Annex C
Study Explanation and Consent Forms

- **Study Explanation and Consent Form for Adult version 9.0 dated 26 June 2020 (English and Bhutanese version)**

- **Study Explanation and Consent Form for Parental /Guardian version 9.0 dated 26 June 2020 (English and Bhutanese version)**

- **Study Explanation and Assent Form (7–17years old) version 9.0 dated 26 June 2020 (English and Bhutanese version)**

STUDY EXPLANATION
AND
CONSENT FORM FOR ADULT

Sentinel Human Surveillance for Influenza in Bhutan
(English Version)

Co-Principal Investigator:

Mr. Sonam Wangchuk, Chief Laboratory Office, Royal Centre for Disease Control , Department of Public Health, Thimphu, Bhutan; Tel: 975-2-323317

Background: Influenza is a respiratory infection that changes and spreads quickly worldwide. The World Health Organization in coordination with many health agencies conducts global medical monitoring for influenza. Also, collecting nose and/or throat samples from influenza patients and determining the type of influenza virus can help determine what goes into the influenza vaccine each year.

Your Participation and Study Procedures: You are asked to participate in this research study because you have fever with cough or sore throat. If you agree to participate in this study, you will be asked to allow your health care provider to take one or two nose and/or throat swabs that will be sent for laboratory testing in Thailand and/or the U.S. An additional nose swab will be tested on-site so that your physician may be able to determine if you have influenza. No more than 3 nose and/or throat swabs will be collected from you. The nose/throat swab sample is collected by running the swab inside the nose or over the throat, respectively. If the throat is sore, sample collection may be uncomfortable. A nose swab may also be a bit uncomfortable, as the swab is inserted and reaches areas inside the nose that are not usually touched. Obtaining the nose and/or throat swab may cause mild irritation and discomfort like sneezing or coughing. This discomfort is reduced by using a swab attached to a thin flexible wire. Only well-trained health personnel will perform the collection to lessen discomfort.
One of the laboratory results from your throat swab/nasal swab will be provided to your physician to guide your care. Your doctor can give you this result. The other results are for research purposes. Your samples will not be used for any human genetic testing.

Amount of time required for completing this study: The duration of participating in this study is one visit for approximately 30 minutes.

Benefit: You will benefit from this study by the result of the rapid test. This can help you potentially avoid the inappropriate use of antibiotics and risking antibiotics side effects. You can participate in this study at no cost.

Risk: You may have some mild discomfort, sneezing, or coughing during sample collection.

Confidentiality: Instead of your name, a code will be used to identify your study records and samples. The study will try to keep all your personal information confidential with access to only study team. However information may be released to the regulatory authorities as part of their responsibility to protect human subjects in research.

Inclusion Criteria:
- You are ≥ 6 months of age (pregnant women can participate)
- If you have a fever for 5 days and cough or sore throat
- You provide us written consent for enrollment into the study

Exclusion Criteria:
- You are immunocompromised including if you have Acquired Immune Deficiency Syndrome (AIDS), lymphoma, leukemia, or TB

Financial Compensation: You will receive no monetary compensation for participation in this study.

Subject Withdrawal: You have the alternative to not participate in this study. Participation is voluntary, refusal to participate will not result in penalty or loss of benefits, and you may discontinue participation at any time. Subjects may be removed from the study by a study investigator or the medical monitor if their continued participation is deemed to be injurious to their health and well-being.

Future Use of Your Samples: Your respiratory sample will be stored at AFRIMS (Thailand) and USAFSAM (United States) for 10 years after study completed. With your permission, your samples will be used for future studies. You will not receive any payment for any future value of your sample which may be found to have. You will not receive any notice of future uses of your sample. Any future research involving your sample will be reviewed by an ethical review committee to ensure the use is confidential, ethical, and meets all government guidelines. You do not have to donate your sample for future research. You can still participate in the study if you decide not to donate your sample for future use. You will not be identified by name in any report, publication, or presentation resulting from this study.

Study related Injury or Illness: If any injury or illness occurs that is directly due to study-related procedures, standard medical care will be provided at no cost to you. You may contact the principal investigator (Mr. Sonam Wangchuk) as detailed below.

