Consent Form Preparation Guidelines

- This guidelines protocol was prepared to help authors appropriately write a well-structured, easy-to-read and appropriate consent form. Throughout this document, explanatory and exemplary statements are provided for each section of the Consent Form.
- Authors are required to prepare a bilingual consent form (Arabic and English versions). Authors may benefit from the Translation Department services, if required.
- Please consider the design and methodology of the proposed research protocol when preparing the Consent Form. Please appropriately complete all the sections required according to the study protocol.
- Please bear in mind that authors are expected to commit to these guidelines. Inability to do so would probably render their application ineligible for review.
  - Authors may refer to the link below to learn more about appropriate language structure in a consent form:

https://prism.kpwashingtonresearch.org/course_introduction/splash_page_before_registration.html

English Version

PART I

Introduction (Invitation to Participate)

Explanation: 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

Example: You are being asked to be in a research study of [*insert general statement about study*]. You were selected as a possible participant because [*explain how subject was identified, include any exclusionary criteria*]. We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Purpose of the Research

Explanation: 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 diseases 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 etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

Example: The purpose of the study is *[explain research question and purpose in lay language]*. Ultimately, this research may be *[published as part of a book on…, presented as a paper, etc.]*.

Type of Research Intervention

Explanation: Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section, but it may be helpful and less confusing 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: In this study, you will be given *[briefly explain the nature of the intervention provided in lay language]*.

Participant Selection

Explanation: 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.

Example: The reason we are asking you to take part in this study is *[state the criteria for which the subject was selected. Consider lay language]*.

Voluntary Participation

Explanation: Indicate clearly that they can choose to participate or not. State what the alternative in terms of the treatment offered by the clinic will be, if they decide not to participate. State only if it is applicable that they will still receive all the services they usually do whether they choose to participate or not this can be repeated and expanded upon later in the form as well, but 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. Whether you choose to participate or not, all the services you receive at this clinic/facility will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier

Procedures and Protocol

Explanation: Describe or explain the exact procedures that will be followed on a step- by step basis, the tests to be done, and any drugs to 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" instead of "we like to ask you".

Example: If you agree to be in this study, you will be asked to do the following things: *[explain procedures and tasks; identify any procedures that are experimental; describe length of time for participation, frequency and duration of procedures; etc.]*

*[If applicable, explain any alternative procedures or courses of treatment available to the subject.]

If the protocol is for clinical research:

Explanation: 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.

If for any clinical study (if relevant):

Explanation: 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 wineglass full will be taken but it may be very appropriate to use pictures or other propos to illustrate the procedure if it is unfamiliar.

(If the samples are to be used only this research, then explicitly mention here that the biological samples obtained during this research procedures will be used only for this research, and will be destroyed after years, when the research is completed. If the issues /

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 and 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. In total, we will take about ……..this much blood in x number of weeks/months. At the end of the research, in 1 year, any left-over blood sample will be destroyed

Description of the Process

Explanation: 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 propos to better illustrate the procedures. A small vial or container with a little water in it 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 questions about your 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.

Duration

Explanation: 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 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.)

Side Effects

Explanation: 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.

Example: 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. 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

Explanation: 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.

Example: The study has the following risks. First, *[explain first risk, including the likelihood of the risk]*. Second, *[explain second risk, including the likelihood of the risk]*. Third, …

If there are no foreseeable risks, state as such *(There are no reasonable foreseeable (or expected)* risks. There may be unknown risks.

OR

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.

Benefits

Explanation: 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. 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.)

OR

The benefits of participation are [explain benefits of participation that will be gained by the participants and/or other. If a benefit is not likely to occur to each participant do not include.

If there are no expected benefits, state as such.]

Reimbursements

Explanation: State clearly what you will provide to the participants with as a result of their participation. PSMCHS 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. The amount should be determined within the host country context.

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

OR

You will receive the following payment/reimbursement: [explain amount of payment or other reimbursement information (e.g., class points, tokens, donations, etc.), as well as when payment and/or reimbursement will occur and in what cases payment will not occur if any. If there will be no payment, state this.]

Confidentiality

Explanation: 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. 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, such as research sponsors, DSMB board, your clinician, etc].

OR

This study is anonymous. We will not be collecting or retaining any information about your identity. The records of this study will be kept strictly confidential. Research records will be kept in a locked file, and all electronic information will be coded and secured using a password protected file. [If audio or video tape recordings are made, explain specifically who will have access to them, if they will be used for educational purposes, and when they will be

erased/destroyed and indicate how they will be destroyed or erased.] We will not include any information in any report we may publish that would make it possible to identify you

Sharing the Results

Explanation: 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.

Example: 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

Explanation: 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 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

The decision to participate in this study is entirely up to you. You may refuse to take part in the study at any time without affecting your relationship with the investigators of this study or PSMCHS. Your decision will not result in any loss or benefits to which you are otherwise entitled. You have the right not to answer any single question, as well as to withdraw completely from the interview at any point during the process; additionally, you have the right to request that the interviewer not use any of your interview material.

Alternatives to Participating

Explanation: 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 centre/institute/hospital. People who have malaria are given….

Whom to Contact

Explanation: Provide the name and contact information of someone who is involved, informed and accessible to be contacted. State also that the proposal has been approved and how.

Example: You have the right to ask questions about this research study and to have those questions answered by me before, during or after the research. If you have any further questions about the study, at any time feel free to contact me, [name] at [email] or by telephone at [phone number]. If you like, a summary of the results of the study will be sent to you.

If you have any other concerns about your rights as a research participant that have not been answered by the investigators, you may contact Institutional Review Board office of the PSMCHS at # 966-3-8440000, Ex. 6288.