Informed consent form for clinical studies

Check list

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Part - II Certificate of Consent

Sample Informed Consent for Clinical Studies on Adults

Institutional Review Board
University of Public Health, Yangon
Ministry of Health
Republic of the Union of Myanmar
Informed Consent Form for Clinical Studies on Adults

Name the group of individuals for whom this consent is written- for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research X.

Name of Principal Investigator :
Name of Organization :
Name of Funding Organization :
Title of the Study :

PART I: Information Sheet

1. 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, that you will take time to explain them as you go along and that they can ask questions now or later.

Example: I am X, working for the Y Research 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. Before you decide to participate, 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.

2. Purpose

Explain in lay terms why you are doing the research. Use **local language 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 technical terms.

Example: 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.

3. Type of Research Intervention

Briefly state the type of intervention that will be undertaken. It will be helpful to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

Example : Those who participate in this research need to take a drug daily for ---- days and ---- follow up visits to the clinic. It will also involve taking blood samples.

4. Participant selection

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

Example: We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug.

5. Voluntary Participation

Indicate clearly that they can choose to participate or not. **State, only if it is applicable**, that they will still receive all the services they usually do whether they choose to participate or not.

Example: 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.

6. **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, taking biological sample* and any drugs that will be given. Explain from the outset what some of the 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….".

*[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 - (see last section)]

Example: We will take blood from your arm using a syringe needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it.) At the end of the research, in one year, your blood sample will be destroyed.

Example for studies that need follow up visits

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--------. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.

• 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….

7. 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.

Example: The research takes place over 6 months. 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. 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.

8. Risks and discomfort

List below all reasonably foreseeable physical and nonphysical risks,(e.g. the inability to work, emotional distress, etc.) and discomforts (e.g. sitting in one place for a long time, being in a confined space, reliving painful memories, receiving multiple injections, etc.) associated with the study. In addition to physiological and psychological risks/discomforts, describe any social, legal or financial risks that might result from participating in the research.

Example: By participating in this research it is possible 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.

By participating in this research it is possible that you may experience some discomfort such as the discomfort of repeated blood pressure readings or repeated blood drawings.

9. 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.

Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you.

Example: 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.

10. Incentives

State clearly what you will provide the participants with as a result of their participation. Reimbursements for expenses incurred as a result of participation in the research is permitted. These may include, for example, travel costs and money for wages lost due to visits to health facilities.

Example: We will give you [amount of money] to pay for your travel to the clinic and for your time. You will not be given any other money or gifts to take part in this research.

11. 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.

Example: The information that we collect from this research project will be kept confidential 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 keep it safely. It will not be shared with or given to anyone except your clinician.

12. Sharing the Results

Where it is relevant, your plan for sharing the information with the participants should be provided. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

Example: The knowledge that we get from doing this research will be shared with you before it is made widely available to the public (only if applicable). Confidential information will not be shared. We will publish the results in order that other interested people may learn from our research.

13. 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.

Example: 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.

14. Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible. 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 Technical and Ethical Review Board, University of Public Health, Yangon which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find out more about the Committee, contact the secretary of the committee at University of Public Health, Yangon, No 246, Myoma Kyaung Street, Latha Township, Yangon, 11131. Office Phone +95 18395213, +9518395214 ext: 20/26.

PART II: Certificate of Consent

This section can be **written in the first person**. It should include a few **brief statements** (study title, procedure, study site, risk and benefits, incentive etc.) about the research and be followed by a statement similar to the one in italic below. A witness must sign the participant's voluntary consent. A researcher or the person going over the informed consent must sign each consent. The certificate is an integral part of the informed consent.

Example: I have been invited to participate in research of a new malaria drug. I understand that it will involve receiving an injection and five follow-up visits. I have been informed that the risks are minimal and may include only _____. I am aware that there may be no benefit to me personally and that I will not be compensated beyond travel expenses. I have been provided with the name of a researcher who can be easily contacted using the number and address I was given for that person.

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 and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

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.

Thumb print of participant

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_____
Signature of witness _____
Date _____
Day/month/year

I have accurately read or 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 Researcher_____
Signature of Researcher _____
Date _____
Day/month/year

A copy of this Informed Consent Form has been provided to participant _____(initialed by the researcher/assistant)

Sample Informed Consent Form for Clinical studies on Children

Institutional Review Board
University of Public Health
Ministry of Health
Republic of the Union of Myanmar

Informed Consent Form for Clinical Studies on Children

Name the group of individuals for whom this consent 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.