Study Duration and Location: The study anticipates enrolling up to 3000 subjects per year from different health facilities and influenza outbreak areas in Bhutan for period of 15 years. This study is being conducted at the health care institutions and both in- out-patient clinics in Bhutan. A list of participating locations is available: Jigme Dorji Wanghck National Referral Hospital, Thimphu, Punakha Hospital, Paro Hospital, Monggar Regional Referral Hospital, Phuntsholing Hospital, Gelephu Regional Referral Hospital, Trongse Hospital, Tsirang Hospital and Trashigang Hospital.

If you have any questions about your right on participation in this research study, you may contact: Research Ethics Board for Health, The REBH Secretariat, Research Unit, Policy and Planning Division, Ministry of Health, Timphu, Bhutan. Phone: 975-2-322602 Fax: 975-2-322941. If you want more information about this study, you may contact the principal investigator as below:

Mr. Sonam Wangchuk
Chief Laboratory Office
Royal Centre for Disease Control
Department of Public Health
Thimphu, Bhutan
Phone: 975-2-323317
Fax: 975-2-332464

Consent for Participation: by signing below,

1. I agree that I have read the information provided above.

2. I also agree I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.

3. I will be given a copy of this form.

4. I may choose not to participate without penalty or loss of benefits to which I am otherwise entitled.

5. I give permission to the investigators to use my samples for the testing approved in this study and furthermore, **DO / DO NOT** (circle one) give permission for my samples to be used for additional research studies.

Name of Participant_____

Signature of Participant_____ Date of consent: _ _/_ _ _/_ _ _
(dd/mmm/yyyy)

Permanent Address: _____

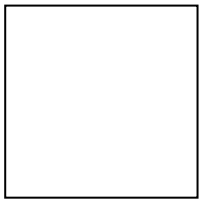
Name of Clinician/representative _____

Signature of Clinician/representative _____Date: _ _/_ _ /_ _ _ _
(dd/mmm/yyyy)

Name of Witness: _____

Signature of witness: _____Date: _ _/_ _ _/_ _ _
(dd/mmm/yyyy)

For participant who cannot read and write will affix their right thumb print on the box below after the clinician/ representative has read the content of this form.



STUDY EXPLANATION
AND
CONSENT FORM FOR PARENTAL/GUARDIAN

Sentinel Human Surveillance for Influenza in Bhutan
(English Version)

Co-Principal Investigator:

Mr. Sonam Wangchuk, Chief Laboratory Office, Royal Centre for Disease Control , Department of Public Health, Thimphu, Bhutan; Tel: 975-2-323317

Background: Influenza is a respiratory infection that changes and spreads quickly worldwide. The World Health Organization in coordination with many health agencies conducts global medical monitoring for influenza. Also, collecting nose and/or throat samples from influenza patients and determining the type of influenza virus can help determine what goes into the influenza vaccine each year.

Your Child Participation and Procedure: You and your child are asked to participate in this research study because your child has fever with cough or sore throat. If you agree to allow your child to participate in this study, your child's health care provider will collect one or two nose and/or throat swabs that will be sent for laboratory testing in Thailand and/or the U.S. An additional nose swab will be tested on-site so that your child's physician may be able to determine if your child has influenza. No more than 3 nose and/or throat swabs will be collected from your child. The nose/throat swab sample is collected by running the swab inside the nose or over the throat, respectively. If the throat is sore, sample collection may be uncomfortable. A nose swab may also be a bit uncomfortable, as the swab is inserted and reaches areas inside the nose that are not usually touched. Obtaining the nose and/or throat swab may cause mild irritation and discomfort like sneezing or coughing. This discomfort is reduced by using a swab attached to a thin flexible wire. Only well-trained health personnel will perform the collection to lessen discomfort.
One of the laboratory results from your child's throat swab/nasal swab will be provided to their physician to guide your care. Your doctor can give you this result. The other results are for research purposes. Your child's samples will not be used for any human genetic testing.

Amount of time required for completing this study: The duration of participating in this study one visit for approximately 30 minutes.

Benefit: You child will benefit from this study by the result of the rapid test. This can help them potentially avoid the inappropriate use of antibiotics and risking antibiotics side effects. You child can participate in this study at no cost.

