Assent form (for children between 10 to 18 years of age)

Sample Assent form

Institutional Technical and Ethical Review Board
University of Public Health, Yangon
Ministry of Health and Sports
Republic of the Union of Myanmar
Assent form for children between 10 to 18 years of age

Research Study Title :

Principal Investigator :

Funding Organization :

Please read carefully/ read the information to the child

Why are we doing this study

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 drug which may work better. The reason we are doing this research is to find out if the drug ABX is better than drug XYZ which is currently being used.

Why have you been selected?

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 malaria drug.

What you will do in this study

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.

*[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 1 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….

Risks for you

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.

Benefits for you and the community

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.

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.

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 question 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 University of Public Health, Yangon, No 246, Myoma Kyaung Street, Latha Township, Yangon, 11131. Office Phone +95 1395213, +951395214 ext: 23/25.

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Agreement to Participate

It should include a few brief statement(as mentioned in the Part I information sheet) about the research and be followed by a statement similar to the one in bold below.

Example: I have been invited to participate in research of on anti-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 I have understood what I read or was explained. I understand the benefits and risks of the study. I agree 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.

I agree to take part in the above study.

_____

Name of study child

_____ _____

Signature or left thumb impression Date

_____

Name of the PI or his/her representative

_____ _____

Signature of the PI or his/her represent Date