**.................. သုတေသနတွင် ပါဝင်ရန်သဘောတူခွင့်ပြုလွှာ**

ဤသဘောတူခွင့်ပြုလွှာသည် ------------------------------------------------------------------------------------------------ သုတေသနစီမံချက်တွင် ပါဝင်ရန် ဖိတ်ခေါ်ခြင်းကို သဘောတူသည့် သဘောတူခွင့်ပြုလွှာဖြစ်ပါသည်။

အဓိကသုတေသီအမည် :

အဖွဲ့အစည်းအမည် :

ထောက်ပံ့ပေးသောအဖွဲ့အစည်းအမည် :

သုတေသနခေါင်းစဉ် :

**အပိုင်း(၁)သုတေသနနှင့်ပတ်သက်သည့် အကြောင်းအရာများမိတ်ဆက်ခြင်း**

ကျွန်ုပ် --------------------- သည်---------------- မှ --------------------- ဖြစ်ပါသည်။ ကျွန်ုပ်သည် ----------------------------- သုတေသနအား ပြုလုပ်မည် ဖြစ်ပါသည်။ သင့်ကို ကျွန်ုပ်တို့၏ သုတေသနတွင် ပါဝင်ရန် ဖိတ်ခေါ်အပ်ပါသည်။ နားမလည်သော စကားရပ်များရှိပါက ကျွန်ုပ် (သို့မဟုတ်) သုတေသနတွင် ပါဝင်သော ဝန်ထမ်း တစ်ဦးဦးအား အချိန်မရွေးမေးမြန်းနိုင်ပါသည်။

**သုတေသန၏ ရည်ရွယ်ချက်**

**သုတေသနဆောင်ရွက်ပုံအမျိုးအစား**

**သုတေသနတွင် ပါဝင်မည့်သူများကိုရွေးချယ်ခြင်း**

**မိမိဆန္ဒအလျောက် သုတေသနတွင် ပါဝင်ခြင်း**

ဤသုတေသနတွင် ပါဝင်ခြင်းမှာ သင်၏ လွတ်လပ်သော သဘောဆန္ဒအလျောက်သာ ဖြစ်သည်။ အကယ်၍ ပါဝင်ခြင်းမရှိပါလျှင် နောင်ရရှိမည့် ကျန်းမာရေးစောင့်ရှောက်မှုမှာ ပြောင်းလဲရပ်တန့်သွားခြင်းရှိမည်မဟုတ်ပါ။ ဤသုတေသနလုပ်ငန်းမှ အချိန်မရွေး အကြောင်းပြချက်မလိုပဲ နှုတ်ထွက်ခွင့်ရှိပြီး ဤသို့ နှုတ်ထွက်ပါကလည်း သင်ရရှိမည့် ကျန်းမာရေးစောင့်ရှောက်မှုအား မည့်သို့မှ ထိခိုက်စေမည်မဟုတ်ပါ။

**သုတေသနလုပ်ငန်းလုပ်ဆောင်ချက် အဆင့်ဆင့်**

**အချိန်ကြာမြင့်မှု**

ဤသုတေသနပြုလုပ်ရန် သင့်အနေဖြင့် ----------------------- မိနစ်ခန့် အချိန်ပေးရမည် ဖြစ်ပါသည်။

**ထိခိုက်မှုနှင့် ကိုယ်စိတ်အနှောက်အယှက်ဖြစ်စေခြင်းများ**

**အကျိုးကျေးဇူးများ**

**ကျေးဇူးတုန့်ပြန်မှု**

**အချက်အလက်များကို လျှို့ဝှက်ထားရှိမှု**

ဤသုတေသနစီမံချက်မှ ရရှိသောသတင်းအချက်အလက်များကို လျှို့ဝှက်ထားမည်။ သင်နှင့်ပတ်သက်သော အချက်အလက်များကို သုတေသနပြုလုပ်သူများမှလွဲ၍ မည်သူတစ်ဦးတစ်ယောက်မျှ ကြည့်ပိုင်ခွင့် မရှိပါ။ သင်၏နာမည်အစား နံပါတ်စနစ်ဖြစ် အချက်အလက်များကို သိမ်းဆည်းထားမည်။ သုတေသနပြုလုပ်သူများသာလျှင် သင်၏နံပါတ်ကို သိရှိပြီး သေချာစွာ သော့ခတ်သိမ်းဆည်းထားမည်ဖြစ်သည်။

**သုတေသနရလဒ်များကိုဖြန့်ဝေမှု**

ဤသုတေသနအဖြေများကိုသုတေသနတွင် ပါဝင်သူအား ပြန်လည်ပေးမည်ဖြစ်ပါသည်။ အခြားစိတ်ဝင်စားသောသူများ လေ့လာနိုင်ရန်အတွက် သုတေသနစာတမ်း ထုတ်ဝေခြင်းတွင် အသုံးပြုမည်ဖြစ်ပါသည်။