Example This informed consent form is for the parents of children between the ages of 1 and 4 years of age who attend clinic Z, and who we are asking to participate in research X

Name of Principal Investigator :

Name of Organization :

Name of Sponsor :

Title of the Study :

PART I: Information Sheet

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

Example: I am X, working for the Y Research 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 have your child participate in this research. You do not have to decide today whether or not you agree that your child may participate in the research. Before you decide, you can talk to anyone you feel comfortable with.
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.

(2) Purpose
Explain the problem/research question in lay terms which will 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 technical terms.

Recognize that parents' feelings about involving their children in research can be complicated. The desire and feeling of responsibility to protect their child from risk or discomfort may exist alongside the hope that the study drug will help either their child or others. It is, therefore, important to provide clear and understandable explanations, and to give parents time to reflect on whether they will consent to have their child participate.

Example Malaria is one of the most common and dangerous diseases in this region. The vaccine that is currently being used is not as good as we would like it to be but there is a new vaccine which may work better. The purpose of this research to test the new vaccine to see if it protects young children better than the current vaccine.

(3) Type of Research Intervention

Briefly state the intervention if you have not already done so. This will be expanded upon in the procedures section.

Example: An injection OR a series of three injections OR taking a vaccine orally, a biopsy.

(4) Participant selection

State clearly, why you have chosen their child to participate in this study. Parents may wonder why their child has been chosen for a study and may be fearful, confused or concerned. Include a brief statement on why children, rather than adults, are being studied.

Example: We are inviting you to take part in this research because it is important that we test a new vaccine on children who do not have malaria but who live in an area where malaria is a serious problem. Because you and your child live in this area and your child does not have malaria, we are asking if you would allow your child to participate.
The vaccine has been found to be effective with adults and older children. Because of how young children grow and develop, we can't assume that the vaccine will be as effective on young children unless we test it on children.

(5) Voluntary Participation

Indicate clearly that they can choose to have their child participate or not. State, if it is applicable, that they will still receive all the services they usually do if they decide not to participate. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

Example: Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive at this clinic will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/or your child receives at the clinic will continue.

(6) Protocol

6.A. Protocol for a clinical trial:

a) Information on the trial drug
b) Procedures and protocol

c) Information on taking samples
d) Description of the process of taking samples

(a) 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 its manufacturer or location of manufacture and 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

Example: The ABX vaccine has been tested twice before but only with older children and adults. In both studies, the vaccine worked better than the vaccine that currently exists. While the current vaccine protects only 60% of people who take the vaccine the new one protected more than 80% of the people the new vaccine also protected for a longer time period. We want to compare those two vaccines - the current one and the new one - in a younger age group, and that is why we are doing this research.
The drug is made by Company AB, who is working with a local hospital to have it tested. It's called a _____type of drug because it helps part of the blood to_____. The new vaccine that we are studying has no known side effects. The current vaccine that is being used in the study also has no known side effects.

(b) 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….".

Explanation of Unfamiliar Procedures

1. Randomization or blinding
2. An inactive drug or placebo
3. Necessitate a rescue medicine

1. Randomization or blinding

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).

Example: Because we do not know if the new vaccine is better than the currently available vaccine for treating this disease, we need to make comparisons. Children taking part in this research will be put into groups which are selected by chance, as if by tossing a coin.

One group will get the vaccine we are testing, and the other group will get the malaria vaccine which is currently used in this region. It is important that neither you nor we know which of the two vaccines your child was 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 vaccines 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 medicines or treatment is doing, we will find out which vaccine your child is getting and make changes.

2. An inactive drug or placebo

It is important to ensure that the participants understand what is meant by a placebo or inactive drug.
Example: 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 or dummy medicine. For the research to be good, it is important that you and your child do not know whether the real medicine or the pretend or dummy medicine was given. This is one of the best ways we have for knowing what the medicine we are testing really does.

3. A rescue medicine

If procedure necessitates a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.
Example: 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".

(c) Information on taking samples

- 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.

Example
We will take blood from your arm using a syringe needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it. At the end of the research, in 1 year, your blood sample will be destroyed.

(d) Description of the process of taking samples

Describe to the participant what will happen on a step-by-step basis.
It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

Example
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 how tall you are and how much you weigh.
- 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….

6.B. Protocol for a clinical research:

a) Procedures and protocol
b) Information on taking samples
c) Description of the process of taking samples

(a) Procedures and protocol

- 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.

Example
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.

(b) Information on taking samples

- 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.

