Consent form for .....

I am Dr ……. Working in the …… as …… I/We am/are doing a research on ……., which is common medical/health problem in the area ……. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Part 1
Information sheet:
Title of the research: ……...
……..……
……

Version Number: …….

Date: ……..

Purpose of the research (briefly describe background of the problem, justification and the intended objectives in lay terms)
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Type of Research: (briefly state the methodology using lay terms).
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Participant selection: (describe how the study subjects are selected for the study)
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic/hospital will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered in this clinic/hospital. You may change your mind later and stop participating even if you agreed earlier.

For 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

Procedures and Protocol
Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research. Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In clinical trials, where randomization or blinding is involved, the participants should be told 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 as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.
If blood samples are to be taken explain how many times and how much in a language that the person understands.
If the samples are to be used only for this research, then explicitly mention here 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.

Duration:
The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days , for ____ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

Side Effects:

This drug can have some unwanted effects. It can make you ..... (tired and it can cause some temporary swelling around the place where the injection goes into your arm). It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may

stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.

Risks:
By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working ..... we will give you ..... which make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with_____.

Benefits:
If you participate in this research, you will have the following benefits:
.....
.....
Or
There may not be any benefit for you 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.

Reimbursements
We will give you Rs..... to pay for your travel to the clinic/parking and we will give you Rs..... for lost work time. You will not be given any other money or gifts to take part in this research.

Confidentiality:
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:
You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.)
OR
You do not have to take part in this research if you do not wish to do so. 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.

Who to Contact:
If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

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

PART II
Certificate of Consent:

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 _____
Day/month/year

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 _____
Day/month/year