CONSENT FORM / AUTHORIZATION (HIPAA) FOR A RESEARCH STUDY

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INTRODUCTION
You are being asked to take part in this research study because you are infected with the human immunodeficiency virus (HIV), the virus that causes AIDS and are receiving the H1N1 flu vaccine as part of your regular care. The study does not involve administration of an experimental vaccine; the study only involves blood drawing when you receive the vaccine in the ID clinic, or if you need a second vaccine, and at a follow up visit. This study is sponsored by the University Of Pennsylvania. The doctor in charge of this study is: Dr. Pablo Tebas. Before you decide if you want to be to be a part of this study, we want you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

PRELIMINARY RESULTS OF THE STUDY
A total of 120 participants were enrolled in the trial, and as of December 21st, 2009, 39 participants had completed 3 weeks of follow up. At week 3, 61% of subjects achieved antibody levels to protect them from the flu. Nine people already had some immunity because of exposure to H1N1; thus only 53% of participants were able develop protective titers by week 3 of the study. The vaccine was well tolerated with minor local reactions at the site of injection observed in 18% of the participants. There were no serious adverse events.

These preliminary results suggest that only half of well controlled HIV infected individuals develop protective antibody titers after immunization with the recommended dose of the H1N1 flu vaccine. Thus, for those persons that did not develop immunity after the vaccine, we would like to administer a second dose of vaccine.

WHY IS THIS STUDY BEING DONE?
H1N1 virus, also known as ‘swine flu virus’, is a new strain of influenza (flu) virus that causes illness in people. However, H1N1 influenza virus has recently been identified as the cause of serious, sometimes
life-threatening illness in some previously healthy people. This illness can result in severe pneumonia, which requires hospitalization, and is life-threatening.

The purpose of this research study is to determine if the H1N1 vaccine is safe and will help the body’s normal defenses against the effects of H1N1 influenza in HIV-infected persons.

There is no information on the safety or immune response to this vaccine in patients with HIV. The “immune response” is how your body recognizes and defends itself against bacteria, viruses, and substances that may be harmful to the body. We want to see if your body will produce antibodies (proteins that fight infection) that will prevent or fight H1N1 virus.

The study will look at:

- The safety of the vaccine. This will be done by observing you following the vaccine shots, and asking you about any adverse (bad) effects you may experience after the shot.
- Your ability to form antibodies against H1N1 in response to the vaccine. This will be done by doing blood tests on you (after each dose and at certain time points described below).
- How your body is responding to the HIV infection by looking at the number of special white blood cells (T cells) that are affected by the HIV virus (CD4 levels).
- Evaluating the ability to make antibodies after a second dose of the vaccine in persons who did not achieve a protective level after one dose.

**WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?**

If you agree to take part in this study, you will be asked some questions to be sure you can participate in this study.

**Vaccine Visit**

We will ask about your family history, including Guillain-Barré Syndrome. Guillain-Barré Syndrome is a very rare but serious disorder where the body’s immune system attacks the peripheral nerves. The peripheral nerves send sensory information (like pain or temperature) from the body to the brain, and motor (movement) signals from the brain to the body. It is not usually seen following routine influenza vaccination. However, some cases of Guillain-Barré Syndrome were reported after mass public vaccination for the 1976 “swine flu”. It is unknown if the H1N1 influenza vaccine will present the same risk. The study staff will assess you for symptoms of Guillain-Barré Syndrome (weakness and numbness or tingling in the legs and arms, and possible loss of movement and feeling in the legs, arms, upper body, and face) at each clinic visit and phone call.

The study staff will ask you some questions about your medical history, as well as the use of any past or present anti-HIV drugs. You will have about 2 tablespoons (32 mls) of blood taken for special lab tests (to test your immune response to the flu virus). You will be asked for permission to review your medical record.

The vaccine will be given as an injection with a needle in a muscle in your upper arm. After vaccine administration, you will remain in the clinic for at least 30 minutes (½ hour) to make sure that no reactions to the vaccine develop.

**After you have received the vaccine**

You will need to contact the study staff immediately to report any unusual or serious reactions that occur after you leave the clinic. You will be asked to take your temperature at the same time every 2
day for the five (5) after the vaccine. You will also be asked to complete a “Vaccine Report Card” and record your temperature and write down any symptoms or unusual reactions that occur during these five days. The study staff will call you approximately 2 days after you receive the vaccine and again approximately 10 days later to ask you about any reactions you may have had.

You will also be asked about any new fever or flu-like illness, such as a sore throat, runny nose or cough. If you are having any of these symptoms, you will be asked to come back to the clinic within 72 hours. If you have any other new symptoms, such as weakness of legs, tingling of hands and/or feet, or difficulty walking, it is important that you contact the study staff immediately and you will be asked to come back to clinic within 24 hours.

