CHAPTER 3.6

USE OF STUDY ASSESSMENT FORM

SOP NUMBER: SOP/012/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

Effective Date: October 1, 2021
Supersedes: SOP/011/yy

Author: SOP Team — Date: September 29, 2021
Approved by: Chairperson, IRB — Date: September 30, 2021
Name: ***Dr. Karma Tenzin***

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1. PURPOSE

This SOP describes how the IRB members shall use the assessment forms when reviewing the study protocols initially submitted for approval. The Assessment Form (AF/01-012/01) is designed to standardize the review process and to facilitate reporting, recommendation and comments given to each individual protocol.

2. SCOPE

This SOP shall apply to the review and assessment of all protocols submitted for initial review and approval from the IRB. The specific questions in the Assessment Form shall be adequately addressed in the protocol itself and/or protocol-related documents under review.
Relevant points made during discussion and deliberation about a specific protocol shall be recorded on the form.

The decision reached by the board and the reasons for its decision is recorded on the Decision Form (AF/04-012/01).

3. RESPONSIBILITY

The reviewers shall be responsible to fill the assessment form along with decision and comments they might have after reviewing each study protocol. The IRB Secretariat shall be responsible for recording and filing the decision made by the IRB, relevant points and deliberation about a specific protocol, including the reasons for that decision on the decision from, ANNEX – AF/04-012/01. The Chairperson of the IRB shall sign and date to approve the decision in the form.

4. FLOW CHART

No.	Activity	Responsibility
1	Summarize the protocol in an Assessment Form ↓	IRB Secretariat
2	Use the Assessment Form to guide the review ↓	IRB members / Reviewers
3	Record the review decision on the Assessment Report ↓	IRB members / Reviewers
4	Gather Assessment Reports	IRB Secretariat
5	Record the IRB Decision on the Decision Form	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Summarize the protocol in an Assessment Form.

Record general information about the protocol in the form, Annex- AF/01-012/01 such as:

5.1.1. Title of the protocol
5.1.2. Protocol number and date
5.1.3. Principal Investigators, license & contact number
5.1.4. Co-investigators & contact number
5.1.5. Funding agency & contact number
5.1.6. Study types
5.1.7. Duration of the study
5.1.8. Status of the protocol – New / Revised / Amended
5.1.9. Review status – Regular / Expedited / Emergency
5.1.10. Reviewer's name

5.1.11. Objective and description of the Study

5.2. Use the Assessment Form to guide the review

Use the Assessment Form to review the protocol and the study related documents, and make the comments on the form.

5.2.1. Review the study protocol (see details in Annex 3).

5.2.1.1. Need for human participants for study
5.2.1.2. Objectives of the study
5.2.1.3. Review of literature
5.2.1.4. Sample size
5.2.1.5. Methodology and data management
5.2.1.6. Inclusion/exclusion criteria
5.2.1.7. Control arms (placebo, if any)
5.2.1.8. Withdrawal or discontinuation criteria

5.2.2. Examine the qualification of investigators and of study sites.

5.2.2.1. Consider whether study and training background of the participating investigators relate to the study.
5.2.2.2. Examine disclosure or declaration of potential conflicts of interest
5.2.2.3. Availability of facilities and infrastructure at study sites to accommodate the study.
5.2.2.4. Non-physician principal investigators (PI) shall be advised by a physician when necessary.

5.2.3. Review study participation (see guidance on ANNEX 7).

5.2.3.1. Voluntary, non-coercive recruitment/participation/withdrawal
5.2.3.2. Procedures for obtaining informed consent
5.2.3.3. Contents of the patient information sheet - title, objective, study design and procedures
5.2.3.4. Contents and language of the informed consent document
5.2.3.5. Translation of the informed consent document in the local language used – simple and easy to understand by general public
5.2.3.6. Contact persons with address and phone numbers for questions about subject's rights and study or injury
5.2.3.7. Privacy and confidentiality
5.2.3.8. Risks and discomforts – physical / mental / social
5.2.3.9. Alternative treatment
5.2.3.10. Benefits – to participants and to others
5.2.3.11. Compensation for participation / for injury– reasonable / unreasonable
5.2.3.12. Involvement of vulnerable participants
5.2.3.13. Provisions for medical/psychosocial support
5.2.3.14. Treatment for study related injuries
5.2.3.15. Use of biological materials
5.2.3.16. New Findings / information
5.2.3.17. No waiver of rights statement
5.2.3.18. Authorization or Release of information
5.2.3.19. Copy of signed and dated consent form
5.2.3.20. Signatures with dates of participant, person conducting informed consent discussion, investigator and witness

5.2.4. Examine community involvement and impact.

5.2.4.1. Community consultation

5.2.4.2. Involvement of local researchers and institutions in the protocol design, analysis and publication of the results

5.2.4.3. Contribution to development of local capacity for research and treatment

5.2.4.4. Benefit to local communities

5.2.4.5. Availability of study results

5.3. Record the review decision on the Assessment Report

5.3.1. Get the assessment report form, Annex- AF/03-012/01

5.3.2. Record the decision by marking in the desired block any of the following: "Approved, Approved with recommendation, Solicited for Resubmission, or Disapproved."

5.3.3. Include comments, suggestion and reason for disapproval.

5.3.4. Check the completeness and correctness of the assessment form.

5.3.5. Sign and date the decision form.

5.3.6. Give or send the complete forms to the IRB Secretariat *2 days* before the board meeting.

5.4. Gather the assessment reports.

5.4.1. Collect the assessment forms and the review result from each reviewer.

5.4.2. Organize the forms in order.

5.4.3. Summarize the comments, suggestions, and opinions of each study in the meeting agenda.

5.4.4. Follow SOP/021/01 Preparation of meeting agenda and minutes.

5.5. Record the IRB decision on the decision form

5.5.1. Get the IRB's decision from, ANNEX – AF/04-012/01

5.5.2. Complete the information. (by the Secretariat)

5.5.3. List participating members and their votes.

5.5.4. Summarize the guidance, advice and decision reached by the IRB members.

5.5.5. Sign and date the document by the Chairperson of the IRB.

5.5.6. Make a copy of the completed decision form.

5.5.7. Keep the original copy in the file labelled "IRB's decision".

5.5.8. Keep the copy of the decision form with the study protocol

5.5.9. Return the file and the protocol to the appropriate shelves.

6. GLOSSARY

Study Assessment Form	An official record that documents the protocol review process.
Document	Document may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.
Pre-clinical study	Animal and *in vitro* studies provide information on possible toxicities and mechanisms of action, and starting doses for human studies.
Vulnerable subjects	A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally

	disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.	
Categories of Risk	Type of risk	Definition/description
	Less than minimal risk (Level I)	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
	Minimal risk (Level II)	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
	Minor increase over minimal risk or Low risk (Level III)	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.
	More than minimal risk or High risk (Level IV)	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

7. REFERENCES

7.1. WHO. Standards and operational guidance for ethics review of health-related research with human participants (2011). (http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf - accessed 28 October 2017)

7.2. ICH HARMONISED GUIDELINE. INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) Current Step 4 version dated 9 November 2016 (https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf - accessed 28 October 2017)

7.3. Ethical Guidelines for Biomedical research on Human Subjects, 2000.

7.4. Cavazos N., Forster D., and Bowen A.J., Ethical Concerns in Placebo-controlled studies: An Analytical Approach, Drug Information Journal 36(2) 2002: pgs 249-259, via WIRB documents