Example
We will take blood from your arm using a syringe needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it. At the end of the research, in 1 year, your blood sample will be destroyed.

(c) Description of the process of taking samples

- Describe to the participant what will happen on a step-by-step basis.
- It may be helpful to the participant if you use drawings or props to better illustrate the procedures.
- A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

Example
- 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 how tall you are and how much you weigh.
- 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….

(7) Duration

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

Example: 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 six months after your last visit for a final check-up. Altogether, we will see you and your child 4 times over a year.

(8) Side Effects

Parents 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.

Example: *These vaccines can have some unwanted effects or some effects that we are not currently aware of. However, we will follow your child closely and keep track of these unwanted effects or any problems. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also bring your child to this health facility at anytime and ask to see [name of nurse, doctor, and researcher].*

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.)

(9) Risks

A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks. Provide enough information about the risks that the parent can make an informed decision. 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.

Example: By participating in this research it is possible that your child will be at greater risk than he/she would otherwise be. There is a possibility that _____may happen as a result of taking this drug. While the possibility of this happening is very low, you should still be aware of the possibility. If something unexpected happens and harm does occur, we will provide you with_____. [explain the level of care that will be available, who will provide it, and who will pay for it. Inform the parent if there is a particular insurance in place.]

(10) Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

Example: By participating in this research it is possible that your child may experience some discomfort such as the discomfort of the injections. There may be a slight hardening and/or swelling where the needle stick goes into the skin. This should disappear in one day. Your child may also be fussier than usual or more tired. These behaviors usually stop within one day but if you are concerned, please call me or come to the clinic.

(11) Benefits

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. Mention only those activities that will be actual benefits and not those

to which they are entitled regardless of participation.

Example: If your child participates in this research, he/she 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 other benefit for your child but his/her 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.

(12) Incentives

State clearly what you will provide the participants with as a result of their participation. Reimbursements for expenses incurred as a result of participation in research is permitted. The expenses may include, for example, travel expenses and reimbursement for time lost.

Example: You will not be provided any incentive to take part in this research. However, you will be reimbursed with - provide a figure if money is involved - for your lost time and travel expense.

(13) 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. Because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

Example: The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her 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, such as research sponsors, DSMB board, your clinician, etc].

(14) Sharing of the results

Your plan for sharing the information with the participants and their parents should be provided. If you have a plan and a timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for example, through publications and conferences.

Example: The knowledge that we get from this study will be shared with you 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. Afterwards, we will publish the results in order that other interested people may learn from our research.

(15) Right to Refuse or Withdraw

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

Example: You do not have to agree to your child taking part in this research if you do not wish to do so and refusing to allow your child to participate will not affect your treatment or your child's treatment at this Centre in any way. You and your child will still have all the benefits that you would otherwise have at this Centre. You may stop your child from participating in the research at any time that you wish without either you or your child losing any of your rights as a patient here. Neither your treatment nor your child's treatment at this Centre will be affected in any way.

(16) 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 your child to take part in the research, your child will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given….

(17) Who to Contact

Provide the name and contact information of someone 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 Technical and Ethical Review Board, University of Public Health which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find out more about the Committee, contact the secretary of the committee at the University of Public Health, No 246, Myoma Kyaung Road, Latha Township, Yangon (11131), Office Phone +95 1395213, +951395214 ext: 23/25.

PART II: Certificate of Consent

This section can be written in the first person. It should include a few brief statements about the research (study title, procedure, study site, risk and benefits, incentive etc.) and be followed by a statement similar to the one in italic 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. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.
Example: I have been invited to have my child participate in research of a new malaria vaccine. I understand that it will involve my child receiving an injection and three follow-up visits. I have been informed that the risks are minimal and may include only _____. I am aware that there may be no benefit to either myself or my child personally and that I will not be compensated beyond travel expenses. I have been provided with the name of a researcher who can be easily contacted using the number I was given for that person.

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 for my child to participate as a participant in this study and understand that I have the right to withdraw my child from the study at any time without in any way affecting either my child's or my own medical care.

Name of Participant_____
Name of Parent or Guardian_____
Signature of Parent or Guardian _____
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.

Name of witness_____ and thumb print of parent
Signature of witness _____
Date (Day/month/year) _____

I have accurately read or witnessed the accurate reading of the consent form to the parent or guardian of the potential participant and the individual has had the opportunity to ask questions.

I confirm that the individual has given consent freely.
Name of Researcher_____
Signature of Researcher _____
Date (Day/month/year) _____

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant _____ (initialed by researcher/assistant)