throughout the study and publishing process
- Do you plan to withdraw the standard therapy during the research period
- (Any other concern)

Any conflict of interest?

STUDY TIMELINE (Gantt Chart)

Particulars (Duration in Months)	**1st Month**	**2nd Month**	**3rd Month**	**4th Month**	**5th Month**	**6th Month**	**7th Month**	**8th Month**	**9th Month**	**10th Month**	**11th Month**	**12th Month**
Development of research protocol												
Proposal writing and finalizing of methodology tools												
Ethics committee submission and permissions												
Data collection												
Data entry & Data analysis												
Report writing												

Dissemination plan

BIBLIOGRAPHY

Memorandum of Understanding (MoU) (If applicable)

Between
Baroda Medical College
Located at: Sayajigunj, Baroda
Represented by:

Dean , Baroda Medical College.
Hereinafter referred to as the "Sending Institution"

And
Mention details of the institution with whom the MoU is proposed

Purpose:
This Memorandum of Understanding (MoU) is entered into by and between the Sending Institution and the Receiving Institution to establish a formal agreement regarding the transfer, handling, and analysis of biological samples for the research project titled: **"(TITLE OF STUDY)"**

1. Scope of Collaboration: 1.1. The Sending Institution agrees to transfer biological samples collected as part of the above-mentioned research project to the Receiving Institution for specialized laboratory analysis.
1.2. The Receiving Institution agrees to conduct the agreed-upon analyses and provide the results to the Sending Institution within the stipulated timelines.

2. Responsibilities of the Sending Institution: 2.1. Collect samples in compliance with ethical guidelines and obtain informed consent from all participants, adhering to the protocols approved by the Institutional Ethics Committee.
2.2. Ensure proper labeling, documentation, and packaging of samples for safe transport to the Receiving Institution.
2.3. Bear the costs associated with sample collection and transportation, unless otherwise agreed.

3. Responsibilities of the Receiving Institution: 3.1. Handle all received samples in accordance with established biosafety and ethical standards.
3.2. Conduct the analyses as described in the agreed project methodology and ensure accurate, reproducible results.
3.3. Maintain confidentiality of all data and results derived from the samples.
3.4. Return or appropriately dispose of any remaining samples as per mutual agreement and applicable legal regulations.

4. Confidentiality: Both parties agree to maintain the confidentiality of all participant data, research findings, and other sensitive information shared under this MoU. Such information shall not be disclosed to any third party without prior written consent from the originating institution.

5. Compliance with Ethical Guidelines: Both institutions affirm that they will adhere to all relevant ethical guidelines, including but not limited to the 2017 ICMR Guidelines for research involving human participants.

6. Intellectual Property: Any intellectual property rights arising from the analysis or findings of the research project shall be mutually discussed and agreed upon by both parties before publication or dissemination.

7. Term and Termination: 7.1. This MoU shall remain in effect for the duration of the research project, starting from [Start Date] and concluding on [End Date].
7.2. Either party may terminate this MoU by providing 30 days' written notice, provided that all samples and data are returned or appropriately handled as per this agreement.

8. Dispute Resolution: Any disputes arising out of this MoU shall be resolved amicably through mutual discussion. If unresolved, the matter shall be referred to arbitration, with the decision of the arbitrator being final and binding.

9. Miscellaneous: 9.1. Any modifications to this MoU must be made in writing and signed by authorized representatives of both parties.
9.2. This MoU is not legally binding but serves as an understanding to guide the collaboration.

Signed by:

For the Sending Institution:

Dean, Baroda Medical College.
Date: _____

For the Receiving Institution:

Date: _____

Witnesses:

1. ---
2. ---

DEPARTMENT OF _____
MEDICAL COLLEGE & S.S.G. HOSPITAL, VADODARA
PARTICIPANT INFORMATION SHEET

To be translated to other vernacular language- Gujarati/Hindi/other as applicable

Title of the study:

Purpose of the study:

General information about the research study:

1. **Title of study**:
2. **Name of Guide:** Name of Guide with designation and department
3. **Name of PG student: Name of researcher,** Resident doctor,
   Contact No.
   Contact email:

4. You are asked to take part in the research study and this is purely voluntary. You may refuse to participate or withdraw your consent at any point of time during the study.
5. All the data collected during the study will remain confidential.
6. It is important for you to understand every information about the study to make an informed decision for participating in the study. You can ask any question related to the study to a researcher at any point of time.
7. You will not receive any financial remuneration for participating in this study. This study will not affect your receiving education or services from the institute.
8. **(Mention if any specific instructions for the participant for your thesis/ study/ research.) Relevant information about the health-related condition may be added**