Risk: Your child may have some mild discomfort, sneezing or coughing during sample collection

Confidentiality: Instead of your child's name, a code will be used to identify your child's study records and samples. The study will try to keep all your child's personal information confidential with access to only study team. However information may be released to the regulatory authorities as part of their responsibility to protect human subjects in research.

Inclusion Criteria:
- Your child are male or female patients ≥ 6 months of age (pregnant child can participate)
- If your child have a fever for 5 days and cough or sore throat

You provide us written consent for enrollment into the study

Exclusion Criteria:
- You child is immunocompromised including if they have Acquired Immune Deficiency Syndrome (AIDS), lymphoma, leukemia, or TB

Financial Compensation: You and your child will receive no monetary compensation for participation in this study.

Subject Withdrawal: You have the alternative of not to letting your child participate in this study. Participation is voluntary, refusal to participate will not result in penalty or loss of benefits, and you and your child may discontinue participation at any time. Your child may be removed from the study by a study investigator or the medical monitor if their continued participation is deemed to be injurious to your child's health and well-being.

Future Use of Your Samples: Your child's respiratory sample will be stored at AFRIMS (Thailand) and USAFSAM (United States) for 10 years after study completed. With your permission, your child's samples will be used for future studies. You and your child will not receive any payment for any future value of your child's sample which may be found to have. You and your child will not receive any notice of future uses of your child's sample. Any future research involving your child's sample will be reviewed by an ethical review committee to ensure the use is confidential, ethical and meets all government guidelines. You do not have to donate your child's sample for future research. You child can still participate in the study if you decide not to donate your's child sample for future use. You child will not be identified by name in any report, publication, or presentation resulting from this study.

Study related Injury or Illness: If any injury or illness occurs that is directly due to study-related procedures, standard medical care will be provided at no cost to you. You may contact the principal investigator (Mr. Sonam Wangchuk) as detail below.

Study Duration and Location The study anticipates enrolling up to 3000 subjects per year from different health facilities and influenza outbreak areas in Bhutan for period of 15 years. This study is being conducted at the health care institutions and both in- out-patient clinics in Bhutan. A list of participating locations is available: Jigme Dorji Wanghck National Referral Hospital, Thimphu, Punakha Hospital, Paro Hospital, Monggar Regional Referral Hospital, Phuntsholing Hospital, Gelephu Regional Referral Hospital, Trongse Hospital, Tsirang Hospital and Trashigang Hospital.

If you have any questions about your right on participation in this research study, you may contact: Research Ethics Board for Health, The REBH Secretariat, Research Unit, Policy and Planning Division, Ministry of Health, Timphu, Bhutan. Phone: 975-2-322602 Fax: 975-2-322941. If you want more information about this study, you may contact the principal investigator as below:

Mr. Sonam Wangchuk
Chief Laboratory Office
Royal Centre for Disease Control
Department of Public Health
Thimphu, Bhutan
Phone: 975-2-323317
Fax: 975-2-332464

Consent for Participation: by signing below,

1. I agree that I have read the information provided above regarding your child's participation in this study.

2. I also agree I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.

3. I will be given a copy of this form.

4. I may choose not to allow my child to participate without penalty or loss of benefits to which my child is otherwise entitled.

5. I give permission to the investigators to use my child's sample for the testing approved in this study and furthermore, **DO / DO NOT** (circle one) give permission for my child's sample to be used for additional research studies.

Name of participant: _____

Permanent Address: _____

Name of Parent/Guardian: _____

Signature of Parent/Guardian: _____Date of consent: _ _/_ _ _ /_ _ _ _
(dd/mmm/yyyy)

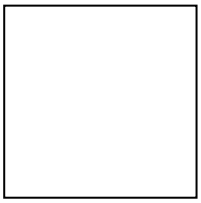
Name of Clinician/representative _____

Signature of Clinician/representative _____Date: _ _/_ _ _ /_ _ _ _
(dd/mmm/yyyy)

Name of Witness: _____

Signature of witness: _____ Date: _ _/_ _ _ /_ _ _
(dd/mmm/yyyy)

For participant who cannot read and write will affix their right thumb print on the above box after the clinician/ representative has read the content of this form.



