Informed Consent Form Template for Clinical Studies

(This template is for either clinical trials or clinical research)

(Language used throughout form should be of such a level that it can be understand by a student of class 6th)

[Name of Principle Investigator]

[Informed Consent form for _____]

Name the group of individuals for whom this informed consent form is written. Because research for a single project is often carried out with a number of **different groups of individuals - for example healthcare workers, patients, and parents of patients -** it is important that you identify which group this particular consent is for.

[Name of Principal Investigator]

[Name of Organization]

[Name of Sponsor]

[Name of Proposal and version]

This Informed Consent Form has two parts:

Part I: Information Sheet (to share information about the research with you)

Part II: Certificate of Consent (for signatures if you agree to take part)

The patient should be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, you will take time to explain them as you go along and they can ask questions now or later.

(Eg: I am X, working for the Y Institute. We are doing research on Z disease, which is very common in this country. 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.

Purpose of the research

Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, “mosquitoes help in spreading the disease” rather than “mosquitoes are the vectors”. Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

(Eg: Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. Eg. **the research involves a vaccine, an interview, a biopsy or a series of finger pricks.**

(Eg: This research will involve a single injection in your arm as well as four follow-up visits to the clinic.)

Participant selection

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

(Eg: We are inviting all adults with malaria who attend X hospital to participate in the research on the new malaria drug.)

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, what the alternative will be - in terms of the treatment offered by the hospital if they decide not to participate. State that they will still receive all the services whether they choose to participate or not.

*(Eg: 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 will continue and nothing will change**. You may change your mind later and stop participating even if you agreed earlier.)*

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

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

2) provide as much information as is appropriate and understandable about the drug such as the **reason for its development**.

3) explain the known experience with this drug

4) **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**

(Eg: The drug we are testing in this research is called ABX. It has been tested before with people who do not have malaria but who live in areas where malaria is common. We now want to test the drug on people who have malaria. This second research is called a "phase 2" trial. The drug ABX has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.

Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known problems. It does not, however, cure malaria as often as we would like.)

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**. Write "we will ask you to…." instead of "we would like to ask you to…."

A. Unfamiliar Procedures

This section should be included if there may be procedures which are not familiar to the participant.

If the protocol is for a clinical trial:

1) Involving **randomization or blinding**, the participants should be told what that means and **what chance they have of getting which drug** (i.e. one in four chances of getting the test drug).

(Eg:. Because we do not know if the new malaria drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for malaria. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research, please talk to me or one of the other researchers)

2) **Involving an inactive drug or placebo**, it is important to ensure that the **participants understand what is meant by a placebo or inactive drug.**

(Eg: A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend / dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) May necessitate a **rescue medicine**, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. Eg, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

(Eg: If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine." The medicine that we will use is called QRS and it has been proven to control pain. ***If you find that the drug we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable****.)*

If the protocol is for clinical research:

Firstly, **explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, 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.

(Eg: You will receive the treatment of your condition according to national guidelines. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. The guidelines say that the sample must be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample.)

For any clinical study (if relevant):

If blood samples are to be taken explain **how many times** and **how much** in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

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 -** (see last section)

(Example: We will take 1 teaspoon of blood from your arm using a syringe and needle. In total, we will take about ……. teaspoons of blood in x number of weeks/months. ***At the end of the research, in 1 year, any left-over blood sample will be destroyed.***

B. Description of the Process

Describe to the participant what will happen on a step-by-step basis. **A small spoon/vial or container with a little water in it is one way of showing how much blood will be withdrawn.**

(Eg: During the research you make five visits to the clinic.

- *In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure – height and weight.*
- *At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.*
- *After one week, you will come back to the clinic for a blood test. This will involve….)*

Duration

Include a statement about the time commitments of the research for the participant including **both the duration of the research and follow-up,** if relevant.

(Eg: 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 hospital__(number of) days , for ____ (number of) hours each day. We would like to meet with you three months after your last visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished. Each visit will correspond with your regular follow-up visit and you will not have to make separate visit for participating in the study).

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(Eg: As already mentioned, 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

Explain and describe any possible or anticipated risks. **Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.** A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

(Eg: 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 and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and 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

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into **benefits to the individual**, benefits to the **community** in which the individual resides, and benefits **to society as a whole** as a result of finding an answer to the research question.

(Eg: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. 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

State clearly what you will provide the participants with as a result of their participation. UCMS does not encourage incentives. However, it recommends that reimbursements for expenses incurred as a result of participation in the research be provided. These may include, for example, **travel costs and money for wages lost due to visits to health facilities, especially if the visits do not coincide with regular follow up visits.**

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. If the data collection involves digital content like google forms or audio /visual recording please explain how the privacy and confidentiality will be maintained(e.g, Password protected files or encrypted files etc.)

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. It will not be shared with or given to anyone. If required, the information will be shared with IEC & other regulatory authorities***

Sharing the Results

Where it is relevant, **your plan for sharing the information with the participants should be provided**. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, **for example, through publications and conferences.**

(Eg: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw

This is a reconfirmation that **participation is voluntary and includes the right to withdraw**. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

*(Eg: 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

*(Example: You do not have to take part in this research if you wish not 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**.)*

Cost of Participation and Compensation:

You do not have to pay any money for participation in this study. Also, you will not be made to pay any charges for any of the investigations or tests that are being carried out as a part of this study. You will also **not get any financial remuneration for participating in this study. You will be provided free medical care in this hospital in case you experience any illness which is likely to be due to the procedures or treatment related to the study.**

Alternatives to Participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the hospital. People who have malaria are given….)

Whom to Contact

Provide the name and contact information of Principal Investigator(official address and phone no.)and supervisor (if applicable official address and phone no.)who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

(Example: 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])

This proposal has been reviewed and approved by the Institutional Ethics Committee for Human Research, University College for Human Research which is a committee whose task it is to make sure that research participants are protected from harm.

Dr Rashmi Salhotra

Member Secretary IEC-HR, UCMS

Room no 303

Phone No. 011-22582972-74 Extn 5312

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section **should be written in the first person** and have a statement similar to the one in bold below. If the **participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent.** The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

Certificate of Consent

Participant:

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_____ If illiterate LTI of participant

Signature of Participant _____

If Minor, signature of parent / legal guardian _____

Date _____

Witness:

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.

Name of Witness_____ If illiterate, LTI of Witness

Signature of Witness _____

Date _____

Researcher/person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name & Signature of the Participant _____

Name & Signature of Researcher/person taking the consent _____

Date _____