**Study Protocol**

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

**Protocol Version**: 02 dated 16/May/2015

**Study Site**: Department of Clinical Pharmacology

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**Confidentiality Statement**

**The information provided in this document is strictly confidential and is available for review to potential investigators and ethics committee. No disclosure should take place without the written authorization from principal investigator**

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**Protocol Summary**

|  |  |
| --- | --- |
| **Title** | Survey of Public Knowledge and perceptions about clinical research in Mumbai |
| **Objectives** | To study gaps in awareness and extent of misinformation about clinical research amongst people of Mumbai |
| **Study Site** | Department of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Mumbai. |
| **Study design** | Cross Sectional Study |
| **Methods** | |
| **Ethical Consideration** | The study will be conducted in accordance with basic principles of ICH-GCP after obtaining ethics committee approval. |
| **Study Duration** | 24 months from the date of ethics committee approval |
| **Study Site** | City of Mumbai |
| **Institute conducting the study** | Department of Clinical Pharmacology, Seth G.S.M.C & KEMH,Parel,Mumbai |
| **Sample Size** | 1200 |
| **Rationale for selection of sample size** | Based on the Published table method6 (reference enclosed), since the size of our total population is > 100,000. Our sample size for the study will be 400. Considering that there are 24 wards in Mumbai, to achieve the target of 400, we need 16-17 participants per ward, which is quite less.  Hence, we will select 50 participants per ward and our total sample size for the study will be 1200. |
| **Sampling method** | Stratified random sampling, a type of probability sampling will be used. We will evaluate percent awareness and extent of misinformation using stratification based on wards.  For each specific ward, while selecting the sample we will use stratification based on socio economic status using Kuppuswamy scale.(Appendix 4)  The information regarding areas within each ward which house people of different socio economic strata will be obtained from the respective ward officer. |
| **Method** | 1. Potential participants will be approached and explained the study objective 2. Those who are interested for participation will be counseled about the study procedure. 3. After counseling if any potential participant shows interest, he/she will be administered informed consent 4. Following informed consent, a 48 – item, open ended questionnaire will be given in his/her language of preference 5. The inputs obtained from each participant will be then analyzed statistically to derive the outcome. |
| **Factors considered while framing the questionnaire** | Following factors were used for framing the questionnaire  1.Knowledge of clinical research  2.Willingness to participate in clinical trials  3.Trust in the clinical research establishment  4. Confidentiality  5. Compensation  6.Altruism  7. Opinion and influence by familiar and respected individuals  8.Safety of research interventions and procedures  9. Access to sufficient information and clarification about the research  10.Collaboration with foreign clinical research entities |
| **Statistical Analysis** | An SPSS 16.0 (for windows. Chicago).Standard Normal deviate test (z test) will be used for the analysis of results.  Subgroup analysis will be done for gender, age, religion, ethnicity and socio economic status of the participant. Socio economic status will be decided based on Kuppuswamy scale (Appendix 4) |
| **Expected Outcome** | To determine the extent of misinformation and awareness about clinical research amongst people of Mumbai based on the results obtained from this survey. |

**Protocol**

**1. Introduction**

**1.1 Background**

Public awareness, perceptions and consequent attitudes towards clinical research may impact regulatory policies, guide research priorities and shape growth in the sector. Distrust, Lack of awareness and misconceptions have been identified as key aspects acting barriers to participation in clinical research. Necessity of greater public awareness amongst people is for three important reasons firstly ethical as informed individuals are better positioned to protect their rights, secondly methodological as wide and representative sample helps in generalization of the findings of the research and thirdly operational since non availability of participants in clinical trials increases cost and delays arrival of new treatments to those who need them [1]

A metaanalysis of 7 studies for factors associated with participation in clinical trials has observed that an overwhelming 64 % denied owing to reasons like mistrust of trial organization, concerns about safety and efficacy and loss of confidentiality [2]. However, a study published by Mackenzie et.al in British Journal of Clinical Pharmacology found that though public awareness does contribute to increase in understanding of clinical research aspects it does not significantly improve willingness to participate [3]. Several studies have been done to assess the public knowledge and awareness of clinical research across some cities in India [1,4,] but no such study to the best of our knowledge has yet been done in Mumbai, a city cosmopolitan in nature and housing people of all socio economic, cultural, ethnic and religious diversity.