7.5. Indian Council of Medical Research, NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS 2017: pg 6 (ISBN: 978-81-910091-94)

8. ANNEX

ANNEX 1	AF/01-012/01	Study Assessment Form (5 pages)
ANNEX 2	AF/02-012/01	Study Assessment Form for case studies and case series
ANNEX 3	AF/03-012/01	Informed Consent Assessment Form
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ANNEX 1

AF/01-012/01 **Study Assessment Form**

Protocol Number:	
Protocol Title :	
Protocol: Version No.... Dated.....	**Informed Consent:** Version No..... Dated.....
Principal Investigators: **Institute**:	
Co-investigator(s):	
Funding Agency:	
Duration of the Study: (From protocol development to report dissemination)	
Start Date of Data Collection:	**Completion Date** of Data Collection:

Type of the Study (Tick all relevant):

☐ Intervention ☐ Epidemiology ☐ Observation
☐ Document based ☐ Individual based ☐ Genetic
☐ Social Survey ☐ Others, specify…….

Description of the Study in brief: (Mark all that applicable to the study)

☐ Randomized ☐ Stratified Randomized ☐ Open-labeled
☐ Double blinded ☐ Placebo controlled ☐ Treatment controlled
☐ Cross-over ☐ Parallel ☐ Interim Analysis
☐ Use of Tissue samples ☐ Use of Blood samples ☐ Use of genetic materials
☐ Multicenter study ☐ Screening ☐ Descriptive
☐ Others, specify …….

Study Objectives: ……
……
……
……
……
……
……

Review Status: ☐ Full board ☐ Expedited ☐ Emergency

Mark and comment on whatever items applicable to the study.		
Study Protocol – Scientific issues		
1.	Objectives of the Study ☐ clear ☐ unclear	What should be improved?
2.	Need for Human Subjects. ☐ Yes ☐ No (Note: Refer SOP/007/03 for more details on the definition of human subject)	
3.	Methodology: (Study design, sampling methodology, Data collection and analysis plan) ☐ clear ☐ unclear	
4.	Background Information and Data ☐ sufficient ☐ insufficient	
5.	Sufficient number of participants? ☐ Yes ☐ No (Note: For quantitative study, is sample size calculation details provided?)	
6.	Inclusion Criteria ☐ appropriate ☐ inappropriate ☐ Not provided	
7.	Exclusion Criteria ☐ appropriate ☐ inappropriate ☐ Not provided	
8.	Discontinuation and Withdrawal Criteria ☐ appropriate ☐ inappropriate ☐ Not provided (Note: The intervention(s) has to be discontinued and withdrawn if there is SAE/AE and there has to be clear criteria for such discontinuation and withdrawal of the intervention(s).	
9.	Data collection tools (such as Questionnaire, Guidelines, Manuals, Forms) ☐ appropriate ☐ inappropriate ☐ Not provided	
Qualifications of Investigators and study sites		

10.	a. Are Qualification and experience of the Participating Investigators appropriate? ☐ Yes ☐ No ☐ CV not attached	
	b. For Clinical Trails only, does the PI and/or Co-PI has proof of GCP training ☐ Yes ☐ No ☐ Proof not attached ☐ NA (Note: Usually the GCP training certificates are valid for only 2-3 years. Check the validity of the certificate)	
11.	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate ☐ Site not mentioned	
12.	Disclosure or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No (Note: Refer serial number 17 of the "AF/01-009/05 APPLICATION FORM for INITIAL REVIEW")	
13.	Is there a Physician if the PI is non Physician ☐ Yes ☐ No ☐ Not applicable	
Study Participation- Ethical Issues		
14.	Categories of Risk ☐ Less than minimal risk (Level I) ☐ Minimal risk (Level II) ☐ Minor increase over minimal risk or Low risk (Level III) ☐ More than minimal risk or High risk (Level IV) (Note: Level I - Probability of harm or discomfort anticipated in the research is nil or not expected. Level II - Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Level III - Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. Level IV - Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Refer SOP/12 for definition/description of Categories of Risk)	

15.	Risks and Benefits Assessment ☐ acceptable ☐ unacceptable (Note: The reviewers shall assess the risks and benefits of the study. Comment on how to protect vulnerable subjects, level of risks, identification of types of risks (e.g. placebo, clinical or social risk, etc.), benefits: benefits to participants, benefits to society, risk/benefit ratio)	
16.	Involvement of Vulnerable Participants ☐ Yes ☐ No (Note: Refer Glossary in the SOP/12 or section 5.1.10 of Chapter 11 for the definition of vulnerable participants.)	
17.	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No ☐ NA	
18.	Are blood/tissue samples sent abroad? ☐ Yes ☐ No (Note: If 'Yes', review the Material Transport Agreement. For details refer SOP/)	
19.	Privacy & Confidentiality ☐ Yes ☐ No (Note: Privacy refers to persons and their interest in controlling access to themselves. Confidentiality refers to agreements with the participant about how data are to be handled.)	
20.	Inducement for Participation ☐ Unlikely ☐ Likely (Note: Among other things like information sheet and examine the budget details)	
21.	Provision for Medical / Psychosocial Support ☐ appropriate ☐ inappropriate ☐ Not mentioned ☐ NA	
22.	Provision for Treatment of Study-Related Injuries ☐ appropriate ☐ inappropriate ☐ Not mentioned ☐ NA	
23.	Provision for Compensation ☐ appropriate ☐ inappropriate ☐ NA	
Community involvement and Impact		

24.	Community Consultation ☐ Yes ☐ No ☐ NA (Note: Community is a group of people living in the same place or having a particular characteristic in common. E.g., epilepsy population, Bhutanese community in Australia, etc.)	
25.	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and Publication of Results ☐ Yes ☐ No	
26.	Contribution to Development of Local Capacity for Research and Treatment ☐ Yes ☐ No	
27.	Benefit to Local Communities ☐ Yes ☐ No	
28.	Availability of similar Study / Results ☐ Yes ☐ No (Note: Refer the list of protocols approved by IRB besides doing literature search online)	

Reviewer's Name and Signature: _____

Date: _____

ANNEX 2
AF/02-012/01 Study Assessment Form for Case Study and Case Series

Protocol Number:
Study Title :
Draft Report or Protocol: Version No... Dated
Principal Investigator(s): **Institute**:
Co – investigator(s):
Funding Agency:
Description of the Case Study in brief:
Review Status: ☐ Full board ☐ Expedited ☐ Emergency

Mark and comment on whatever items are applicable to the study.		
Scientific issues		
1	Is the case or case series report or protocol scientifically sound ☐ Yes ☐ No	
Qualifications of Investigator(s) or Author(s)		
2	Are Qualification and experience of the Participating Investigators appropriate? ☐ Yes ☐ No ☐ CV not attached	
3	Disclosure or Declaration of Potential Conflict of Interests ☐ Yes ☐ No (**Note:** Refer serial number 11 and 12 of the "AF/05-008 APPLICATION FORM for Initial Review of CASE STUDY / CASE SERIES")	
Privacy and Confidentiality		