9. This study has been approved by the Instituitional Ethical Committee, Medical College, Baroda and will be conducted according to ethical guidelines and principles of the International Declaration of Helsinki.
10. **What is this research study all about?**
    The purpose of this study is_____.
    If you agree to be part of this study you will be interviewed for_____. This research will take **(duration of study)**, but your interview will take around**(duration of interview**), **(mention the number of times the participant will be interviewed) .**
11. **Why have you been invited to participate?**
    (Explain about factors in questionnaire/interview).
12. **What will your responsibilities be?**
    Please try to answer frankly without any hesitation. Let me know if any question makes you feel uncomfortable. You do not have to answer any question that you do not wish to, for any reason.
13. **Will you benefit from taking part in this research?**

This research is designed to **(aim)**. Your participation is important to help us understand the situation of menopausal women. We will try our level best to sort out local problems, if any, to the best of our ability. However, you may not personally benefit from being in this research study. Your participation is important for us to gain knowledge, so we can help other people like you.

If you agree, we would like to take your (**mention the sample to be taken in your study ex:blood/urine and the investigation ex:to measure calcium levels**) . The results will be conveyed to you, along with specific action to be taken based on these results.

14. Will photographs be taken or tape recordings made?

We will be taking notes of what you say. No names will be mentioned. No photographs or tape recordings will be done, thereby ensuring your privacy.(**if no photo will be will be taken**)(**If photo will be taken ,mention when,where,of what and mention the same in consent form also and mention here that if not consented the same will not be done**)

15. Are there any risks involved in your taking part in this research?

We are not interfering with any of your ongoing health conditions and any kind of experiment is not being done on you, so; we do not expect any risks or discomforts in this research study.

16. Who will have access to the results of this study?

In order to protect your privacy, the interview will be held at a place where you wish; with privacy ensured. No information that could identify you will be used when presenting this research to others.

17. Where can participants get results of the study should they wish to have them?

18. You have the right to ask any questions you may have about this research at any point of time during the interview or thereafter. You can contact (**mention name of the researcher with contact number**)to get the results of the study.

19. Are there any costs involved and will you be paid to take part in this study?

There are no costs to you if you participate in this study except giving your valuable time. However, we would not be paying you for taking part in the study.

20. Do you have any questions about the research?

21. If there is anything else that you want to know, if you have any further queries or concerns you can contact (**mention name of the researcher with contact number**)

Procedure after participation:

ડિપાર્ટમેન્ટ _____

મેડિકલ કોલેજ અને એસ.એસ.જી. હોસ્પિટલ, વડોદરા

સહભાગી માહિતી શીટ (સ્થાનિક ભાષામાં)

Title of the study:

Purpose of the study:

General information about the research study:

1. **Title of study**:
2. **Name of Guide:** Name of Guide with designation and department
3. **Name of PG student: Name of researcher,** Resident doctor,
   Contact No.
   Contact email:

4. તમને આ સંશોધન અભ્યાસમાં ભાગ લેવા માટે કહેવામાં આવ્યું છે અને તે સંપૂર્ણપણે સ્વૈચ્છિક છે. તમે સંશોધનમાં ભાગ લેવા માટે મનાઈ કરી શકો છો અથવા સંશોધન દરમ્યાન કોઈપણ સમયે તમારી સંમતિ પાછી ખેંચી શકો છો.

5. સંશોધન દરમિયાન ભેગી કરવામાં આવેલી તમામ માહિતી ગોપનીય રાખવામાં આવશે.

6. સંશોધનમાં ભાગ લેવા માટે તમારે સંશોધન અંગેની તમામ માહિતી સમજવી જરૂરી છે, જેથી તમે જાણકારીપૂર્ણ નિર્ણય લઈ શકો. તમે સંશોધન અંગે કોઈપણ પ્રશ્ન સંશોધકને કોઈપણ સમયે પૂછી શકો છો.

7. સંશોધનમાં ભાગ લેવા માટે તમને કોઈ આર્થિક વળતર મળશે નહીં. આ સંશોધનથી તમને સંસ્થામાં શિક્ષણ અથવા અન્ય સેવાઓ મેળવવા પર કોઈ અસર પડશે નહીં.

8. (તમારા અભ્યાસ/સંશોધન/થિસિસ માટે કોઈ વિશિષ્ટ સૂચનાઓ હોય તો અહીં ઉલ્લેખ કરો.) આરોગ્ય સંબંધિત સ્થિતિ વિશે જરૂરી માહિતી ઉમેરવી.

9. આ સંશોધન મેડિકલ કોલેજ, બરોડાની સંસ્થાકીય નૈતિક સમિતિ દ્વારા મંજૂર કરવામાં આવ્યું છે અને આંતરરાષ્ટ્રીય હેલસિંકી ઘોષણાના નૈતિક માર્ગદર્શિકા અને સિદ્ધાંતો અનુસાર કરવામાં આવશે.

10. આ સંશોધન અભ્યાસ શું છે?

