**Consent Form**

**Introduction:**

I am Dr./Mr./Mrs./Ms. ………………. working in the (Department/Faculty/Iinstitute)………… ………………………… as (your designation)…………………**(OR)** We are (final year/fourth year/etc.) students of the (Department/Faculty/Institute). I/We am/are doing a research on (topic of research)………….. This form provides you information and invites you to be part of this research. You do not have to decide whether or not you will participate in the research today/now. You may discuss the research with anyone you are comfortable with before making a decision to participate or not.

This form may contain certain words that you not clearly understand. Please do not hesitate to stop me/us to inquire from me/us at any point if you have any questions or need clarification. If any questions/doubts arise at a later time, you may inquire from me/us at any time during this research.

**Part 1: Information sheet**

**Title of the research:** ………………………………………………………………………... …………..……………………………………………………………………………………… ………………………………………………………………………………………………….

**Version Number:** …………………………

**Date:** ………………………..

**Purpose of the research:**

Briefly describe background of the problem, justification and the objectives of the research in layman’s terms.

**Procedures of Research:**

In layman’s terms, give a concise description of the exact procedures in the exact order in a step by step manner. Include information on many assessments, tests, measurements that will be performed. Please indicate which procedures are routine and which are experimental or research.

Participants should understand clearly what to expect and what is expected of them. Use active language, such as "we will ask you to…." instead of conditional language, such as "we would like to ask you to….".

In clinical trials where randomization or blinding is involved, the participants should be told cin clear language what that means and what chance they have of getting which drug. Where an inactive drug or placebo is involved, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

In clinical research, explain that there are standards/guidelines that will be followed for the treatment of their condition. If blood samples are to be taken, explain how many times and how much of blood will be drawn. If the samples are to be used only for this research, then clearly mention that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after \_\_\_\_ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study.

**Participant selection and voluntary participation:**

Briefly describe how and from where participants are selected for your study. Justify if needed. To inform about the voluntary participation, you may use the following format with necessary modifications as needed:

“Your participation in this research is entirely voluntary. It is your choice whether to participate or not. (Your decision will not affect any services you may receive at this facility). If you choose not to participate in this research project, please do not hesitate to let me/us know of your decision. You can change your mind at any time during this research and stop participating even if you agreed to participate now.”

**For clinical trials only:** (Omit this section if this is not a clinical trial)

Information on the Trial Drug [Name of Drug]

• give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.

• provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

• explain the known experience with this drug

• explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

**Duration:**

Mention the estimated duration of your project; specify dates if possible. You may use the following format with necessary modifications as needed:

“The research takes place over \_\_\_ (number of) days/ or \_\_\_ (number of) months in total. During that time (please explain what the person is expected to do for the research briefly).”

**Risks/Hazards/Discomforts:**

If there are any risks/hazards/discomforts involved in your research study, please mention all clearly.

**Potential Benefits:**

If there are any potential benefits to the participants, to the researchers, and/or to the society as a whole as a result of your research study, all benefits should be mentioned.

You may use the following format with necessary modifications as needed:

“If you participate in this research, you will have the following benefits:” ...................................................................................................................................................... ......................................................................................................................................................

**(OR)**

There are no (direct) benefits for you by participating in this research, but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

**Reimbursement:**

If the participants are reimbursed either monetarily or otherwise (e.g., gifts), please mention the details, including any payment to the participant indicating the amount or details of the gift(s) if necessary, when it would be paid/given and any conditions attached to it.

If no reimbursements will be given, please mention this as well.

You may use the following format with necessary modifications as needed:

“We will pay you Rs............. to pay for your travel/time as a token of appreciation for participating in this research **(OR)** We will give you (gift/s) as a token of appreciation for participating in this research.

**(OR)**

“We unable to reimburse you for your participation in this research either monetarily or any other form of gift(s). We are grateful for your participation.”

**Confidentiality:**

Briefly describe what measures are taken to ensure the participants’ confidentiality by participating in your research study.

You may use the following format with necessary modifications as needed:

“The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except (name who will have access to the information: .....................................................)”

**Right to Refuse or Withdraw:**

Include a statement informing about their right to withdraw from participation or refuse to participate. You may use the following format with necessary modifications as needed:

“You do not have to take part in this research if you do not wish to do so (and your decision will not affect any services you may receive at this facility/by me/by us as part of routine care). You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.”

**Whom to Contact:**

Include a statement such as “If you have any questions, you may ask us now or later, even after the study has started. If you wish to ask questions later, you may contact any of us or our supervisor(s) through following contact details.”

Please provide details of ALL researchers that should be contacted in the following format.

Name with title:- ..............................................................................................................................

Address:- .......................................................................................................................... Telephone number/e-mail:- ..............................................................................................

This research proposal has been reviewed and approved by the Ethics Review Committee of the Faculty of Allied Health Sciences.

**PART II: Certificate of Consent**

**To be completed:**

**A. By the participant**

The participant should complete the whole of this sheet himself/herself.

1. Have you read the information sheet? (Please keep a copy for yourself) YES/NO

2. Have you had an opportunity to discuss this study and ask any questions? YES/NO

3. Have you had satisfactory answers to all your questions? YES/NO

4. Have you received enough information about the study? YES/NO

5. Who explained the study to you? …………………………………………………………

6. Do you understand that you are free to withdraw form the study at any time,

without having to give a reason and without affecting your future medical care? YES/NO

7. Sections of your medical notes, including those held by the investigators relating

to your participation in this study may be examined by other research assistants.

All personal details will be treated as STRICTLY CONFIDENTIAL. Do you

give your permission for these individuals to have access to your records? YES/NO

8. Have you had sufficient time to come to your decision? YES/NO

9. Do you agree to take part in this study? YES/NO

I have read the foregoing information, or it has been read to me. 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.

Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(DD/MM/YYYY)

**If illiterate:**

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). 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.

Print name of witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of participant

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

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(DD/MM/YYYY)

**B. By the investigator**

I have explained the study to the above volunteer and he/ she has indicated her willingness to take part.

Signature of investigator……………………....…………..Date……………………….

Name (BLOCK CAPITALS)……………………………………………………………

**NOTE:**

* **You should make the above available in all relevant languages.**
* **Do not duplicate the above sample consent form. Use it as a guide to prepare the consent form for your own research study.**