4	Is the personal identifiers removed from study-related information or report? ☐ Yes ☐ No ☐ NA	
5	(For prospective case or case series studies only) Is the issues of Privacy & Confidentiality adequately addressed in the protocol? ☐ Yes ☐ No ☐ NA (Note: Privacy refers to persons and their interest in controlling access to themselves. Confidentiality refers to agreements with the participant about how data are to be handled.)	
Informed Consent and/or Informed Assent		
6	Is there a written permission to use the patient information for research from the patient or their parent(s)/legal guardian? ☐ Yes ☐ No ☐ NA	
7	(For prospective case or case series studies only) Is there an Informed Consent documents submitted for review? ☐ Yes ☐ No ☐ NA (Note: For prospective case or case series studies, use AF/03-012 Informed Consent Assessment Form to assess the Informed Consent documents)	

Reviewer's Name and Signature: _____

Date: _____

ANNEX 3

AF/03-012/01 **Informed Consent Assessment Form**

Protocol Number:		
Protocol Title :		
Protocol: Version No.... Dated.....	**Informed Consent:** Version No..... Dated.....	
Principal Investigators: **Institute**:		
Co-investigator(s):		
Sl.No	Informed Consent Information	Comments
1.	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	
2.	Is there an informed consent information to be provided for the participants ☐ Yes ☐ No	
3.	Contents of the Informed Consent clear ☐ clear ☐ unclear	
4.	Language of the Informed Consent ☐ clear ☐ unclear	
5.	Information contents for the informed consent adequate ☐ Adequate ☐ Inadequate	
6.	Is the informed consent information translated into local language ☐ Yes ☐ No ☐ NA	
7.	Form for signature to ensure the administration of informed consent form, witness and person conducting informed consent form ☐ appropriate ☐ inappropriate ☐ Not available ☐ NA	
8.	Contact Persons for Participants ☐ Yes ☐ No (**Note:** Name and contact number of the investigator(s) and IRB shall be there in the information sheet)	

Reviewer's Name and Signature: _____

Date: _____

Annex 4
AF/04-012/01 Assessment Report Form

Review Date (DD/MM/YYYY): **.....**
Protocol number: …… Version No.: .....Dated: .....

Protocol Title :		
Elements Reviewed (AF/01-012/01)	☐ Attached	☐ Not attached
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:	
DECISION : (**Note:** Refer "ANNEX 9 of SOP/012/01" for the criteria)	Protocol (Version No._____): ☐ Approved ☐ Approved with Recommendation ☐ Solicited for Resubmission (Expedited ☐ Full Board ☐) ☐ Disapproved If approved, the frequency for continuing review: _____	
	Informed Consent Form (Version No._____): ☐ Approved ☐ Approved with Recommendation ☐ Solicited for Resubmission (Expedited ☐ Full Board ☐) ☐ Disapproved	
	Tools (Version No._____): ☐ Approved ☐ Approved with Recommendation ☐ Solicited for Resubmission (Expedited ☐ Full Board ☐) ☐ Disapproved	
	Other related documents (ex. Advertisement), Yes ☐ No ☐ If Yes, specify: _____ ☐ Approved ☐ Approved with Recommendation ☐ Solicited for Resubmission (Expedited ☐ Full Board ☐) ☐ Disapproved	
Comment (**Note:** Mention recommendations/clarification to be sought from the assessment form AF/01or2-012/01 and any other additional comments here):		
Signature :		Date:

ANNEX 5
AF/05-012/01 **IRB Decision Form**

Meeting No.: ……../…….. Date (D/M/Y):

Protocol number…… Version No.: …… Dated: .....

Protocol Title :		
Principal Investigators:		
Institute:		
Elements Reviewed (AF/ 01-012) :	☐ Attached ☐ Not attached	
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:	
Decision of the meeting: (Note: Refer "ANNEX 12 of SOP/012/05" for the criteria)	☐ Approved ☐ Approved with Recommendation ☐ Disapproved ☐ Resubmission (Expedited ☐ Full Board ☐) If approved, the frequency for continuing review:	

No.	Voting IRB members	Decision			
		AP	AR	RES	DA

Note: AP - Approved; AR – Approved with recommendation;

RES – Resubmission for re-review; DA – Disapproved

Signature: ……

Chairperson
Date:

ANNEX 6
- AF/06-012/01 **Action letter template**

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Khesar Gyalpo University of Medical Sciences of Bhutan
Royal Government of Bhutan

Ref. No. / / / Date:

IRB REVIEW LETTER (This is not an approval letter)

Protocol No: .....
Principal Investigator: .....
Institute: .....
Co-Investigator(s): .....
Proponent of the study: .....

Dear .....,
Please find the review summary of your protocol titled "....." version "..." dated "DD/MM/YYYY" submitted to IRB on "DD/MM/YYYY". The protocol was reviewed by ...th IRB full board meeting (or The protocol was reviewed through expedited review process by IRB).

Upon review of the protocol and/or other document(s) the board made the following decision:	
LIST OF DOCUMENTS	DECISION
Protocol	Approved/Approved with recommendations/Solicited for resubmission/Disapproved
Informed Consent Form	Approved/Approved with recommendations/Solicited for resubmission/Disapproved
Tools (Questionnaire/forms/guides/etc)	Approved/Approved with recommendations/Solicited for resubmission/Disapproved
Advertisements (Recruitment materials)	Approved/Approved with recommendations/Solicited for resubmission/Disapproved
Others (Specify).....	Approved/Approved with recommendations/Solicited for resubmission/Disapproved
Recommendation(s)/clarification(s):	

PLEASE NOTE THAT:

a. If any of the documents listed above is either *'Approved with Recommendations' or* '*solicited for Resubmission'*, you shall make revisions as per the recommendation(s) or provide the clarification(s), if any, and **resubmit it for final Approval within 3 months from the issuance date of this review letter**. If resubmission is not done within the given deadlines then the protocol file will be closed. Although resubmission of the revised documents or clarifications after the deadline is strongly discouraged, any such resubmission has to be submitted as a new protocol.
b. The study can be conducted **ONLY after obtaining Final Approval** from the IRB.

If disapproved, please include the following lines;
"If you wish to appeal to this decision, please contact the IRB and submit your appeal in writing within 3 months from the issuance date of this review letter, addressed to the IRB Chairperson with justification as to why the appeal shall be granted. If appeal is not done within the given deadlines then the protocol file will be closed."

Signature
(Name)
Chairperson

For further information please contact: *...@kgumsb.edu.bt; IRB Member Secretary*

ANNEX 7

- AF/07-012/01 Approval Letter Template

ཀོ་སར་རྒྱལ་པོ་གསོ་རིག་གཙུག་ལག་སློབ་སྡེ།།

Khesar Gyalpo University of Medical Sciences of Bhutan
Royal Government of Bhutan

Ref. No. **IRB/Approval/YYYY/002** **Approval Date: DD/MM/YYYY**

IRB APPROVAL LETTER (valid through DD/MM/YYYY)

