UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

IRC 005, Version 2.0, June 15, 2016, Letter of Amendment #1, dated October 25, 2016:
A Randomized Double-Blind, Phase 3 Study Comparing the Efficacy and Safety of High-Titer versus Low-Titer Anti-Influenza Immune Plasma for the Treatment of Severe Influenza A

CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Your contacts for this study at the Hospital of the University of Pennsylvania [HUP] are:

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Address: 502 Johnson Pavilion, Philadelphia, PA 19104
24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

Introduction:
We invite you to take part in a research study. This study is funded by the National Institutes of Health (NIH). The doctor in charge of this study at this site is Pablo Tebas, MD and will be paid by the NIH to conduct this research study. Before you decide if you want 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 be offered a signed copy of the consent form prior to any study-related evaluations to keep.

First, we want you to know that:

Taking part in NIH-funded research at the University of Pennsylvania is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled.

You may receive no benefit from taking part in this study. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your University of Pennsylvania doctors or research team before you agree to the study.

Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at University of Pennsylvania, or with family, friends, or your personal physician or other health professional. This consent form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

High titer vs Low Titer Anti-Influenza Immune Plasma for the Treatment of Influenza A

Why Is This Study Being Done?

Influenza (flu) is a virus (a type of germ) that can cause infections in people. Most people infected with this virus have mild symptoms including fever, cough, muscle aches, diarrhea, and headaches. Some people get very sick from this virus. These people tend to be older and have chronic (ongoing) medical problems, but it can affect younger people too. It is estimated that 30,000 people in the United States die each year from influenza. You may be eligible to participate in this study because you may have been infected with influenza.

Currently treatments are available for influenza, but there is concern that the rate of death is still high even with treatment, and that these treatments may no longer work against the virus (resistant to the treatment).

The purpose of this study is to develop a possible new treatment for influenza. This new treatment uses antibodies against this virus. Antibodies are natural proteins made by the body that attack influenza and other germs. These antibodies are found in plasma, the yellow, clear part of the blood. There have been other studies using plasma to treat other types of viruses that showed some positive results. The NIAID Influenza Research Collaboration (NIRC), the sponsor of this study, conducted a randomized study using high-titer anti-influenza plasma. Subjects of any age were eligible if they had confirmed influenza A or B and had evidence of severe influenza. Ninety-eight subjects were enrolled between January 2011 and March 2015, including 11 children and 2 pregnant women. Subjects were randomized to receive standard care (including antivirals) or standard care plus 2 units of high-titer anti-influenza plasma. The primary endpoint was proportion of participants with normalized respiratory status over time. Forty-three percent of subject in the standard care arm and 61% of subjects in the plasma treatment arm normalized respiratory status by Day 28. The data from this study strongly suggests that the addition of high-titer immune plasma to standard care can improve outcomes in this population. This present study aims to confirm these results in a continued search for better treatments for severe influenza. The present study has been designed to remove potential bias noted in the previous one: the low titer plasma group will be the control group. It is not known if this plasma is therapeutic or not. However, this control arm was chosen to provide the best scientific design, and ensure the study is blinded. It is only by using the best design possible that we can hope to settle the question of if there is therapeutic benefit from the anti-influenza plasma.

We have collected plasma from people who had high levels of the antibodies either because they have been infected with the influenza virus or because they have been vaccinated against the infection. In this study, we will transfuse this high antibody plasma into one group of people currently infected with influenza. We will also transfuse plasma with low or no antibodies against the influenza virus to a different group of people with influenza infections. We want to see if the plasma with higher levels of antibodies helps people with influenza improve more than plasma with lower levels or no antibodies. The plasma is given in addition to standard anti-influenza medications.

How Many People Will Take Part in This Study?

The University of Pennsylvania is one site of this multicenter study. Across all sites, approximately 150 volunteers will participate in this study; about 10-15 persons may enroll at the University of Pennsylvania. The study will last for 28 days for each volunteer. If you are pregnant or become pregnant while on this study, we will ask to check on you once a month until after your child is born**.**

Criteria to Take Part in This Study

To participate in this study you must be hospitalized with influenza. You will not be able to receive any unlicensed medications for influenza (those not approved by the FDA), though you will receive

standard medications for influenza as part of this study (such as oseltamivir or zanamivir). This study will infuse blood products (plasma), so you will not be able to participate if you have had allergic reactions to blood products, or your doctors think giving you this amount of blood product would be dangerous to you. You will also not be eligible to participate if you are not willing or able to participate in follow up visits.

What Do I Have To Do If I Am In This Study?