Conducting a public perception and awareness survey in clinical research can greatly improve public understanding of clinical research terminologies and help eradicate misconceptions which hamper participation in clinical research. Being home to some of the most premier clinical research centres, this survey can improve willingness for participation amongst general public and can greatly boost the prospects of having improved recruitment in future clinical trials.

**2.0 Rationale for Conduct of the study**

We wish to conduct a 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, and to improve the understanding of clinical research amongst general public which will improve participation in clinical research.

**3.0 Objectives**

* To study gaps in awareness and extent of misinformation about clinical research.

**4.0 Study Design**

**4.1 Study Type**: Cross Sectional Study

**4.2 Study Duration**: 24 Months from the date of ethics committee approval

**4.3 Study Site**: City of Mumbai

**4.4 Study Participants**: Citizens of Mumbai

**4.5 Sample Size:** 1200 participants

**4.6 Rationale for sample size selection**: Based on the Published table method (Appendix 1), since the size of our total population is > 100,000. Our sample size for the study will be 400. Considering that there are 24 wards in Mumbai, to achieve the target of 400, we need 16-17 participants per ward, which is quite less.

Hence, we will enroll 50 participants from each ward (total 24 wards) and our total sample size for the study will be 1200.

**4.7 Sampling technique**:

* We will select participants from the city by stratified random sampling, a type of probability sampling. We will evaluate percent awareness and extent of misinformation using stratification based on wards.
* For each specific ward, while selecting the sample we will use stratification based on socio economic status using kuppuswamy scale.
* The information regarding areas within each ward which house people of different socio economic strata will be obtained from the respective ward officer.

**4.8 Eligibility:**

**Inclusion Criterion**

* Males and Females above 18 years of age
* Willing to give written informed consent
* Resident of Mumbai and suburban region since last 5 years
* No current participation in any research study

**5.0 Ethical Consideration**

**Ethics**: The study will be initiated after obtaining Ethics Committee approval. Ethics committee approval will be obtained for protocol, source documents, case record forms, informed consent document in English, Marathi and Hindi.

**Good Clinical Practice**: The study will be conducted in concordance with the good clinical practices which has its origin in the declaration of Helsinki.

**6.0 Methods**

**Validation:**

20 participants will be used for the validation of the Hindi and Marathi questionnaire. 10 for each language. All validation parameters will be determined and the results will be submitted to IEC-2. Since the English questionnaire is an already validated and published version, it will not be included in the validation process.

**Study procedure:**

1. After obtaining IEC-2 approval, ward officers of each ward of the city will be approached for data on areas housing people of different socio economic strata.
2. After obtaining this data, potential participants from each stratum will be approached and explained the study objective for the respective wards.
3. Those who are interested for participation will be counseled about the study procedure.
4. After counseling if any potential participant shows interest, he/she will be administered informed consent
5. Following informed consent, a 48 – item, open ended questionnaire will be given in his/her language of preference.
6. The inputs obtained from each participant will be then analyzed statistically to derive the outcome.
7. All participants enrolled in the survey will be assessed separately by us for their socio economic strata using Kuppuswamy scale.(Appendix 4)

**7.0 Study Flow Chart**

Institutionalethics committee approval

Validation of questionnaire (Marathi and Hindi version)

Submissionof validation results to ethics committee

Administration of survey questionnaire to willing individuals

Evaluation of the filled questionnaire and statistical anlysis of results

**8.0 Statistical Analysis**

SPSS 16.0 version software will be used for data analysis. Responses obtained will be expressed in terms of percentages as ‘True’, ‘False’ and ‘Not aware’. Perceptions of clinical research across the socio economic status of the respondents will be assessed such as education, income and occupation. The p value for differences will be calculated using the standard normal deviate test (Z test).Also, the difference in perceptions between the group which heard of clinical research and the one which did not hear will be computed on the basis of p value obtained using standard normal deviate test (Z test).