PI: **Institute:**	**Study Title**:
Co-Investigator(s): **Proponent of the study:**	
Mode of Review: Initial Review: ☐ *Full Board Review (Meeting No. X/YYYY-XXth)* ☐ *Expedited review* Resubmission (1): ☐ *Full Board Review (Meeting No. X/YYYY-XXth)* ☐ *Expedited review* Resubmission (n): ☐ *Full Board Review (Meeting No. X/YYYY-XXth)* ☐ *Expedited review*	
Date of continuing review: DD/MM/YYYY Note: *Please submit continuing review report along with application form AF/01/015/05 at least seven days before the date of continuing review. If the study is completed then please submit final report of the study.*	
List of document(s) approved: Protocol : Version No. ... Dated: ..... Informed Consent Form : Version No. ... Dated: ..... Tools (Questionnaire/forms/guides/etc) : Version No. ... Dated: ..... Others (Specify) ..... : Version No. ... Dated:	
Conditions for Approval: 1. *This approval is granted for the scientific and ethical soundness of the study. The PI shall be responsible to seek all other clearances/approvals required by law/policy including permission from the study sites before conducting the study.* 2. *Report serious adverse events to IRB within 10 working days after the incident and unexpected events should be included in the continuing review report or the final report.* 3. *No biological material shall be used for other research purpose beyond which is specified in this protocol.* 4. *Any new research study with stored biological material from this study will need a new approval from the IRB before study begins.* 5. *Any changes to the proposal or to the attachments (informed consent and research tools such as forms) shall be approved by IRB before implementation.* 6. *Final report of the study shall be submitted to IRB at the end of the study for review and protocol file closure.*	

Signature
(Name)
Chairperson

For further information please contact: *IRB Member Secretary:*
Tel: +975-
E-mail:

ANNEX 8

Guidance for reviewing a study protocol

Reviewers shall think about and try to find answers to the following questions:

1. How will the knowledge, result or outcome of the study contribute to human well-being?
   - ❑ Knowledge from the basic research may possibly benefit.
   - ❑ A new choice of method, drug or device that benefits the subject during the study and others in the future.
   - ❑ Provide safety data or more competitive choices.

2. Does the study design give answers to the objectives? Whether
   - ❑ The endpoints are appropriately selected.
   - ❑ The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - ❑ The control arm is appropriately selected for best comparison.
   - ❑ The placebo is justified.
   - ❑ The number of study participants in non-treatment (or placebo) arm is minimized.
   - ❑ Unbiased assignment (e.g. Randomization, etc.) Is in practice.
   - ❑ Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
   - ❑ The sample group size appropriate with the given statistical assumptions.
   - ❑ Predictable risks are minimized.
   - ❑ The tests and procedures that are more than minimal risk are cautiously used.
   - ❑ Subject deception is avoided.
   - ❑ Instruction and counselling for study participants are included (if needed) when deception is integral to the study design.
   - ❑ The study participants are adequately assessed and provided follow-up care, if needed.

3. Who will be the participants in the study? Whether
   - ❑ The described population is appropriate for the study.
   - ❑ Predictable vulnerabilities are considered.
   - ❑ It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
   - ❑ There will be secondary participants.

4. Do the inclusion and exclusion criteria
   - ❑ Selectively include participants most likely to serve the objective of the study?
   - ❑ Equitably include participants?
   - ❑ Properly exclude participants who can predictably confound the results?
   - ❑ Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?

5. Does the study design have adequate built-in safeguards for risks?
   - ❑ Appropriate screening of potential participants?
   - ❑ Use of a stepwise dose escalation with analysis of the results before proceeding?
   - ❑ Does the frequency of visits and biological samplings reasonably monitor the expected effects?
   - ❑ Are there defined stopping (discontinuation) /withdrawal criteria for participants with worsening condition?
   - ❑ Is there minimized use of medication withdrawal and placebo whenever possible?
   - ❑ Will rescue medications and procedures be allowed when appropriate?

- Is there a defined safety committee to perform interim assessments, when appropriate?
- Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.

6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?

- The animal study and *in vitro* testing results?
- Previous clinical results, if done?
- Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
  - The selected dose based on adequate prior results?
  - Monitoring tests designed to detect expected possible risks and side effects?

7. Does the study and the informed consent process include issues of special concern, such as:

- Waiver or alteration of consent?
- Delayed consent (e.g., emergency treatment, etc.)?
- Deception?
- Sensitive information of participants that may require a confidentiality statement?

ANNEX 9

Informed Consent Process

The actual **process of informed consent** shall:

- Give the participants significant **information** about the study.
- Make sure the participants have **enough time** to carefully read and consider all options.
- **Answer all questions** of the participants before making decision to participate.
- Explain **risks or concerns** to the participants**.**
- Make sure that all information is **understood and satisfied by the participants**.
- Make sure the participants understand the study and the consent process.
- Obtain **voluntary** informed **consent** to participate.
- Make sure the participants can **freely consent without coercion, pressure or other undue influences.**
- Consent shall be **informally verified on a continuing basis.**
- **Continue to inform** the participants throughout the study.
- **Continue to re-affirm** the **consent** to participate throughout the study.

Procedures or methods used in the informed consent process for recruitment of study participants include:

- A consent form-See template below
- Brochures, Pamphlets or other reading materials (i.e., letters to participants, phone pre-screening questionnaires, phone hold messages)
- Internet information
- Instruction sheets
- Audio-visual presentations
- Charts, diagrams or posters
- Discussions
- Consultation with others

For participants ≥ 18 years

- Informed Consent

For participants 12 years through <18years

- Informed Consent from the parent(s) or legal guardian
- Informed Assent from the participant

For participants 7 years through <12 years

- Informed Consent from the parent(s) or legal guardian
- Verbal Informed Assent from the participant

For participants <7 years

- Informed Consent from the parent(s) or legal guardian
- Any obvious signs or indication of denial by the minors shall be respected.

Techniques to improve the readability of consent forms:

- Use short sentences and paragraphs
- Limit to one thought or topic in a sentence, avoid run-on sentence
- Use simple words, less syllables in a word.
- Use common words, remove technical jargon and medical terms.

- Try to use correct basic grammar and form.
- Use "gene **transfer**" instead of "gene **therapy**" (less implied effectiveness).
- Use "**agent**" instead of "**drug**" or "**medicine**" (less implied effectiveness).
- Try to avoid the use of "**treatment**", "**therapy**" or "**therapeutic**" in studies involving gene transfer (because these words imply effectiveness)

Waiver/alteration of Informed Consent

In certain situations, the IRB may approve a consent procedure that does not include, or which alters (e.g. deferral), some or all of the elements of informed consent, or waive the requirement to obtain informed consent. The Examples of such studies may include but not limited to:

- The research involves no more than minimal risk to the participants ,
- The waivered or altered consent does not involve a therapeutic intervention,
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participant,
- The research could not practicably be carried out without the waiver or alteration,
- The information is used in a manner that will ensure its confidentiality,
- The public interest in conducting the research exceeds the public interest in protecting the privacy of the individuals,

Waiver of signature in informed consent (Verbal Consent)

In certain situation when obtaining ICF is required but obtaining written informed consent is not feasible or verbal consent is more appropriate then IRB may approve waiver of signature in informed consent (verbal consent).

ANNEX 10

Informed consent Form (ADAPTED FROM WHO-GUIDELINE)

Notes to Researchers:

1. This informed consent contents different sections. Please chose the section which is relevant to your study
2. Language used throughout form shall be at the level of a local student of class 6th/8th standard
3. Please note that this is a template developed by the IRB to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.
4. Each section of the informed consent form consists of two parts: the information sheet and the consent certificate.
5. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
6. This template includes examples of key questions that may be asked at the end of each section that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.
7. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which shall be included
   - Standard lettering is used for explanations to researchers only and shall not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

Annex 10.1:

Informed Parental Consent Form Template for Research Involving Children (Clinical Studies)

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

Name of Principle Investigator:

[Informed Consent Form for _____]

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.