Screening

If you agree to join this study, you will be asked to sign this consent form. After you have signed this form, you will be asked some questions and will undergo some tests to see if you can take part in this study. The screening visit will take about 45 minutes to one hour.

At the screening visit, we will go over with you the criteria to take part in this study.

- We will record your demographic information, for example, date of birth, gender, ethnicity and race.
- We will ask you about your health, including your medical illnesses or medical procedures, and any medicines you are taking.
- For females we will also do a pregnancy test.
- We will take about 2-4 tablespoons of blood to determine your blood type and also to check flu antibody levels.
- If you have not had a recent influenza test, we will need to test you for influenza.

From these tests we will be able to determine if you qualify for this study, and if we have plasma that matches your blood type.

On-study evaluations

Once we determine that you qualify for this study, you will be assigned randomly (like rolling dice) to receive either plasma containing high levels of antibody against the influenza virus or plasma containing low levels or no antibodies against the influenza virus. Of every 3 participants in this study, 2 will receive the plasma with high levels of antibody against the influenza virus and 1 will receive the plasma with low levels or no antibodies against the influenza virus. All participants will also receive routine care. Neither you nor the study team will know which plasma you receive until the end of the study.

While we prepare the plasma, we will collect some baseline information about what symptoms you have, your vital signs (temperature, pulse, respiration rate, and blood pressure), and some other clinical information (such as whether you require any supplemental oxygen and whether you are in the ICU). We will also need to collect about 6 tablespoons of blood from you. We will also swab the back of your throat to look at how much influenza virus is there. We will then administer the study plasma (see below).

On 1, 2, 3, 7, 14, and 28 days after you receive the study plasma we will evaluate you. If you are no longer in the hospital, we will need you to return to the clinic for the visits on Day 3 and Day 7 at a minimum. The Day 2, Day 14, and Day 28 visits can be in the hospital, clinic, or completed over the phone. Each visit should take up to 1 hour. At each of these time points, we will ask questions about your symptoms and collect some clinical information. If your visits are at the hospital or clinic, we will also check your vital signs and perform a brief exam. On Days 1, 3, and 7 we will collect up to 3 tablespoons of blood for safety tests and other research tests at each visit. We will also swab the back of your throat at Day 3.

If you are pregnant, in addition to the above, we will want to contact you each month until after your delivery to ask about the health of your child and any complications during pregnancy or delivery.

If you are discharged from the hospital and do not participate in scheduled follow-up visits, we will try to reach you by phone. If we cannot reach you or you are unable to answer questions yourself, we may contact your health care providers or emergency contacts to ask about your health**.**

Study Treatment

All participants will receive treatment for influenza with standard anti-influenza medications and the choice of these medications is up to your doctor. In addition to these medications, we will give you study plasma. In both groups, the plasma will be given through an IV catheter (tube) placed in a vein. You will receive 2 doses of the study plasma on the same day.

All of the plasma was collected from male donors. Some of the donors may have been compensated for the time they spent donating the plasma. All plasma was tested to determine the amount of antibodies it has against the influenza virus. The plasma containing high levels of antibody against the influenza virus was collected from people who either recovered from influenza or were vaccinated against the influenza virus. All of the plasma has also been tested for the infectious diseases that can be transmitted in blood, including HIV, hepatitis viruses, and syphilis. The plasma used in this study has been tested in similar ways and meets the same standards as plasma used in any hospital blood bank.

Special Concerns

If you decide to participate in this study, you will not be able to donate blood for at least one year from the day you received the plasma.

If you are pregnant, you may not be able to participate in this study at this time. This may change over the course of the study. We will enroll pregnant women at this center.

Stored Samples and Future Research

Some of the blood work we are taking is for additional research laboratory testing. By participating in this study, you are agreeing to the storage of your blood for this testing. Your specimens will be collected and stored for up to 10 years. Influenza related testing of the samples will be performed in the within these 10 years to meet the study objectives. Additional non-influenza related testing of these stored samples may be performed. The research tests we will use may not be like medical tests. We may not know how the results relate to your care. Therefore, we may not put future test results in your medical record. However, if you ask, someone on the study team will discuss the test results with you. We will not share these test results with your private doctor unless you ask us to do so.

By agreeing to participate in this study, you do not waive (or give up) any rights that you have regarding access to and disclosure of your records. For further information on those rights, please see the section "What Do I Do If I Have Questions or Problems?"of this consent form for contact information.

Future Studies

Other investigators may want to study your stored samples. If so, the University of Pennsylvania study team may send your samples to them, without any information that can be traced to you. The study team may also share information such as your gender, age, health history, or ethnicity. In some

cases, an Institutional Review Board (IRB) will review new research that uses your samples. The IRB is a committee that oversees medical research studies to protect volunteers' rights and welfare.