STUDY EXPLANATION
AND
ASSENT FORM (7-17 years old)

Sentinel Human Surveillance for Influenza in Bhutan
(English Version)

Introduction:
We invite you to participate in this research study. Before you decide whether or not to volunteer for this study, you will be informed in detail on the purpose, how it may help you, what the risks are, and what is expected of you. If you agree to participate in this study, you will be asked to sign this form. You can only be in the study if your parent(s) or guardian(s) agree.

The doctor or nurse will talk to you about the study and answer any question you have. This form gives you information about this research study. We will ask you to sign this form and give a copy of this form for you to keep.
It is important that you know:

a. You do not have to participate in this study if you do not want to.
b. You may change your mind and drop out of the study at any time.
c. If we make any important change to the study, we will tell you about it and ask if you still want to be in the study.

Purpose of Study:
You came to the see the doctor because you have flu-like illness. The purpose of this research study is to find out what is the cause of your illness. Collecting respiratory specimens from flu-like illness patients like you will help us find the type of flu virus that are circulating in Bhutan and the basis of the influenza vaccine that is manufactured each year to prevent the circulating influenza virus.

Procedure:
If you agree to be in the study, we will ask you questions about your illness. The doctors or nurses will take throat swab/nasal swab as samples for testing. The nasal swab is taken by placing one small swab into the back of your nose for 5 seconds. The throat swabs are taken by placing one small swab into the back of your throat for 5 seconds. These tests don't hurt, but may cause a little discomfort. Your samples will not be used for any human genetic testing.

Potential Risks/Discomfort:
Obtaining the throat/ nasal swab might cause you only a little discomfort and sneezing/coughing. Only well-trained health personnel will perform the collection to minimize discomfort.

Benefits:
The benefit of participating in this study is that all the influenza tests involved in this study will be provided free of cost. The results of these tests would help your doctor determine whether influenza virus is the cause of your illness. This will also help to stop inappropriate use of antibiotics for viral illness. The results of these tests may be critical to your care. Your doctor will receive the results of one test which will directly help your doctor for planning your healthcare. Also, the information learned may help prevent such infections in others.

Alternatives to participation:
You can choose not to participate in the study.

Confidentiality:
We will keep your records as confidential as possible. The study will try to keep all your personal information confidential with access to only study team. We will only use a code to identify the stored sample, not your name.

Future use of your samples used in this study:
After this study any leftover from the samples you gave us could be used for other studies. This would not benefit you directly but could help further medical science in general. You do not have to allow your samples to be used in the future. You will not be notified of future value or use of your donated samples. They would only be used if approved by a review committee and with your permission. If you don't want your samples used in the future, please check and initial: I do not want my samples stored for future use.
If you have any questions regarding your rights as a research volunteer in Bhutan, you may contact the Research Ethics Board for Health, Research unit, Policy and Planning Division, Ministry of Health, Thimphu, Bhutan. Phone: 975-2-322602, Fax: 975-2-322941.

ASSENT: By signing your name below, you agree that the doctor or nurse has been explained to you and you have read the information provided about the study. You also agree you have been given time to ask questions and all of your questions have been answered at this time. You may drop out of the study at any time and no one will mind and nothing will change about your medical care other than not being in the study. Please talk with the doctor that asked you to enter the study if you have any questions or call Principal Investigator Mr. Sonam Wangchuk, Chief Laboratory Office, Royal Centre for Disease Control , Department of Public Health, Thimphu, Bhutan, Phone: 975-2-323317, Fax: 975-2-332464
A copy of this form will be given to you and your parent/guardian.

Name of participant _____

Signature of participant _____Date of consent: _ _/_ _ _ /_ _ _ _
(dd/mmm/yyyy)

Permanent Address _____

INDIVIDUAL OBTAINING ASSENT: I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.
Name of clinician/representative _____

Signature of clinician/representative _____Date: _ _/_ _ _ /_ _ _ _
(dd/mmm/yyyy)

WITNESS: I have witnessed the explanation of the research study to the participant. The participant was given an opportunity to ask questions, and the participant's questions, if any, were answered.

Name of Witness: _____

Signature of witness: _____Date: _ _/_ _ _/_ _ _ _
(dd/mmm/yyyy)

For participant who cannot read and write will affix their right thumb print on the box below after the clinician/ representative has read the content of this form.