Form Approved
OMB Number 0925-XXXX
Exp. Date:
XX/XX/XXX

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Sponsor's Name: National Institute of Allergy and Infectious Diseases (NIAID)

Principal Investigators: TBD based on study

Introduction:

This consent form describes a research study and what you can expect if you decide to participate. We are inviting you to take part in a research study conducted at the 'SITE_NAME'. Please read this consent form carefully. You are encouraged to ask the person who presents it any questions you have before making your decision about whether or not to participate. Feel free to ask if you need more information or clarification about what is stated in this form and the study as a whole.

Study Overview:

The purpose of this research study is to improve our knowledge and understanding of influenza ("flu"), and how to best respond to an influenza pandemic. This study has the following goals:

1) To identify the type of influenza that is making people sick and understand if the virus has any features that increase its chances of rapidly spreading and possibly leading to a pandemic that could infect many people all over the world. This information may help to develop new flu vaccines, advance new treatment, and develop plans to help fight against different kinds of influenza viruses.
2) To see if our current influenza tests do a good job of detecting influenza in a person. It may be that we are missing people who have influenza because our tests are not accurate. This will help us understand who has flu and may need treatment – and who doesn't have flu.
3) To understand how the immune system (the parts of the body that help protect itself from viruses and infections) responds to infections from the flu virus in patients who are very sick, and others who are not very sick. This will help us understand why some people get very sick from flu and need to be hospitalized, and other people do not. This will help us develop treatments to try to prevent people from getting so sick.

Your participation in this study will last 3-4 weeks. The study as a whole, will run for 7 years.

Inclusion criteria:

In order to take part of the study, you must meet the additional criteria for either symptomatic or asymptomatic subjects as listed below:

Symptomatic subjects:

Must have new onset within the past 7 days of:

Documented fever (≥ 38°C) or report of fever

Either cough, headache, or sore throat

Asymptomatic subjects:

Must have none of the following symptoms within the past 7 days

Documented fever (≥ 38°C)
Report of fever
Cough
Headache
Sore throat
Myalgia
Rhinorrhea/nasal congestion
Shortness of breath

Procedures:

This is an observational study. It is not a treatment study. Participation in this study will not change your clinical evaluation and treatment or what your doctor decides to do for you.

If you agree to be in this study, we will ask you to do the following things during your initial visit:

Data Collection

You will be asked to answer a brief survey while you are in the emergency department that asks information about your symptoms, medications, and medical history. We will also collect basic information about you such as your age, gender, race, and telephone number. This will take approximately 10 minutes to complete.

Sample Collection

We will collect the following samples:

- Blood: we will collect 10 mL or 1 tablespoon of blood from your vein.
- Nasopharyngeal swab: we will insert a small swab into your nose and twist.
- Nasal wash: we will squirt a small amount of salt water into your nose and catch it as it runs out.

These samples are sometimes, but not always, collected when patients with possible influenza come to the emergency department.

Influenza Testing

We will test the nasal secretion sample with a rapid influenza test. This test takes approximately an hour and a half to two hours to yield results.
If your test is positive for influenza, we will ask you for an additional sample from your nose. We will collect a "nasal wash" which involves squirting a small amount of salt water into your nose and catching it as it runs out.

We will ask you to return to this study site for a second visit 3-4 weeks later. At this second visit we will:

- Ask you to answer a follow up questionnaire. This questionnaire will ask you about your health, whether you were admitted to the hospital, treated for influenza, and/or saw any other doctors about your symptoms.
- Collect another blood sample. We will collect 10mL or 1 tablespoon of blood from your vein.

After this second visit, the study is complete, and you do not need to make any further visits.

After you complete the study, we will review your medical record to see if you were treated or hospitalized for influenza.

Optional Stored Samples
In case your blood or other samples are not completely used during this study, we or other investigators may be interested in using them later for future studies related to influenza and/or other respiratory infections or diseases. The results of the future tests performed on your samples will not be provided to you or kept in your medical record. Your samples will be labeled only with a unique tracking number and protected with the same level of confidentiality as your medical records, described in the Confidentiality section below. You can decide if you want your samples to be used for future research. Your decision can be changed at any time prior to the end of this study by notifying the study staff in writing. However, we may continue to use any data generated from your samples before you change your decision. If you decide not to allow your samples to be stored and tested in the future, your samples will be destroyed at the end of this study. Storing your samples for use in possible future research studies or having them used in future research studies may not benefit you directly. Please check below to indicate whether you agree or do not agree to future use of your samples and sign where indicated.