Subgroup analysis will be done for gender, age, religion, and socio economic status of the participant. Socio economic status will be decided based on Kuppuswamy scale **(Appendix 4)**

**9.0 Anticipated Outcomes**

To determine the extent of misinformation and awareness about clinical research amongst people of Mumbai based on the results obtained from this survey.

**10.0 References**

1. Burt T, Dhillon S, Sharma P, Khan D, Mv D, Alam S, Jain S, Alapati B, Mittal S, Singh P. PARTAKE survey of public knowledge and perceptions of clinical research in India. *PLoS One*. 2013 Jul 16;8(7).
2. Shah JY, Phadtare A, Rajgor D, Vaghasia M, Pradhan S, et al. (2010) What leads Indians to participate in clinical trials? A meta-analysis of qualitative studies*. PLoS One* 5: e10730.
3. Mackenzie IS, Wei L, Rutherford D, Findlay EA, Saywood W, Campbell MK,Macdonald TM. Promoting public awareness of randomised clinical trials using the media: the 'Get Randomised' campaign. *Br J Clin Pharmacol*. 2010 Feb;69(2):128-35
4. Joshi V, Kulkarni AA. Public awareness of clinical trials: A qualitative pilot study in Pune. Perspect Clin Res. 2012 Oct; 3(4):125-32.
5. Ravi Kumar et.al. Kuppuswamy socio economic status scale: A revision of socio economic parameter for 2012 ; 2013 ; Vol 1 (1): 2-4
6. Israel G D; Determining Sample Size. University of Florida; Pg: 1-5

**Appendix 1:** Sample size as per published table method

Sample Size for ±3%, ±5%, ±7%, and ±10% Precision Levels where Confidence Level Is 95% and P=.5.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Size of Population** | **Sample Size (n) for Precision (e) of:** | | | |
| **±3%** | **±5%** | **±7%** | **±10%** |
| 500 | a | 222 | 145 | 83 |
| 600 | a | 240 | 152 | 86 |
| 700 | a | 255 | 158 | 88 |
| 800 | a | 267 | 163 | 89 |
| 900 | a | 277 | 166 | 90 |
| 1,000 | a | 286 | 169 | 91 |
| 2,000 | 714 | 333 | 185 | 95 |
| 3,000 | 811 | 353 | 191 | 97 |
| 4,000 | 870 | 364 | 194 | 98 |
| 5,000 | 909 | 370 | 196 | 98 |
| 6,000 | 938 | 375 | 197 | 98 |
| 7,000 | 959 | 378 | 198 | 99 |
| 8,000 | 976 | 381 | 199 | 99 |
| 9,000 | 989 | 383 | 200 | 99 |
| 10,000 | 1,000 | 385 | 200 | 99 |
| 15,000 | 1,034 | 390 | 201 | 99 |
| 20,000 | 1,053 | 392 | 204 | 100 |
| 25,000 | 1,064 | 394 | 204 | 100 |
| 50,000 | 1,087 | 397 | 204 | 100 |
| 100,000 | 1,099 | 398 | 204 | 100 |
| >100,000 | 1,111 | 400 | 204 | 100 |
| a = Assumption of normal population is poor (Yamane, 1967). The entire population should be sampled. | | | | |

**Appendix 2:**

**Survey of Public Knowledge and Perception of Clinical Research in Mumbai**

1. Have you heard about clinical research? **Yes / No**
2. [If ‘Yes’]: What was the source:

* Doctor
* media
* internet
* relatives
* friends
* colleagues
* other:

[A standard definition of clinical research will be read to the person and opportunity is provided to ask questions and/or contact a clinical research professional for further clarifications]

**Definition:** Clinical research is a scientific method of studying the effects, both positive and negative, of proposed new treatments [medications or devices] in human volunteers (healthy individuals or patients). Government authorities require convincing demonstration of benefit of a new treatment before giving approval to use it in the public at large. If adverse effects are found with a new treatment then the benefits should outweigh the risk of adverse effects. Clinical trial, clinical study, and clinical research are all similar terms. Every medication in every pharmacy had to go through the clinical research process. Do you have any questions?