આ સંશોધનનો હેતુ _____ છે. જો તમે સંશોધનમાં ભાગ લેવા માટે સંમત હો, તો તમારું _____ માટે ઇન્ટરવ્યૂ લેવામાં આવશે. સંશોધનનો કુલ સમયગાળો (અવધિ) છે, પરંતુ તમારું ઇન્ટરવ્યૂ અંદાજે (ઇન્ટરવ્યૂની અવધિ) સુધી રહેશે. (પ્રતિભાગીનું ઇન્ટરવ્યૂ કેટલા વખત લેવામાં આવશે તેનો ઉલ્લેખ કરો.)

11. તમને સંશોધનમાં ભાગ લેવા માટે આમંત્રિત કેમ કરવામાં આવ્યા છે?

(પ્રશ્નાવલી/ઇન્ટરવ્યૂમાં રહેલા પરિબળોની સમજૂતી આપો.)

12. તમારી જવાબદારીઓ શું હશે?

કૃપા કરીને નિઃસંકોચ અને સચોટ જવાબ આપો. જો તમને કોઈ પ્રશ્નના કારણે અસ્વસ્થતા લાગે, તો તેની મને જાણ કરો. તમારી ઇચ્છા ના હોય એવા કોઈ પણ પ્રશ્નનો જવાબ આપવાની જરૂર નથી.

13. શું તમે સંશોધનમાં ભાગ લઈને કોઈ ફાયદો મેળવી શકશો?

આ સંશોધન (ઉદ્દેશ્ય) માટે ડિઝાઇન કરવામાં આવ્યું છે. તમે સંશોધનમાં ભાગ લેશો તો, એ અમને _____ સમજવામાં મદદ કરશે. જો સ્થાનિક સમસ્યાઓ હોય, તો અમે શ્રેષ્ઠ પ્રયાસ કરી તેનો ઉકેલ લાવવાનો પ્રયત્ન કરીશું. તેમ છતાં, તમારે વ્યક્તિગત લાભ ના પણ થઈ શકે. તમારો ભાગ લેવો અમારે માટે મહત્વપૂર્ણ છે, જેથી અમે તમારાથી મળેલી જાણકારીના આધારે બીજાં લોકોને મદદ કરી શકીએ. જો તમે સંમત હો, તો અમે તમારું (સેમ્પલનું ઉલ્લેખ કરો, જેમ કે: લોહી/મૂત્ર) અને (અધ્યયન માટેની તપાસ, જેમ કે કેલ્શિયમ સ્તર માપવું) લઈશું. પરિણામો તમને જણાવવામાં આવશે અને તેના આધારે જરૂરી પગલાં લેવામાં આવશે.

14. શું ફોટોગ્રાફ કે ઓડિયો રેકોર્ડિંગ કરવામાં આવશે?

અમે તમારા જવાબો અંગે નોંધબુકમાં નોંધ લેશું. તમારું નામ ક્યાંય ઉલ્લેખવામાં નહીં આવે. (જો ફોટો/ઓડિયો રેકોર્ડિંગ નહીં થાય તો તે જણાવો.)

(જો ફોટોગ્રાફ લેવાશે તો, ક્યાં, ક્યારે અને શાનું લેવામાં આવશે તે ઉલ્લેખ કરો, અને સંમતિ પત્રમાં એ સ્પષ્ટ લખી દો. જો સંમતિ નહીં આપો તો ફોટો લેવામાં આવશે નહીં.)

15. શું સંશોધનમાં ભાગ લેવા માટે કોઈ જોખમ છે?

અમે તમારી હાલનની આરોગ્ય પરિસ્થિતિમાં કોઈ હસ્તક્ષેપ કરી રહ્યા નથી અને કોઈ પ્રયોગ કરવામાં આવી રહ્યો નથી. તેથી, સંશોધન અભ્યાસમાં કોઈ જોખમ કે તકલીફની અપેક્ષા નથી.

16. આ સંશોધનના પરિણામો કોણ જોઈ શકે?
તમારા ગોપનીયતા સુરક્ષિત રાખવા માટે, તમારું ઇન્ટરવ્યૂ તમારી પસંદગીની જગ્યાએ ગોપનીયતાને ધ્યાનમાં રાખી લેવામાં આવશે. સંશોધન રજૂ કરતી વખતે તમારી ઓળખ પ્રગટ કરાતી નથી.

17. જો પ્રતિભાગી સંશોધનના પરિણામો જાણવા માંગે, તો તે ક્યાંથી મેળવી શકશે?

તમે (શોધકનું નામ અને સંપર્ક નંબર ઉમેરો) દ્વારા સંશોધનના પરિણામો મેળવી શકો છો.