_____YES, I give permission for my samples to be stored for future use in similar studies by these investigators and by other investigators at this or other institutions.

_____NO, I DO NOT give permission for my samples to be stored for future use in similar studies by these investigators and by other investigators at this or other institutions.

_____ _____
Signature of Participant **Date**

Risks and Discomforts:

Blood Draw
To draw your blood, we will place a small needle into your vein and draw 1 tablespoon of blood. This can be briefly painful, and can result in some bruising and/or infection in that area.

Nasal Swab
The small swab placed in your nostril may cause brief pain, and cause your nose to itch, your eyes to water or you may sneeze.

Nasal Wash You will feel slight discomfort when the wash enters your nostrils, and it may cause you to gag or cough.

Questions
Questions that you will be asked to complete during the study may contain questions that could be embarrassing and/or make you feel uncomfortable. You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

To minimize these risks and discomforts, a trained physician, nurse, study coordinator, or designee will collect the specimens. Care will be taken to obtain these specimens in a safe and hygienic manner.

Subject confidentiality will be held strictly in trust by the investigators and staff. This confidentiality will be extended to cover testing of biological specimens in addition to the clinical information relating to subjects.

New Information:

It is possible that the study investigators will learn something new during the study that may affect your health or your decision as to whether you want to stay in the study or not. If this happens, we will tell you about it. Then you can decide if you want to continue to be in this study or not.

Benefits:

By participating in this study, you and your doctor may learn whether you have influenza. In case your swabs test positive for influenza, we will inform you of this result and inform your physician. There will otherwise be no direct benefit to you from being in this study.

If you participate in this study, you may help others in the future. This study will help the hospital and public health organizations understand how much influenza is in the community. This study will also help them to understand if their current methods of influenza surveillance are giving them accurate information about influenza. Also, samples from this study will help future understanding of how our bodies react to influenza.

Compensation:

You will be paid $125 if you join this study – $50 dollars for your initial enrollment and $75 dollars upon your follow up visit. Compensation will be made in the form of gift cards.

Confidentiality:

SITE_NAME has rules to protect information about you. Federal and state laws also protect your privacy.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and other details.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at SITE_NAME may see or give out your information. These include people who review research studies, their staff, or other SITE_NAME staff.

People outside of SITE_NAME may need to see your information for this study. Examples include staff from Johns Hopkins University, our collaborating partner in this study, government groups, the hospital Institutional Review Board, and representatives from the agency that sponsors the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will only use and disclose your information as described in this form; however, people outside SITE_NAME who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

In case of injury:

SITE_NAME and the federal government do not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at SITE_NAME is open to you as it is to all sick or injured people.

By signing this form you will not give up any rights you otherwise have to seek compensation for injury.

Costs:

You will not have any costs for taking part in this study.

Withdrawal from the study:

You are free to choose whether or not to participate in this study. The alternative to choosing to be in this study is to not be in the study. Your participation in the study is voluntary.

You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time for any reason. There will be no penalty or loss of benefits if you decide to quit the study.

You can agree to be in the study now and change your mind later.

If you wish to stop, please tell us right away.

Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, SITE_NAME may use or give out your health information that it already has if the information is needed for this study or any follow-up activities**.** The information you have already provided will be kept in a confidential manner.

The researchers also have the right to stop your participation in this study without your consent if:

- The principal investigators determine that it is in your best interest to discontinue participation.
- The study is terminated.

Contact Information:

For more information concerning this research, or if you feel that you have suffered a research-related injury, contact:

'STUDY PI INFORMATION HERE'

Consent (or Signature Page):

Participant's Consent:

I have read or have had read to me and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I am not waiving any legal rights by signing this form. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

_____ _____

Participant Name Signature or Mark

_____

Date

Statement of Person Obtaining Consent:

I have discussed, in detail, the informed consent document for this research study with the participant including the purpose of the study and its risks and benefits. I have answered all the participant's questions clearly. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

Name of Investigator or designee Signature

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