1. Have you ever participated in clinical research? **Yes / No**
2. Do you know what clinical research is? **Yes / No**
3. Do you know anyone who participated in clinical research? **Yes / No**
4. [If yes]: How many?
5. Do you know individuals who believe they were coerced to participate in clinical research? **Yes / No**
6. [If ‘Yes’]:Who were they coerced by:

* Doctor
* recruitment team
* relatives
* friends
* not aware

1. Will you be willing to participate in clinical research? (Answer ‘Yes’ if there is any reasonable circumstance under which you see yourself participating) **Yes / No**
2. [If Yes]: What kind of involvement in clinical research would you be willing to undertake? (Choose all appropriate answers; choose an answer if there is any reasonable circumstance where you see yourself accepting the option)

* Single questionnaire (up to 20 minutes in duration)
* Single blood draw
* Single visit (up to a few hours in duration with multiple interventions)
* Multiple visits (each up to a few hours in duration)
* Multiple days of stay in a confined unit (including overnight stay)
* Research done together with administration of standard medical care
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. If No, will you state any particular reason/s?
2. Would you have to take permission from someone else in order to participate in research? **Yes / No**
3. If yes who would it be

* spouse,
* parents,
* children,
* friends,
* physician,
* others

1. Minimal compensation appropriate for one-day’s participation in a clinical trial (no overnight stay) is:

* Altruism
* The worth of one day’s work plus expenses
* Less than the worth of one day’s work plus expenses
* More than the worth of one day’s work plus expenses
* Just expenses (e.g., travel, parking expenses)
* Free medical care
* Depending on expected benefit (less benefit = more compensation)
* Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please indicate if you believe the following statements are true, false, ‘not aware’, or ‘not relevant’:**

1. If you decide not to participate in research your doctor will not give you good care

1. Confidentiality is a matter of importance to research participants
2. Confidentiality of research participants is adequately protected
3. Clinical research information provided by pharmaceutical companies can be trusted
4. Clinical research information provided by academic institutions can be trusted
5. The most important reason for developing new treatments is financial gain
6. Clinical research benefits society
7. Volunteers in clinical research get adequate compensation for their participation
8. Clinical research is an essential step in developing new treatments
9. Human participants in clinical research are treated like experimental animals (‘human Guinea Pigs’)
10. The most important reason for developing new treatments is the advancement of science
11. Altruism is the only valid reason for participation in research
12. Volunteers in clinical research get adequate information about the research they participate in
13. Participation in research is entirely voluntary
14. Participants in clinical research get adequate compensation for any adverse outcomes
15. Clinical research harms society
16. The government always adequately protects the public against unethical clinical research
17. Hospitals that participate in clinical research provide better healthcare
18. All the results of clinical research are made available to the public
19. Doctors force their patients to participate in research
20. You have had an opportunity to participate in clinical research
21. Researchers make sure research is safe for participants
22. The media accurately describes clinical research
23. Experiments on humans are essential to developing new treatments
24. Harmful events occurring during a clinical trial must be due to experimental treatment
25. The public should be involved in clinical research (eg: design, oversight and funding)
26. Other beliefs or statement you wish to make regarding clinical research:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. What is the impact on clinical research for collaborations with non-Indian Industry partners?

