APPENDIX 1 | PATIENT INFORMATION AND SAMPLE INFORMED CONSENT FORM

(Should be translated into the local language for field trials)
(A separate patient information sheet containing this information should also be provided)

Principal Investigator: _____
Organization: _____
Sponsor: _____
Study title: _____

A | PURPOSE OF THE STUDY

The World Health Organization is working with (NAME OF CLINCAL SITE) to make sure that the dengue tests we are using are working well. For this purpose, we will need to collect blood samples and store them in a freezer so that we can use them now and in the future to evaluate the quality of dengue tests that are used worldwide. We collect blood samples from patients that have acquired a dengue virus infection but also from patients with clinical symptoms compatible with dengue but caused by different pathogens.

B | STUDY PROCEDURES

If you agree to give your blood for this specimen bank, a nurse or doctor will collect about 25 ml of blood from you (this is the volume of approximately 5 teaspoons). You will receive the standard medical care services in your area for the disease you are found to have.

C | BENEFITS AND COMPENSATION

There will be no direct benefit from your taking part in this project but your participation may allow public health programmes and doctors worldwide to be sure that the dengue tests used are of good quality and give accurate results. There will be no compensation if you decide to take part in this study.

D | RISKS AND DISCOMFORT

The risks involved in this study are minimal. They include the discomfort of drawing a sample of blood, rare bruising and infection at the site of needle stick, and very rarely, fainting. New needles will be used for each patient so there is no risk for transmitting diseases.

E | CONFIDENTIALITY

All information that you provide will be considered confidential, and no mention of your name or any other identifying information will appear on the samples or in any publication in connection with this study. The information will be NOT be stored together with the samples. No persons other than the research staff and the doctors/nurses overseeing your care will have access to any information that identifies you individually. Only these persons will have the key to link the samples and the information attached to your name.

F | FREEDOM TO REFUSE OR WITHDRAW

You may also choose not to participate in this study and you may refuse to participate at any time without penalty or loss of benefits to which you would otherwise be entitled. You do not have to explain why you do not wish to participate or withdraw.

G | DISSEMINATION OF RESULTS

Data from the study will be kept as long as the blood sample is part of the serum bank. When the researchers have analysed the data, the results of the dengue test performance and the explanation of its implications will be given to laboratories and health facilities that test patients for dengue, to Ministries of Health in countries where dengue occurs, and to other stakeholders.

H | CONTACT INFORMATION

If you have any questions, or if any problems arise, please contact:

(NAME OF RESPONSIBLE INVESTIGATOR AT CLINICAL SITE)

I | PARTICIPANT'S STATEMENT

I have been invited to participate in the above mentioned research on dengue and I understand that it will involve blood being taken. I have been informed that the risks are minimal. I am aware that there will be no benefit to me personally and that I will not be compensated. I have been provided with the name of a researcher who can be easily contacted using the number and address I was given. 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 in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

Date: _____

Name of participant: _____
Signature (or thumb print or cross if illiterate) of participant: _____

Date: _____
Name of witness (if illiterate participant):_____

Signature of witness: _____

J | INVESTIGATOR'S STATEMENT

I, the undersigned, have defined and explained to the volunteer in a language he/she understands, the procedures of this study, its aims and the risks and benefits associated with his/her participation. I have informed the volunteer that confidentiality will be preserved, that he/she is free to withdraw from the trial at any time without affecting the care he/she will receive at the clinic. Following my definitions and explanations the volunteer agrees to participate in this study.

_____ _____
Date Name of investigator who gave the information about the study

Signature: _____