(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]
[Name of Proposal and version]

PART I: Information Sheet
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.

(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.)

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 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.

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.

(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 is to test the new vaccine to see if it protects young children better than the current vaccine).

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

(An injection OR a series of three injections OR taking a vaccine orally, a biopsy).

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.

(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

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.)

- ***Example of question to elucidate understanding:*** *Do you know why your child has been identified as a potential research participant? Do you know what the study is about?*

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.

(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.)

- ***Examples of question to elucidate understanding:*** *If you decide that you do not want your child to take part in this research study, do you know what your options for him/her are? Do you*

know that you do not have to accept that your child takes part in this research study? Do you have any questions?

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 parent 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

(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 exist. 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.)

Procedures and Protocol

It is important that the parents know what to expect and what is expected of them and their child. Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given. It is also important to explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Describe very clearly which procedure is routine and which is experimental or research. Explain that the parent may stay with the child during the procedures. If the researchers are to have access to the child's medical records, this shall be stated.

Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to…."

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

If the protocol is for a clinical trial:
1) involving randomization or blinding, the participants shall 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). A very minimal statement is provided below to give you an example. You may need to be more explicit about what is exactly involved.

(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) While Involving a placebo, it is important to ensure that the participants understand what is meant by a placebo. An example for a placebo is given below.

(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) which 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. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine

(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.".)

B. Description of the Process

Describe the process on a step-by-step basis.

(You may stay with your child during each of the visits and during the procedures. In the first visit, a small amount of blood, equal to about a teaspoon will be taken from your child's arm. This will be tested for the presence of substances that help your child's body to fight infections. Your child will feel some discomfort when the needle stick goes into her/his arm but this will go away very quickly. There may be slight bruising but this will disappear in a few days.

In the next visit, your child will be given either the test vaccine or the vaccine that is currently being used for malaria in this region. Neither you nor we will know, until later in the study, which vaccine your child was given. The vaccine will be given by a trained healthcare worker. After the vaccine, we ask that you and your child stay at the clinic for 30 minutes so that the healthcare worker can observe any immediate changes in the child's mood, and if swelling occurs around the injection site. We will give you and your child juice and something small to eat.

We will ask your child's physician to give us the details of your child's health and illness related information. If you do not wish us to do that, please let us know. However, because your child's health records are very important for the study, if we cannot look at the health records, we will not be able to include your child in the study.

At the end of the study, we will contact you by letter to tell you which of the two vaccines your child was given….)

In case of a clinical research:
Explain that there are standards/guidelines that must be followed. If 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.

(Your child will receive the treatment for his/her condition according to national guidelines, etc. The sample will be taken using a local anesthesia which means that only the part of your child that we are taking the sample from, and a small surrounding area, will lose feeling for a short time. Your child shouldn't feel pain, etc.)

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 table-spoon full will be taken.

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)

If not, 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.

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.

(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).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

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.

(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, 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.)

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.

(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 your child 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.])

Discomforts

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

(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.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine your child is receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that your child may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not your child is in the research study? Etc. Do you have any questions?*

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.

(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.)

Reimbursements
State clearly what you will provide the participants with as a result of their participation. IRB does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(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.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know if the study will pay for your and your child's travel costs and your time lost, and do you know how much you will be re-imbrued? Do you have any other questions?*

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.

(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].)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you and/or your child will remain confidential? Do you have any questions about them?*

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.

(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).

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.

(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.)

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.

(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….)

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.

(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 [name of the IRB e.g. IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, and telephone number.])

PART II: Certificate of Consent

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 all 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…

(I have been invited to have my child participate in research of a new malaria vaccine). **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.**

Print Name of Participant_____

Print 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 parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness*_____ *AND* *Thumb print of parent

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:
1.
2.
3.
I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent 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.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

An Informed Assent Form will_____ OR will not _____ be completed.

ANNEX 10.2
Informed Parental Consent Template for Research Involving Children (Qualitative Studies)

L C
(For use with Participant Observation, Focus Group Discussions, Interviews, and Surveys)

[Informed Consent Form for _____]
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.

(E.g. This informed consent form is for parents of adolescent girls and boys participating in the research titled. "What do we want: Adolescents and health systems "?)

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will 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 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 may ask questions now or later.

(Example: I am X, and I work at Y organization in _____. I am doing some research which might help your clinic/hospital do more to help teenagers become and stay healthier. In our research we will talk to many teenagers, both girls and boys, and ask them a number of questions. Whenever researchers study children, we talk to the parents and ask them for their permission. After you have heard more about the study, and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before I can begin.

You do not have to decide today whether or not you agree to have your child participate in this 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 or of another researcher.)

Purpose
Explain in lay terms why the research is being done and what is expected from the results. Explain why you need to conduct the research with children.

(Example: It is possible that the clinics and the hospital in this region are not providing some of the services that are important for teenagers. In this study we will talk to teenage girls and boys about what they know about caring for their bodies in a healthy way including sexual and reproductive health. We will invite them to share their knowledge and understanding with us so that we can find ways of meeting their needs at the local clinics and hospital.)

Type of Research Intervention
Briefly state the intervention. This will be expanded upon in the procedures section.

(Example: A questionnaire OR a focus group OR an interview)

Selection of Participants
State clearly why you have chosen their child to participate in this study. Parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned.

(Example: We want to talk to many teenagers about their health and what information or services they want for themselves. One part of health that we want to talk to them about is sexuality. We would like to ask your daughter/son to participate because she/he is a teenager and lives in this region.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking your child to take part in this study? Do you know what the study is about?*

Voluntary Participation
Indicate clearly that they can choose for their child to participate or not and reassure they will still receive all the services they usually do if they choose not to participate. Also inform them that their child will also have input into the decision. 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. Participants may also be more alert at the beginning.

(Example: You do not have to agree that your daughter/son can talk to us. You can choose to say no and any services that you and your family receive at this centre will not change. We know that the decision can be difficult when it involves your children. And it can be especially hard when the research includes sensitive topics like sexuality. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you decide later.)

- ***Examples of question to elucidate understanding:*** *If you decide not to allow your child to take part in this research study, do you know what the options for him are? Do you know that your child does not have to take part in this research study, if you do not wish so? Do you have any questions?*

Procedure

Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

(Examples:
1) The following applies only to focus group discussions*:*
Your daughter/son will take *part in a discussion with 7-8 other teenagers, or a mix of teenagers and social service workers from the community. The girls and boys will be in separate groups. This discussion will be guided by [give name of moderator] or me.*

2) The following applies only to interviews*:*
Your daughter/son will participate in an interview with [name of interviewer] or myself.

3) The following applies only to questionnaire surveys*:*
*Your daughter/son will fill out a questionnaire which will be provided by [name of distributor of blank questionnaires] and collected by [name of collector of completed questionnaires].**OR** the questionnaire can be read aloud and she/he can give me the answer which she/he wants me to write.)*

Explain the type of questions that the participants are likely to be asked in the focus group discussion, interview or in the questionnaire. If the questions are sensitive, acknowledge this, try to anticipate parents' concerns and protective responses, and address these. Parents may be concerned that if researchers talk to their children about sexuality it may encourage them to explore sexual activities with their peers. Other concerns may include disbelief that their child is ready to talk about sexuality, or parents may be personally embarrassed.