18. તમે સંશોધન વિશે કોઈપણ પ્રશ્ન પૂછવાનો હક રાખો છો.
તમે ઈન્ટરવ્યૂ દરમિયાન કે પછી સંશોધન વિશે કોઈપણ પ્રશ્ન પૂછી શકો છો. તમે (શોધકનું નામ અને સંપર્ક નંબર ઉમેરો) દ્વારા સંશોધનના પરિણામો મેળવી શકો છો.

19. શું સંશોધનમાં ભાગ લેવા માટે કોઈ ખર્ચ છે? શું તમે કોઈ ચૂકવણી મેળવશો?
આ સંશોધનમાં ભાગ લેવા માટે તમારે કોઈ ખર્ચ નહીં થાય, સિવાય કે તમારો કિંમતી સમય આપવા. અમે આ સંશોધનમાં ભાગ લેવા માટે કોઈ પણ પ્રકારનું વળતર ચૂકવતા નથી.

20. શું તમારી પાસે સંશોધન વિશે કોઈ પ્રશ્નો છે?

21. જો તમારે વધુ માહિતી જોઈએ કે જો તમને કોઈ પ્રશ્ન કે ચિંતા હોય, તો તમે (શોધકનું નામ અને સંપર્ક નંબર ઉમેરો) સંપર્ક કરી શકો છો.

DEPARTMENT OF _____

MEDICAL COLLEGE & S.S.G HOSPITAL VADODARA

INFORMED CONSENT FORM IN ENGLISH

To be translated to other vernacular language- Gujarati/Hindi/other as applicable

Written Informed Consent Section - *Please read carefully*

By signing below, I **(optional)**……..……. voluntarily agree to take part in the research study titled____(**title of the study).**The focus of the study is to (aim). **HONEST ANSWERS** are critical to the study's effectiveness and the appropriate planning of subsequent interventions aimed at (describe your study). You will not be asked to write your name since it is confidential. I agree for the investigations/ blood tests (wherever required as per the study protocol).

I declare that:

- I have read this information and consent form and understand the contents
- I have had a chance to ask questions and all my questions have been adequately answered
- I understand that taking part in this study is voluntary and I have not been pressurised to take part
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way
- I agree to give my sample for the blood test **(if any)**
- I am aware that I will be called for follow up after___duration
- I am aware that I will not require to incur any additional expenses for participating in the study

I have decided to participate in this research without any coercion.

Signature: _____

Date:

Thanking you for your willingness to participate in this study.

સંમતિ પત્ર

(Consent form)

Declaration by participant

આથી હું નીચે સહી કરનાર **(optional)**_____

સંમતિ આપું છું કે, આ સંશોધન વિષયક અભ્યાસ_____ માં મારે શો ભાગ ભજવવાનો છે, તેની મને બરોબર સમજણ આપેલ છે.

મેં આ માહિતી અને સંમતિ પત્રક વાંચ્યું છે અને તેમાં લખેલી વિગતોને સમજી છે. મને એ સમજણ પણ આપેલ છે કે, મારા દ્વારા આપવામાં આવતી તમામ માહિતી અત્યંત ગુપ્ત રાખવામાં આવશે અને મને આજ સુધી મળેલ કે હવે પછી જરૂર હોય ત્યારે મળવાપાત્ર તમામ સેવાઓ ઉપર તેની કોઇ અસર થશે નહિ. મને પ્રશ્નો પૂછવાની તક મળી છે અને મારા બધા પ્રશ્નોના પર્યાપ્ત જવાબ આપવામાં આવ્યા છે. હું સમજું છું કે આ અભ્યાસમાં ભાગ લેવો એ સ્વૈચ્છિક છે અને ભાગ લેવા માટે મારા પર દબાણ કરવામાં આવ્યું નથી. હું મારી મરજી પ્રમાણે કોઇ પણ સમયે વાર્તાલાપ (ઇન્ટરવ્યુ) છોડીને જઇ શકું છું. તમામ પ્રશ્નોના જવાબ આપવા માટે હું બંધનકર્તા નથી. હું જાણું છું કે મને ફોલોઅપ માટે બોલાવવામાં આવશે.....(સમયગાળો) આથી હું મારી સ્વેચ્છાએ આ સંશોધન વિષયક અભ્યાસમાં ભાગ લેવા અને બ્લડ ટેસ્ટ કરાવવા માટે મારી પૂરેપૂરી સંમતિ પાઠવું છું.

....

સહી/ અંગુઠાનું નિશાન સાક્ષીની સહી

(signature/ thumb impression) (signature of witness)

નામ :

તારીખ:

સ્થળ:

.સંશોધન અભ્યાસ વિષયક માહિતીની એક નકલ અભ્યાસમાં સામેલ દરેકને.

Questionnaire (In English) To be translated to other vernacular language- Gujarati/Hindi/other if applicable

Consider only those variables that are relevant to your objectives

પ્રશ્નાવલી

References (also attach three most relevant ones)