**ဆက်သွယ်နိုင်မည့် ပုဂ္ဂိုလ်များ**

အကယ်၍ သင်၌ မေးစရာမေးခွန်းများရှိပါက အချိန်မရွေးမေးမြန်းနိုင်ပါသည်။ မေးစရာရှိလျှင်၊ ကျွန်ုပ် ----------------------------- ဖုန်း --------------------------- ၊ လိပ်စာ------------------------------------ သို့ ဆက်သွယ်နိုင်ပါသည်။

ဤအဆိုပြုချက်သည် သုတေသနကျင့်ဝတ်နှင့် ကျွမ်းကျင်မှုပိုင်းဆိုင်ရာ ဆန်းစစ် သုံးသပ်မှုဘုတ်အဖွဲ့၊ အမှတ်(၂)၏ ဆန်းစစ်သဘောတူအတည်ပြုချက် ရပြီးဖြစ်သည်။ အကယ်၍ သင်သည် ဘုတ်အဖွဲ့နှင့်ပတ်သက်၍ သိလိုသည်များရှိပါက အတွင်းရေးမှူး၊ သုတေသနကျင့်ဝတ်နှင့် ကျွမ်းကျင်မှုပိုင်းဆိုင်ရာ ဆန်းစစ်သုံးသပ်မှု ဘုတ်အဖွဲ့၊ အမှတ်(၂)၊ ကျန်းမာရေးနှင့်အားကစားဝန်ကြီးဌာန၊ ရုံးအမှတ်(၄)၊ နေပြည်တော်၊ ဖုန်း ၀၆၇-၃၄၃၂၄၃၂ သို့ ရုံးချိန်အတွင်းတွင် ဆက်သွယ်နိုင်ပါသည်။

**အပိုင်း(၂)သဘောတူညီချက်**

ကျွန်ုပ်သည် -------------------------------- သုတေသနစီမံချက်တွင် ပါဝင်ရန် ဖိတ်ခေါ်ခြင်း ခံရပါသည်။ သုတေသနပြုလုပ်သူတို့သည် ---------------------------------သုတေသနပြုလုပ်မည်ဖြစ်ကြောင်း သိရှိနားလည်ပြီးဖြစ်ပါသည်။ ဤသုတေသနတွင် ပါဝင်ပါက ကျွန်ုပ်အနေဖြင့် ----------------------- ပြုလုပ်ရမည် ဖြစ်ပြီး ---------------------- ခန့် ကြာမြင့်မည် ဖြစ်ကြောင်းသိရှိပြီးဖြစ်ပါသည်။ ကျွန်ုပ်တွင် မည်သည့်အန္တရာယ်မျှ မရှိကြောင်းလည်းသိရှိနားလည်ပြီးဖြစ်ပါသည်။ သုတေသနပြုလုပ်သူနှင့် ဆက်သွယ်ရန် လိပ်စာ၊ ဖုန်းနံပါတ်များကိုလည်း သိရှိပြီး ဖြစ်ပါသည်။

ကျွန်ုပ်သည် ရှေ့မှ အချက်အလက်များကိုဖတ်ရှုပြီးဖြစ်သည်။ (သို့မဟုတ်) ကျွန်ုပ်အား ဖတ်ပြပြီးဖြစ်သည်။ ကျွန်ုပ်တွင် မေးခွန်းမေးပိုင်ခွင့်နှင့် ထိုမေးခွန်းများကို ကျွန်ုပ် ကျေနပ်သည်အထိ ဖြေကြားပြီးဖြစ်သည်။ ကျွန်ုပ်သည် သုတေသနတွင် မိမိဆန္ဒအလျောက် ပါဝင်ရန် သဘောတူပါသည်။ ဤသုတေသနလုပ်ငန်းများမှ အချိန်မရွေးနှုတ်ထွက်ခွင့်ရှိပြီး၊ ယင်းသို့ နှုတ်ထွက်ခြင်းကြောင့် ကျွန်ုပ်အပေါ် မည်သို့မျှ ထိခိုက်ခြင်းမရှိကြောင်းနားလည်ပြီးဖြစ်ပါသည်။

ပါဝင်သူအမည် --------------------------------------------------

ပါဝင်မည့်သူလတ်မှတ်------------------------------------------

နေ့စွဲ---------------------------------------------------------------

(ရက်၊လ၊နှစ်)

**အကယ်၍ စာမတတ်သူဖြစ်လျှင်**

ကျွန်ုပ်၏ ရှေ့မှောက်၌ သုတေသနတွင် ပါဝင်မည့်သူများအား သဘောတူညီချက်ကို တိတိကျကျ၊ ရှင်းရှင်းလင်းလင်းဖတ်ပြပြီးဖြစ်သည်။ နားမလည်သည်များကို မေးပိုင်ခွင့်ရှိသည်။ ထိုသူသည် ဆန္ဒအလျှောက် သဘောတူညီချက်ကို လွတ်လွတ် လပ်လပ် ပေးခြင်းဖြစ်ကြောင်း ထောက်ခံအတည်ပြုအပ်ပါသည်။