Day 21 Visit/Early Discontinuation Visit
You will be asked to return to clinic approximately 3 weeks after you receive the vaccine, when we will do the following procedures. This visit will take approximately 30 minutes. These evaluations will also be conducted if you decide to leave the study early.

- Study staff will ask you some questions about how you have been feeling since your last visit.
- About 2 tablespoons (28 ml) of blood will be taken for special lab tests (to test your immune response to the flu virus).

Extra Visit for Participants Who Did Not Achieve Therapeutic Response
The study staff will review your medical history to assure it is accurate, as well as the use of any past or present anti-HIV drugs. You will have about 2 tablespoons (32 mls) of blood taken for special lab tests (to test your immune response to the flu virus).

The vaccine will be given as an injection with a needle in a muscle in your upper arm. After vaccine administration, you will remain in the clinic for at least 30 minutes (½ hour) to make sure that no reactions to the vaccine develop.

After you have received the second vaccine
You will need to contact the study staff immediately to report any unusual or serious reactions that occur after you leave the clinic. The study staff will call you approximately 2 days after you receive the vaccine and again approximately 10 days later to ask you about any reactions you may have had. You do not need to complete a second vaccine report card.

You will also be asked about any new fever or flu-like illness, such as a sore throat, runny nose or cough. If you are having any of these symptoms, you will be asked to come back to the clinic within 72 hours. If you have any other new symptoms, such as weakness of legs, tingling of hands and/or feet, or difficulty walking, it is important that you contact the study staff immediately and you will be asked to come back to clinic within 24 hours.

Follow Up Visit After Second Vaccine
You will be asked to return to clinic approximately 3 weeks after you receive the vaccine, when we will do the following procedures. This visit will take approximately 30 minutes.

- Study staff will ask you some questions about how you have been feeling since your last visit.
- About 2 tablespoons (28 ml) of blood will be taken for special lab tests (to test your immune response to the flu virus).

Sick visits
At any time during the course of the study, if you have fever of 100.0°F or above, or any signs or symptoms of a flu-like illness such as cough, runny nose or sore throat, you will be asked to come in to the clinic. After evaluation by your healthcare provider, a nasal specimen may be taken. The procedure involves placing a long Q-tip into your nose and swabbing the inside of your nose. This test will be done to see if certain types of flu virus are found in your nasal passages and if so, how much is present. This study test will be performed after the study is completed and you will not be told your results. This visit will take approximately 30 minutes.

OTHER INFORMATION
When the study is over, results will be available from your study site. You will be given the results of your routine lab tests when they become available. The results of special lab tests (to test your immune response to the flu virus) and any respiratory specimens will not be provided to you or your doctor. These tests will not be run at the time they are received. Instead they will be run in batches or at the end of the study. Any blood samples that are not used after 3 years following the end of the study will be destroyed.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
About 130 people will take part in this study.

HOW LONG WILL I BE IN THIS STUDY?
The longest length of time you will be in this study will be approximately one month. If you are one of the participants who is asked to come back for a second vaccine, you will be on the study for an additional month.

WHAT ARE THE RISKS OF THE STUDY?
Risk of Blood Draws
You may feel faint or may feel some discomfort while having blood taken. There may be some swelling, bleeding, or bruising where the needle goes into the skin, or a small blood clot may develop. There is a small risk of infection forming where the needle goes into the skin to take blood.

Risks Related to the Vaccine
Side effects that might be expected as a result of the H1N1 influenza vaccine would be those which are sometimes observed in other commonly used vaccines, including fever, skin redness, pain, tenderness, soreness and swelling at the site of injection. In addition, there is also a possibility your HIV viral load will increase. Any information on side effect or risks that is gathered from H1N1 vaccination on other groups of people will be provided to you as quickly as possible.
Occasionally, there can be a serious allergic reaction to a vaccine. These reactions can cause any of the following symptoms:

- skin rash (hives)
- fever
- nausea
- vomiting
- difficulty breathing
- diarrhea
- abdominal pain
- cough
- sore throat
- achiness
- feeling tired (fatigue)
- swelling around the mouth, throat, or eyes
- a fast pulse
- sweating
- general feeling of illness

If these reactions occur they can usually be stopped by the study staff giving emergency medications. These symptoms usually occur soon after having the vaccine. As with any vaccine or medication, there is a very small chance of a fatal reaction, although researchers do not expect this to occur.

Rare Occurrence
- Guillain-Barré Syndrome (see Vaccine Visit for information)

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?
The study doctor may take you off study if:
- The study is cancelled by the Office for Human Research Protections (OHRP), or the University of Pennsylvania’s Institutional Review Board (IRB). An IRB is a committee that watches over the safety and rights of research subjects.