* Good
* Bad
* None
* Not aware

1. Statethe extent of the impact**:**

* Large
* Moderate
* Minimal

1. What is the impact on clinical research for collaborations with non-Indian academic partners?

* Good
* Bad
* None
* Not aware

1. State the extent of the impact:

* large,
* moderate
* minimal

1. **What does ‘human guinea – pig’ mean to you (include all)?**
2. Being used without your consent or understanding
3. Being used for someone else’s benefit
4. Possibility of being exposed to unsafe interventions
5. Being disrespected
6. Being subjected to uncomfortable situation/condition
7. Other
8. **The public should be involved in the following clinical research activities (include all that apply)**
9. As participants/Volunteers in clinical trials
10. Advocating for research public policy
11. Providing funds for clinical research
12. Collecting data
13. Are there any other comments you would like to bring to our attention:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Appendix 3: Analysis of results in terms of percentage**

|  |  |  |  |
| --- | --- | --- | --- |
| **Questions** | **True (%)** | **False**  **(%)** | **Not aware**  **(%)** |
| **General** |  |  |  |
| Clinical research benefits society |  |  |  |
| Clinical research harms society |  |  |  |
| The most important reason for developing new treatments is the advancement of science |  |  |  |
| Clinical research is an essential step in developing new treatments |  |  |  |
| Hospitals that participate in clinical research provide better healthcare |  |  |  |
| The most important reason for developing new treatments is financial gain |  |  |  |
| **Trust in Clinical Research** |  |  |  |
| The government always adequately protects the public against unethical clinical research |  |  |  |
| Clinical research information provided by pharmaceutical companies can be trusted |  |  |  |
| Clinical research information provided by academic institutions can be trusted |  |  |  |
| If you decide not to participate in research your doctor will not give you good care |  |  |  |
| **Ethics in Clinical Research** |  |  |  |
| Doctors force their patients to participate in research |  |  |  |
| Human participants in clinical research are treated like experimental animals (‘human Guinea Pigs’) |  |  |  |
| Participation in research is entirely voluntary |  |  |  |
| Volunteers in clinical research get adequate compensation for their participation |  |  |  |
| Participants in clinical research get adequate compensation for any adverse outcomes |  |  |  |
| Confidentiality is a matter of importance to research participants |  |  |  |
| Confidentiality of research participants is adequately protected |  |  |  |
| All the results of clinical research are made available to the public |  |  |  |
| Altruism is the only valid reason for participation in research |  |  |  |
| Volunteers in clinical research get adequate information about the research they participate in |  |  |  |
| Harmful events occurring during a clinical trial must be due to experimental treatment |  |  |  |
| Experiments on humans are essential to developing new treatments |  |  |  |
| Researchers make sure research is safe for participants |  |  |  |
| The public should be involved in clinical research (eg: design, oversight and funding) |  |  |  |
| You have had an opportunity to participate in clinical research |  |  |  |
| The media accurately describes clinical research |  |  |  |

**Appendix 4: Kuppuswamy scale for determining socio economic status5**

**Education Score**

|  |  |  |
| --- | --- | --- |
| Sr. No | Parameter | Score |
| 1 | Profession or Honours | 7 |
| 2 | Graduate or post graduate | 6 |
| 3 | Intermediate or post high school diploma | 5 |
| 4 | High school certificate | 4 |
| 5 | Middle school certificate | 3 |
| 6 | Primary school certificate | 2 |
| 7 | Illiterate | 1 |

1. Occupation Score

|  |  |  |
| --- | --- | --- |
| Sr.No | Occupation | Score |
| 1 | Profession | 10 |
| 2 | Semi-Profession | 6 |
| 3 | Clerical, Shop-owner, Farmer | 5 |
| 4 | Skilled worker | 4 |
| 5 | Semi-skilled worker | 3 |
| 6 | Unskilled worker | 2 |
| 7 | Unemployed | 1 |

1. Monthly family income in Rs Modified for 2012

|  |  |  |
| --- | --- | --- |
| Sr.No | Range | Score |
| 1 | ≥32050 | 12 |
| 2 | 16020 – 32049 | 10 |
| 3 | 12020 – 16019 | 6 |
| 4 | 8010 – 12019 | 4 |
| 5 | 4810 – 8009 | 3 |
| 6 | 1601 – 4809 | 2 |
| 7 | ≤ 1600 | 1 |

**Total Score Socioeconomic class**

26-29 Upper (I)

16-25 Upper Middle (II)

11-15 Middle/Lower middle (III)

5-10 Lower/Upper lower (IV)

<5 Lower (V)