သက်သေ၏အမည်-------------------------------------------

သက်သေ၏လတ်မှတ်---------------------------------------- ပါဝင်သူ၏လက်ဗွေ

နေ့စွဲ ----------------------------------------------------------- (ရက်၊လ၊နှစ်)

ကျွန်ုပ်၏ ရှေ့မှောက်၌ သုတေသနတွင် ပါဝင်မည့်သူများအား သဘောတူညီချက်ကို တိတိကျကျ၊ ရှင်းရှင်းလင်းလင်းဖတ်ပြပြီးဖြစ်သည်။ နားမလည်သည်များကို မေးမြန်းပြီးဖြစ်ပါသည်။ ထိုသူသည် ဆန္ဒအလျှောက် သဘောတူညီချက်ကို လွတ်လွတ်လပ်လပ် ပေးခြင်းဖြစ်ကြောင်း ထောက်ခံအတည်ပြုအပ်ပါသည်။

သုတေသီအမည်-----------------------------------------------

သုတေသီလတ်မှတ်-------------------------------------------

နေ့စွဲ--------------------------------------------------------------

(ရက်၊လ၊နှစ်)

ဤသဘောတူခွင့်ပြုလွှာ မိတ္တူတစ်စောင်ကိုသုတေသနတွင် ပါဝင်မည့်သူအား ပေးအပ်ပြီးဖြစ်သည်။

---------------------------------------------------------- (သုတေသီ/သုတေသီလက်ထောက်)

**Sample informed consent (18 year and above)**

**Institutional Review Board (2)**

**Ministry of Health and Sports**

**Republic of the Union of Myanmar**

**Informed Consent Form (18 year and above)**

**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 counselors, community members, clients of services - it is important that you identify which group this particular consent is for.

Example: *This informed consent form is for social service providers in the community X and who we are inviting to participate in research Y, titled "The Community Response to Malaria Project".*

Name of Principal Investigator :

Name of Organization :

Name of Funding Organization :

Title of the Study :

**PART I: Information Sheet**

**Introduction**

Briefly state who you are and that you are inviting them to participate in research which 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 at anytime.

*Example: I am X, working for the Y organization. I am doing research on the disease malaria which is very common in this country and in this region. 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.*

*This consent form may contain 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 or of another researcher.*

**Purpose of the research**

Explain the research question in lay terms. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information.

*Example: Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general . We want to learn what people who live or work here know about the causes of malaria and why some people get it. We want to learn about the different ways that people try to stop malaria before someone gets it or before it comes to the community, and how people know when someone has it. We also want to know more about local health practices because this knowledge might help us to learn how to better control malaria in this community.*

**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 questionnaire, or a series of finger pricks.

*Example: This research will involve your participation in a group discussion and a one hour interview.*

**Participant Selection**

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

*Example: You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of local health practices.*

**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 if they choose not to participate. It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. 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 participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Centre will continue and nothing will change.*

*OR*

*The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.*

*OR*

*You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected.*

**Procedures**

A. Provide a brief introduction to the format of the research study.

*Example: We are asking you to help us learn more about malaria in your community. We are inviting you to take part in this research project. If you accept, you will be asked to:*

B. Explain the type of questions that the participants are likely to be asked in the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

*Example 1 (for* ***questionnaire surveys****)*

*fill out a survey which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys].OR You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down.*

*If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to your survey.*

**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 \_\_\_ (number of) days/ or \_\_\_ (number of) months in total. During that time, it will be necessary for you to come to the study site \_\_\_\_\_\_\_(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 (number of )times over (time period).*

**Risks and Discomforts**

Explain and describe any risks or discomforts that you anticipate or that are possible.

*Example: There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.*

**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: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community.*

**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 reimbursement for time lost. The amount should be determined within the host country context.

*Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).*

**Confidentiality**

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that 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 therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

*Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. 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, such as research sponsors, DSMB board, your clinician, etc].*

**Sharing the Results**

Your plan for sharing the findings with the participants should be provided if you plan to do so. You may 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 this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.*

**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 can ask them now or later. 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 Review Board (2), Ministry of Health and Sports, 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 ……………………………………………………...*

**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 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. The certificate is an integral part of the informed consent.

*Example: I have been invited to participate in research about malaria and local health practices. 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 be paid only for my travel expenses. I have been given with the name and address of a researcher who can be easily contacted.*

(This section is mandatory)

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 I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study and understand that I have the right to withdraw from the [discussion/interview] at any time without in any way affecting my medical care.

Name of participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Day/month/year

*If illiterate*

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.

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.

Name of witness\_\_\_\_\_\_\_\_\_\_\_\_ and Thumb print of participant

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 the participant \_\_\_\_\_ (initialed by the researcher)