WHAT HAPPENS IF I AM INJURED?
If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you. There is no program for compensation either through this institution or the National Institutes of Health. If you have an illness or injury during this research trial that is not
directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

You do not give up your legal rights by signing this form.

**WILL I RECEIVE ANY COMPENSATION?**
At the final study visit you will receive $25 upon successful completion of the study: handing in your Vaccine Report Card and having a second blood draw for the study. If you are asked to return for a second vaccination, you will receive $25 at the follow up visit.

**ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?**
It is possible that you may receive no benefit from being in this study. Information learned from this study may help others who have HIV and receive the H1N1 flu vaccine.

**WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?**
Alternatives to your participation in this study include receiving the vaccine from your health care provider (your primary doctor or HIV provider) and not providing the extra blood samples.

**WHAT ABOUT CONFIDENTIALITY?**
We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

*What personal health information is collected and used in this study, and also might be shared?*
Personal health and contact (phone number, address) information collected as part of this study is recorded in your clinical trial chart. This record is separate from your medical chart. Data collected for the study is reported to the study team on a case report form, which includes the information listed below, but not your name or other identifying information.

Personal health information that is collected and will be disclosed to the agencies listed on the following page as part of this research study is:
- Demographics (Race, Gender)
- Signs and symptoms you experience while on the study
- Current and past medical diagnoses; allergies
- Current and past medications and therapies
- Data from laboratory tests
- Data from Vaccine Report Card
- Dates of clinic visits

*Why is your personal health information being used?*
Personal contact information, such as phone number and address, will be used only by clinical trial staff to get in touch with you while you are participating in this study. Your health information and results of tests and procedures are being collected as part of the research study and for the advancement of
medicine and clinical care. The Principal Investigator will use the results to monitor your safety and ability to tolerate the study medications.

**Which of our personnel may use or disclose your personal health information?**

The following individuals and organizations may use or disclose your personal health information for this research project:
- The Principal Investigator and other University staff associated with this study;
- The University of Pennsylvania Institutional Review Boards (the Committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine work force who may need to access your information in the performance of their duties, for example, to provide treatment, to ensure the integrity of the research, accounting or billing matters, etc.

**Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive your personal health information?**

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:
- Government Agencies: Data from this study will be made available to the Food and Drug Administration for them to evaluate the safety and efficacy of the treatments being used in this study.

Study staff will inform you if there are any changes to this list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by federal privacy protection regulations.

In all disclosures outside the University of Pennsylvania Health System or School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier, unless disclosure of the direct identifier is required by law. Personal health information will be disclosed by a unique code number. Only study staff can break the code and identify you to your code.

**How long will the University of Pennsylvania Health System and the School of Medicine be able to use or disclose your personal health information?**

Your authorization for use of your personal information for this specific study does not expire. This information may be stored in a database (research repository). However, the University of Pennsylvania Health System and the School of Medicine may not re-use or re-disclose your personal health information collected for this study for another purpose other than the research described in this consent form unless you have given written permission to the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care will not be included in your medical record unless you want

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**IRB Approval From:** 3/8/2010 **To:** 10/28/2010

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them to be sent to your primary care provider. You will need to complete a medical records release of information to allow us to provide study data to your doctor.

**Will you be able to access your records?**
You will be able to request access to your medical record when the study is completed. During your participation in the study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know the information to best treat you. You will have access to your medical record and study information that is part of that record when the study is over. The Investigator is not required to release to you research information that is not part of your medical record.

**Can you change your mind?**
You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at 502 Johnson Pavilion. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

**WHAT ARE THE COSTS TO ME?**
There are no costs to you for study visits or study procedures.

**WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?**
Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you the same no matter what you decide. We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

**WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?**
For questions about this study or a research-related injury, contact:
- Pablo Tebas, MD (215-349-8092)
- Clinical Trials Unit (215 349-8092)

For questions about your rights as a research subject, contact:
- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

**CONSENT**

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.
UNIVERITY OF PENNSYLVANIA HEALTH SYSTEM

Safety and Immunogenicity of an Inactivated Swine-Origin H1N1 Influenza Vaccine in HIV-1 Infected Patients

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine’s Notice of Privacy Practices that contains more information about the privacy of your health information.

________________________________________  _____________________________________
Name of Subject (Please Print)  Signature of Subject              Date

________________________  _____________________________________
Name of Person Obtaining Consent (Please Print)  Signature                                  Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

________________________________________  _____________________________________
Authorized subject representative [print]  Authorized subject representative Signature    Date

Provide a brief description of above person authority to serve as the subject’s authorized representative.

