**Participant Information Sheet and Informed Consent Form**

**Name of the study:** Survey of Public knowledge and perceptions about clinical research in Mumbai.

**Name of the Principal Investigator**: Dr. Urmila Thatte

**Name of the Institute conducting the study:** Department of Clinical Pharmacology, Seth G.S.M.C & KEMH, Parel, Mumbai-12

**Contact Details of the Institute:** +91-22-24133767

**Introduction**: You are invited to participate in a survey based research study to investigate the public awareness and knowledge regarding clinical research in Mumbai. It is important for you to read the description given below to know the details of this study before you decide to participate in the survey.

Clinical research is a type of research in which new drugs and treatments are tested in humans before they are introduced in the healthcare. To make any clinical research successful there should be involvement of not only researchers but also participants. A participant can get actively involved in research process if he is better informed about the purpose of research, his rights as a participant in research as well as the risks and benefits associated with it. To make a participant better informed creating awareness amongst participants about clinical research is very important. At our centre we conduct clinical research and we observe that many participants are not aware of what a clinical trial is until they get enrolled in a trial. It is very important to make participants aware of the difference between clinical research and clinical care. Hence, it is very important to create awareness amongst clinical trial participants.

Understanding the existing knowledge and misinformation amongst people regarding clinical research can help us devise suitable strategies to improve awareness. At our centre we get most of the clinical trial participants from in and around Mumbai, and hence as an initiative towards achieving this objective we wish to conduct this survey about perception and public knowledge about clinical research.

**Purpose of the study:** We wish to conduct this survey of public knowledge and perceptions in clinical research in Mumbai, to study gaps in awareness and extent of misinformation about clinical research amongst people of Mumbai.

**Procedures:** If you agree to participate in this survey based research study

* You will be administered a questionnaire which you will have to answer in a span of 15-20 minutes.
* The response to each question is to be provided based on your own opinion and without consulting anybody.
* The completed questionnaire is to be handed over back to the study personnel.

**Benefit:** You will not get any benefit directly from this survey. However, your response will be valuable and will be counted in the process of deriving inference from the information collected during the survey.

**Legal Rights**: You will not give up any legal rights by signing this document

**Confidentiality:** All study documents will be kept confidential at all times. The personal details which you will provide will be kept confidential except when required by law. The results which emerge from this survey may be published. However, your identity will not be revealed in these publications. Publication rights are reserved by department of Clinical Pharmacology and Institutional Ethics committee. Prior permission of all investigators will be obtained for publication.

**Right to Refuse and withdraw**: Participation in this study is entirely voluntary. You may choose not to participate in this survey based study.

**Contact for Further Information:** If you have any doubts regarding this study you may contact

1. **Ms. Brinal Figer**

**Department of Clinical Pharmacology**

**Seth G.S.M.C &KEM Hospital, Parel, Mumbai-12**

**Telephone no: +91- 22 24133767**

1. **Dr Urmila Thatte**

**Dept. of Clinical Pharmacology,**

**Seth G.S Medical College & KEM Hospital, Parel, Mumbai 400 012**

**Telephone no.: +91-22 24133767**

If you have any questions about your rights as a participant or want to complain or seek

Clarification regarding the study, you should call Dr. Sharmila Jalgaonkar and Dr.Snehalata Gajbhiye; the Member Secretaries of the Institutional Ethics Committee of Seth G.S.Medical College and KEM Hospital on the following telephone number: +91 22 24122188.

**Informed Consent Form**

|  |  |
| --- | --- |
| **Name of the Participant:**  **Name of the impartial witness (If applicable):** | |
| **Participant Initials:**  **Gender: Male Female**  **Date of Birth/Age:** | |
| **Education:** | **Occupation:** |
| **Religion:** | **Mother Tongue:** |
| **Address:** | **Monthly Family Income:** |

I have read or have had read to me the information given in this document regarding a study entitled ‘Survey of Public Knowledge and perceptions of Clinical Research in Mumbai’

**Yes** / **No**

I have received information about the nature and purpose of the survey and what I am expected to do in this survey.

**Yes**  / **No**

All my study related doubts have been answered to my satisfaction

**Yes** / **No**

I understand that my participation in the survey is entirely voluntary and I have right to refuse or withdraw from participation in the survey

**Yes** / **No**

I have been fully made aware about the maintenance of Confidentiality of my records.

**Yes** / **No**

Institutional ethics committee authorities may wish to examine my records to verify

the study information collected. By signing/giving a thumb impression on this document, I give permission for this review of my records.

**Yes / No**

I understand that my identity will not be revealed in any report or publication.

**Yes / No**

I agree to take part in the survey

Y**es / No**

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**Name of the subject Signature/Thumb Impression Date**

**of the Subject**

**Name of the impartial witness\* Signature of the impartial witness Date**

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**Name of person Signature of person Date**

**administering consent administering consent**

(\*Impartial witness signature only if applicable)