(Examples:
1) The following applies only to focus group discussions:
The group discussion will start with me, or the focus group guide (use the local word for group discussion leader), making sure that the participants are comfortable. We will also answer questions about the research that they might have. Then we will ask questions about the health system in this community. We will talk about where they go for information about health, and whether they get the information and services they need and want. We will encourage them to talk about sexual and reproductive health as well as other important health topics such as food and nutrition. These are the types of questions we will ask. We will not ask them to share personal stories or anything that they are not comfortable sharing.

The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and the guide or I will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s) with access to the tapes] will be allowed to listen to the tapes. [The tapes will be destroyed after ____period of time.]

2) The following applies only to interviews:
If your daughter does not wish to answer any of the questions during the interview, she may say so and the interviewer will move on to the next question. The interview will take place in [location of the interview], and no one else but the interviewer will be present unless your child asks for someone else to be there. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to the information documented during your interview.) [The tapes will be destroyed after _____period of time.]

3) The following applies only to questionnaires and surveys:
If your daughter/son does not wish to answer some of the questions included in the questionnaire, she/he may skip them and move on to the next question. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to her questionnaire. [The questionnaires will be destroyed after _____period of time.])

Duration
Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

*(Example: We are asking your child to participate in an interview which will take about 1 hour of her/his time. We can do this outside of school/work hours. There is also a questionnaire that we will either provide to your child or which we will do together with her/him. This also takes about an hour. Altogether, we are asking for about 2 hours of your child's time.***)**

- ***Examples of question to elucidate understanding:*** *If you decide that your child can take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending a transport to pick up your child from your home? Do you know how much time will the discussion with other people take? If you agree that your child can take part, do you know if he/she can stop participating? Do you know that your child may not respond to the questions that he/she does not wish to respond to? Etc. Do you have any more questions?*

Risks and Discomforts
Explain any risks or discomforts including any limits to confidentiality.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking your son/daughter to share with us some very personal and confidential information, and he/she may feel uncomfortable talking about some of the topics. You must know that he/she does not have to answer any question or take part in the discussion/interview/survey if he/she doesn't wish to do so, and that is also fine. He/she does not have to give us any reason for not responding to any question, or for refusing to take part in the interview"

OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that your son/daughter may share some personal or confidential information by chance, or that he/she may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You must know that he/she does not have to answer any question or take part in the discussion/interview/survey if he/she feels the question(s) are too personal or if talking about them makes him/her uncomfortable.)
Your daughter/son may choose to tell you about the interview and the questionnaire but she/he does not have to do this. We will not be sharing with you either the questions we ask or the responses given to us by your child.)

Benefits
Describe any benefits to their child, to the community, or any benefits which are expected in the future as a result of the research.

(Example: There will be no immediate and direct benefit to your child or to you, but your child's participation is likely to help us find out more about the health needs of teenage girls and boys and we hope that these will help the local clinics and hospitals to meet those needs better in the future.)

Reimbursements
State clearly what you will provide the participants with as a result of their participation. IRB does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(Example: Your daughter/son will not be provided with any payment to take part in the research. However, she/he will be given with [provide a figure, if money is involved] for her/his time, and travel expense (if applicable).)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbrued? Do you have any other questions?*

Confidentiality:
Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

(Examples:
Because something out of the ordinary is being done through research in your community, it will draw attention. If your daughter/son participates, she and you may be asked questions by other people in the community.

We will not be sharing information about your son or daughter outside of the research team. 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].

The following applies to focus groups*:*
We will ask your child and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each participant to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about your child will remain confidential? Do you understand that the we cannot guarantee complete*

confidentiality of information that your child shares with us in a group discussion Do you have any more questions?

Sharing of Research Findings
Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for examples, through publications and conferences.

(Example: At the end of the study, we will be sharing what we have learnt with the participants and with the community. We will do this by meeting first with the participants and then with the larger community. Nothing that your child will tell us today will be shared with anybody outside the research team, and nothing will be attributed to him/her by name. A written report will also be given to the participants which they can share with their families. We will also publish the results in order that other interested people may learn from our research.)

Right to refuse or withdraw
Explain again the voluntary nature of consent. Also explain that their child will be asked to agree - or assent - and that the child's concerns and wishes will be taken very seriously.

(Example: You may choose not to have your child participate in this study and your child does not have to take part in this research if she/he does not wish to do so. Choosing to participate or not will not affect either your own or your child's future treatment at the Centre here in any way. You and your child will still have all the benefits that would otherwise be available at this Centre. Your child may stop participating in the discussion/interview at any time that you or she/he wish without either of you losing any of your rights here.)

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 [name of the IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, and telephone number.])

- *<u>Example of question to elucidate understanding:</u> Do you know that you do not have to allow your child take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

PART II: Certificate of Consent
Certificate of Consent
This section can be written in the first person. It should include a few brief statements about the research and be followed by 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. 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.

I have been asked to give consent for my daughter/son to participate in this research study which will involve her completing one interview and one questionnaire **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.**

Print Name of Parent or Guardian _____

Signature of Parent of 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 parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ ***AND*** ***Thumb print of participant***

Signature of witness **_____**

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:
1.
2.
3.
I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her 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 Informed Consent Form has been provided to the parent or guardian of the participant ____

Print Name of Researcher/person taking the consent_____

ANNEX 10.3

Informed Consent Form Template for Consent for Storage and Future Use of Unused Samples

Additional Consent to [Name of Project]

Include the following section if the research protocol calls for storage and future use of samples

This Statement of Consent consists of two parts:

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

You will be given a copy of the full Statement of Consent

Part 1. Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood/tissue/sperm/sputum sample because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. Use lay terms to explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

Right to Refuse and Withdraw

Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact.

Confidentiality

Briefly explain how confidentiality will be maintained including any limitations.

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

Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

☐ I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.

☐ I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

☐ I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project : [give name of current research]

☐ I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

☐ I want my identity to be removed from my (TYPE OF SAMPLE) sample.

☐ I want my identity to be kept with my (TYPE OF SAMPLE) sample.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print 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.

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.

Print name of witness_____ ***AND*** ***Thumb print of participant***

Signature of witness _____

Date _____
Day/month/year

Statement by the 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 nature and manner of storage of the samples, 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.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

ANNEX 10.4

Informed Assent Form Template for Children/Minors

An Informed Assent Form does not replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.

[Informed Assent Form for _____]

Name the group of individuals for whom this assent is written. Because research for a single project is often carried out on a number of different groups of individuals - for example children with malaria, children without malaria, students - it is important that you identify which group particular assent is for.

(This informed assent form is for children between the ages of 12 - 18 who attend clinic X and who we are inviting to participate in research Y.)

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet
Introduction
This is a brief introduction to ensure the child knows who you are and that this is a research study. Give your name, say what you do and clearly state that you are doing research. Inform the child that you have spoken to their parents and that parental consent is also necessary. Let them know that they can speak to anyone they choose about the research before they make up their mind.

(Example: My name is ____and my job is to research and test vaccines to see which work best to stop malaria before it makes someone sick .We want to know if this new vaccine will stop children from getting sick and we think this research could help tell us that.

I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/guardian and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But if you do not wish to take part in the research, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at anytime and I will take time to explain).

