If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: CEIRS: Human Influenza Surveillance of Health Care Centers in the United States and Taiwan

Application No.: IRB00052743

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

Principal Investigator:

Clinical Site Principal Investigator:
Andrea Dugas, MD
Assistant Professor
Department of Emergency Medicine
Johns Hopkins Medical Institutions
5801 Smith Avenue
Davis Building, Suite 3220
Baltimore, MD 21209
Phone: 410-735-6453
Fax: 410-735-6425
Email: adugas1@jhmi.edu

Prime Principal Investigator:
Richard E. Rothman, MD, PhD
Professor
Department of Emergency Medicine
Johns Hopkins Medical Institutions
5801 Smith Avenue
Davis Building, Suite 3220
Baltimore, MD 21209
Phone: 410-735-6428
Fax: 410-735-6425
Email: rrothma1@jhmi.edu

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- 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. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- If you receive routine medical treatment (including medical or laboratory tests) in the study or if you are taking part in the study at the Clinical Research Unit, information about your research study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.

- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- The Johns Hopkins School of Medicine Institutional Review Board (IRB) sometimes reviews studies that are conducted at other institutions. These other institutions are solely responsible for conducting the study safely and according to the protocol that the Johns Hopkins IRB has approved. Information about how to contact the investigator at the institution that is responsible for the study is included in this form. When another institution is conducting the study, the word "we" in this consent form may include both Johns Hopkins and the participating institution.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

2. Why is this research being done?

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.

How many people will be in this study?

About 1500 adult participants will take part in this study at Johns Hopkins Hospital.

Inclusion criteria:

In order to take part of the study, you must meet the following criteria:

- Present to an eligible emergency department
- Age 18 years of age or older
- 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 (greater than or equal to 100.5°F or 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 (greater than or equal to 100.5°F or 38°C)
    - Report of fever
    - Cough
    - Headache

- Sore throat
- Muscle pain
- Runny nose or nasal congestion
- Shortness of breath

3. What will happen if you join this study?

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.

Initial Visit

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

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 about 10 minutes to complete.

Sample Collection

We will collect the following samples:

- Blood: we will collect 10 mL or 2 teaspoons of blood from your vein.
- Nasopharyngeal swab: we will gently insert a small cotton-tipped swab into your nose and twist it quickly to collect secretions.

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, and will tell you and your doctor the result of the test. It takes about an hour and a half to two hours to get the results.

If your test is positive for influenza, we will ask you for an additional sample from your nose. We will collect the additional samples using a "nasal wash" which involves squirting a small amount of salt water (about 1 teaspoon) into your nose and catching it as it runs out.

Second Visit

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 10 mL or 2 teaspoons 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.

Request to collect and store biospecimens for future research

As part of this research study, we would like to ask you to let us store your biospecimens and health information for future research. This research could include other diseases and involve research tools such as gene sequencing or the creation of cell lines.

- Gene sequencing of your DNA provides researchers with the code to your genetic material.
- Cell lines are living tissue samples that can be grown in a laboratory. A cell line can provide an unlimited supply of cells in the future without requiring more samples from you. Each cell contains your complete DNA.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*

Will you allow us to store the biospecimens we collect for this study for use in future research*?*

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

How long will you be in the study?
Your participation in this study will last 3-4 weeks. The study as a whole will run for 7 years.

4. What are the risks or discomforts of the study?

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 (Influenza Positive Participants Only)
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.

5. Are there benefits to being in the study?

There may or may not be a 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.

6. What are your options if you do not want to be in 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 do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

There is no cost to you for participating in this study.

8. Will you be paid if you join this study?

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

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us

9. Can you leave the study early?

- 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, Johns Hopkins may use or give out your health information that it already collected if the information is needed for this study or any follow-up activities**.**

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- The principal investigators determine that it is in your best interest to discontinue participation.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

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 information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

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

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (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 authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect

information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

If you are a participant at Howard County General Hospital, you may contact Jay Blackman (IRB office at that site) at 410-740-7720.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Dugas at 410-735-6453. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

13. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.