Purpose: Why are you doing this research?
Explain the purpose of the research in clear simple terms.
(Example: We want to find better ways to prevent malaria before it makes children sick. We have a new vaccine to prevent malaria which we are hoping might be better than the one that is currently being used. In order to find out if it is better we have to test it.)

Choice of participants: Why are you asking me?
Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

(Example: We are testing this vaccine on children who are your age - between 12 and 18 years old - who live in a place where there is malaria. We are only testing the vaccine on children who do not have malaria.)

Participation is voluntary: Do I have to do this?
State clearly and in child-friendly language that the choice to participate is theirs. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

(Example: You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, it's okay and nothing changes. This is still your clinic, everything stays the same as before. Even if you say "yes" now, you can change your mind later and it's still okay.

If applicable: If anything changes and we want you to stay in the research study even if you want to stop, we will talk to you first .)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

I have checked with the child and they understand that participation is voluntary __ (initial)

Information on the Trial Drug [Name of Drug]: What is this drug and what do you know about it?
Include the following section only if the protocol is for a clinical trial:

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 vaccine we are testing in this research is called ABX. It has been tested twice before with adults who do not have malaria but who live in areas where malaria is common. We now want to test the vaccine on teenagers who do not have malaria. This second research is called a "phase 2" trial.

The vaccine ABX is made by Company C. It has very few side effects. It can make you feel tired for the first 24 hours 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 greater risk or other side effects. 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 side effects.)

Procedures: What is going to happen to me?
Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

(Example: We are going to test the vaccine by giving some of the children in the research study the new vaccine and the others are going to get the vaccine that is already being used to prevent malaria. Neither you nor the researchers will know which vaccine you were given until after the study is over. By doing the research like this, we can compare which of the vaccines is better without being influenced by what we think or hope the research will show.

If you decide that you want to do this, there will be three things that happen.
1. In about ten days, you will come to the clinic with your parents and you will get an injection/shot in your arm. This is either the vaccine that we are testing or the vaccine that is usually used to prevent malaria.

2... At the clinic we will also give you a mosquito net to take home and sleep under. Maybe you have seen these before. They stop mosquitoes from biting you during the night when you sleep.

3. Once a month for six months after that, you will come to the clinic and the nurse will take your temperature. She will also take a little bit of your blood, about three or four drops, from your finger with a finger prick. This might hurt a little but the hurt will go away before very long.

Altogether you will come to the clinic 7 times over 7 months. At the end of seven months, the research will be finished.

I have a picture here to show you what will happen. You can ask me to stop and explain again at any time and I will explain more about the process).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? How many times extra will you have to come if you decide to take part in the research study? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

I have checked with the child and they understand the procedures _____ (initial))

Risks: Is this bad or dangerous for me?

Explain any risks using simple, clear language.

(Example: The vaccine is considered safe. It has already been tested on adults and on other children. There has been nothing that has worried us at all. If anything unusual happens to you, however, we need to know and you should feel free you to call us anytime with your concerns or questions. Another way of us knowing how you are is by having you come to the clinic every month for a check-up. If you get sick or have concerns or questions in-between the scheduled visits to clinic, you should let me or the staff nurse know. You don't have to wait for a scheduled visit.)

Discomforts: Will it hurt?
If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

(Example: There are a few other things that I want you to know.

The injection might hurt for just a second when it goes into your arm. It might get a little bit red and hard around the place where the injection/needle goes in. That should go away in a day. If it hurts longer than that, or if it stays hard for longer or swells up, tell your parents or me. If you feel bad or strange, tell us.

Sleeping under a mosquito net can be uncomfortable because it can be hot and stuffy.

Sometimes you may not want to come to the clinic to get your blood checked or have your temperature taken. It's important that you try to come. It won't take very long. You will miss a little bit of school - about an hour every month - and we will tell your teacher about that so that she knows its okay.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

I have checked with the child and they understand the risks and discomforts ____ (initial)

Benefits: Is there anything good that happens to me?
Describe any benefits to the child.

(Example: Nothing really good might happen to you. The vaccine may not stop you from getting malaria. But this research might help us to find a vaccine now or later that could help other children. There are a couple of good things if you do decide that you want to do this. You do get regular check-ups with the nurse so that if you are sick, we will know very soon and this can be important. And you will keep the mosquito net which will help keep mosquitoes away from you. Because mosquitoes cause malaria, this is important.)

I have checked with the child and they understand the benefits_____ (initial)

Reimbursements: Do I get anything for being in the research?

Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research? These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

(Example: Because you live quite far from the clinic, we will give your parents enough money to pay for the trip here and (whatever other expense is reasonable).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality: Is everybody going to know about this?
Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

(Example: We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study. After the research is over, you and your parents will be told which of the two injections you received and the results.

Information about you 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 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].)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Compensation: What happens if I get hurt?
Describe to the ability of the child to understand and explain that parents have been given more information.

(Example: If you become sick during the research, we will look after you. We have given your parents information about what to do if you are hurt or get sick during the research.)

Sharing the Findings: Will you tell me the results?
Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.

(Example: When we are finished the research, I will sit down with you and your parent and I will tell you about what we learnt. I will also give you a paper with the results written down. Afterwards, we will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we do.)

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?
You may want to re-emphasize that participation is voluntary and any limits to this.

(Example: You do not have to be in this research. No one will be mad or disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.)

Who to Contact: Who can I talk to or ask questions to?
List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

(Example: You can ask me questions now or later. You can ask the nurse questions. I have written a number and address where you can reach us or, if you are nearby, you can come and see us. If you want to talk to someone else that you know like your teacher or doctor or auntie, that's okay too.)

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

- *Example of question to elucidate understanding:* ***Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.***

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

PART 2: Certificate of Assent
This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead. A researcher or the person going over the informed assent with the child must sign all assents.

(Example: I understand the research is about testing a new vaccine for malaria and that I might get either the new vaccine which is being tested or the vaccine which is currently being used. I understand that I will get an injection and that I will come for regular monthly check-ups at the clinic where I will give a blood sample with a finger prick.)

I have read this information (or had the information read to me). I have had my questions answered and know that I can ask questions later if I have them. I agree to take part in the research.

OR

I do not wish to take part in the research and I have not signed the assent below._____ (initialled by child/minor)

Only if child assents:

Print name of child _____

For child 12 years through <18 years: Signature of child: _____

For child 7 years through <12 years: Verbal assent provided: ☐Yes ☐No

Date: _____
Day/month/year

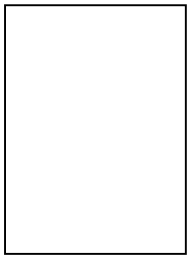
If illiterate:
A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) _____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year



I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher_____

Signature of researcher_____

Date_____
Day/month/year

Statement by the 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 child understands that the following will be done:
1.
2.
3.
I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her 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 assent form has been provided to the participant.

Print Name of Researcher/person taking the assent_____

Signature of Researcher /person taking the assent _____

Date _____
Day/month/year

Copy provided to the participant _____ (initialed by researcher/assistant)

Parent/Guardian has signed an informed consent ___Yes ___No _____ (initialed by researcher/assistant

Annex 10.5:

Informed Consent Form Template for Qualitative Studies

(This template is for research interventions that use questionnaires, in-depth interviews or focus group discussions)

[Informed Consent Form for _____]

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".)

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

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 which will clarify rather than confuse. 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. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

(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. 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 questionnaire, or a series of finger pricks.

(Example: This research will involve your participation in a group discussion that will take about one and a half hour, 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.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

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. Explanation: 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. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

(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.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

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 focus group, the interviews, or 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 focus group discussions)
Take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself.
The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the malaria and give you time to share your knowledge. The questions will be about malaria in your community, how is it recognized, what people do to stop it from spreading to other people, who people go to for help and what happens when people become sick with it.
We will also talk about community practices more generally because this will give us a chance to understand more about malaria but in a different way. These are the types of questions we will ask…... ***We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.***
The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 2 (for interviews)
Participate in an interview with [name of interviewer] or myself.
During the interview, I or another interviewer will sit down with you in a comfortable place at the Centre. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 3 (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, your name is not being included on the forms, only a number will identify you, 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, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)

- ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

Risks

Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview"
OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "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).

Reimbursements

State clearly what you will provide the participants with as a result of their participation. IRB does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. 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).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

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])

The following applies to focus groups:
Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

(Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you understand that we cannot guarantee complete confidentiality of information that you share with us in a group discussion Do you have any more questions?*

Sharing the Results
Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. 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.)

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 community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

(Example: 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. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)

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 the name (and contact details) of the local IRB that has approved the proposal. State also that the proposal has also been approved by the IRB.

(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 [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact _____.)

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, and telephone number.]).
Example of question to elucidate understanding: *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

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 must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar 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. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. 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.

Example: I have been invited to participate in research about malaria and local health practices.

(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

Print Name of Participant_____
Signature of Participant _____
Date _____
Day/month/year

If illiterate [1]

[1] 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.

Print name of witness_____ **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the 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.
Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

Annex 10.6

Informed Consent Form Template for Clinical Studies

L C

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

[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.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "……..")

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will 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, 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. 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.

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.)

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.

(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.)

Type of Research Intervention
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: 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.

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

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation
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 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.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

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 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 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 is made by Company C. You should know that it 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. Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to…."

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

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).

(Example: 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.

(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 do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) Which 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. 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." 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.

(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.)

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 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 leftover blood sample will be destroyed.)

B. Description of the Process

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….)*

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 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.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

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.

(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. 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.

(Example: 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_____.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

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. 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. WHO 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.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

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. Note 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 is therefore more likely to be stigmatized.

(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

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].)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

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.

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

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 <u>established</u> 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….)

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 [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, and telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- *<u>Example of question to elucidate understanding:</u>* ***Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know***

that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.

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.

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.

Print 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.

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.

Print name of witness_____ ***AND*** ***Thumb print of participant***

Signature of witness _____

Date _____
Day/month/year

Statement by the 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.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

ANNEX 11

Guide to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered. The followings are some guides to ease committee decision.

I. Benefits of standard treatment

1) Is there a standard treatment?
2) Is the standard treatment widely accepted?
3) Has efficacy of the treatment been consistently proven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
6) Are most (≥85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

If the answer of* (1) *to* (6) *are "yes", placebo is not recommended.
If any one or more answers are "no", placebo may be possible.

7) Are the side effects of the standard treatment severe?
8) Does standard treatment have many uncomfortable side effects?
9) Does standard treatment have contraindications that prevent some subjects from being treated?
10) Is there substantial (≤25%) placebo response in this disease or symptom?

If the answer of* (7) *to* (10) *are "no", placebo is not recommended.
If any one or more answers are "yes", placebo may be possible.

II. Risks of placebo

1) Is the risk of using placebo instead of treatment life threatening?

If yes, placebo is not acceptable.

2) Is the use of placebo instead of treatment likely to lead to permanent damage?

If yes, placebo is not acceptable.

3) Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?

If yes, placebo is not acceptable.

4) Can the use of placebo instead of treatment lead to an acute emergency?
5) Is the risk of using placebo instead of treatment not relieve the distressing symptoms?

If the answer of* (4) *to* (5) *are "yes", placebo is not acceptable unless risk management is adequate.

III. Risk management

1) Is there benefit in the overall management of the subject?

☐ *Yes, consider placebo*
☐ *No, placebo not recommended*.

2) Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?

☐ *No, consider placebo*
☐ *Yes, placebo not recommended*.

3) Are subjects at high risk for the use of placebo excluded?

☐ *Yes, consider placebo*
☐ *No, placebo not recommended*.

4) Is the duration of the study, the minimum necessary in relation to the duration of the action of the study drug?

☐ *Yes, consider placebo*
☐ *No, placebo not recommended*.

5) Are there clearly defined stopping provision to withdraw the subject in case he/she does not improve?

☐ *Yes, consider placebo*
☐ *No, placebo not recommended*.

6) Is risk monitoring adequate to identify progression of the disease before the subject experience severe consequences?

☐ *Not applicable.*
☐ *Yes, consider placebo*
☐ *No, placebo not recommended*.

7) Are there clearly defined stopping rules to withdraw the subject before the advent of severe disease progression?

☐ *Yes, consider placebo*
☐ *No, placebo not recommended*.

8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?

☐ *Not applicable.*
☐ *Yes, consider placebo*
☐ *No, placebo not recommended*.

9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?

☐ *Not applicable.*
☐ *Yes, consider placebo.*
☐ *No, placebos not recommend*.

10) If the risk of placebo is severe physical discomfort or pain, is there rescue medication?

☐ *Not applicable.*
☐ *Yes, consider placebo.*
☐ *No, placebos not recommend*.

IV. Risk disclosure in the consent form

1) Are the risks of getting placebo instead of active treatment fully disclosed?
   ☐ *Yes, consider placebo.*
2) Are the risks of the test drug disclosed?
   ☐ *Yes, consider placebo.*
3) Are the advantages of alternative treatments explained?
   ☐ *Yes, consider placebo.*

Conclusions:

1. The use of placebo is ethically acceptable because:
   - ☐ Subjects are not exposed to severe or permanent harm by the use of placebo.
   - ☐ Subjects under placebo will benefit from the overall treatment of the disease.
   - ☐ Risks of the use of placebo are minimized.
   - ☐ Risks are adequately disclosed in the consent form.

2. The use of placebo in this study could be reconsidered if the following conditions are met:

   ……
   ……
   ……
   …
   .

3. The use of placebo in this study is ethically unacceptable because:
   - ☐ Subjects are exposed to severe or permanent harm by the use of placebo instead of active treatment.
   - ☐ Due to the nature of the disease, the risks of placebo can not be minimized.

ANNEX 12

Criteria for Research Protocol Approval

In order to **approve** research, IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects
9. Protocol is technically sound (background, objectives, methodology and data collection tools)

Approved with recommendations

The protocols will be "approved with recommendations" when all the criteria for approval are satisfied. However, the following conditions needs to be fulfilled:

1. Obtain administrative clearances as required by law/policy including permission from the study sites before conducting the study.
2. Minor modification(s) such as typographical errors, grammar, references

The protocols "approved with recommendation" can be reviewed by the Chairperson, after receipt of the requested modifications.

Solicited for Resubmission

If the criteria for approval are not satisfied then the protocol will be "solicited for resubmission".

The review of the resubmitted protocol will be guided by the decision of the preceding review and/or "SOP/008/05 Expedited Review".

Disapproval

The protocols will be “disapproved” under following conditions, but not limited to:

1. Major violation of ethical principles.
2. If the plagiarism is identified.
3. Any other reason as decided by the board.