Investigators will only use your samples for research. We will not sell them. Future research that uses your samples may lead to new products, but you will not receive payment for these products.

If you agree to participate in this study, you agree to let us store your samples for future research. No matter what you decide, you may still participate in other studies at the University of Pennsylvania. However, if you refuse to let us store your samples, we may withdraw you from this specific study.

Samples will not be stored for genetic testing.

What Are The Risks Of The Study?

Risk of Treatment with Plasma:

We do not know if you will benefit from receiving plasma therapy. A prior study suggested there was benefit to people that received plasma with high levels of anti-influenza antibodies. However, we do not know if this is certain, and this study is being conducted to confirm that finding. Most risks associated with plasma therapy are those that occur regardless of the type of antibodies in the plasma.

Plasma transfusion reactions including allergic transfusion reactions occasionally happen. These may include fevers, rashes, hives, itching and/or headaches. More rare side effects would include serious allergic reactions including anaphylaxis, which may be associated with a rash, swelling of face, lips, tongue or throat, and difficult breathing, low blood pressure, and can be life threatening.

Infections may also occur. Rarely, bacterial infections can occur if bacteria contaminate the bag of plasma. Viral infections like hepatitis B, hepatitis C, and HIV may occur even though we screen for these diseases. There may be other diseases, such as Zika, that could be transmitted by plasma. In all cases, we will follow the FDA guidance for screening the plasma and the donors to minimize the risk of any such infection.

A type of lung injury has been seen with some transfusions. This transfusion-related acute lung injury (TRALI) has been shown to be related to antibodies against your cells that come from other people's plasma. This has mainly been shown to come from plasma from women who have had children (antibodies probably made during pregnancy). In this study, this risk is minimized by only using plasma donated from males. However, this may not eliminate the risk entirely. The risk of TRALI is reported as 1 out of 5,000 transfusions. If this happens it could make it hard to breathe, or you may have to be put on a breathing machine.

There is also the risk that the proteins in the plasma will cause blood clots to form. These blood clots could go to your heart or lung making it difficult to breathe and may be life-threatening.

The plasma volume to be given to you is roughly 500-600 mL (slightly more than 2 cups) for adults, though could be up to 700 mL (up to 3 cups) depending on the size of the plasma units. There is a risk that if you cannot tolerate this amount of volume it may become harder to breathe or put a strain on your heart. People that are known to have conditions that would not tolerate this volume of blood are excluded from the study. However, this condition could still occur.

If you are male or a non-pregnant female, your doctor may ask you to wait at least 5-6 months before receiving a live attenuated (weakened) influenza vaccine, the measles, rubella, mumps

vaccine, or the varicella (Chickenpox) vaccine. This is because the plasma you receive in this study may temporarily interfere with the body's ability to mount as good of an immune response to those vaccines as desired. For pregnant females, the considerations are even more complex, and your doctor may ask you to still receive one or more of these vaccines. If there is a need to receive ANY vaccine within 7 months of receiving the study plasma, you should make sure your doctor is aware of your participation in this study and the date you received plasma. You and your doctor should discuss what would be most appropriate for your situation.

There is the risk that plasma could make either the infection, or the inflammation associated with the influenza infection, worse.

If you are pregnant, there may be additional risks that are currently unforeseeable both to you and your fetus or neonate. Plasma is sometimes used during pregnancy, so we do not anticipate any additional risk with this plasma, but we do not know for certain. There is the risk that the plasma could cause premature labor, complications after the child is born, or miscarriage.

Risk of Blood Draw:
You may feel some pain at the needle entry site. There is a slight risk of bleeding around the site. This is not dangerous, but it could result in a bruise. Some people feel lightheaded or dizzy after having blood drawn. To reduce the risk of injury because of a fall, you will be closely monitored and asked about these symptoms before you are allowed to stand up. There is also the possibility of infection at the site where the needle went in, but this rarely happens.

Risk of Throat Swabs:
Generally these procedures are well tolerated. It may cause discomfort, though we try to minimize it the best we can. Occasionally, a throat swab can cause you to cough or gag, and rarely vomit.

Are There Benefits to Taking Part in This Study?

You may not receive any direct benefit for participating in this study. The benefits of using plasma to treat patients who are actively infected with influenza are unknown. It is possible that receiving plasma with high levels of antibody against the influenza virus in addition to standard antiviral therapy will make the infection get better faster.

ENDING PARTICIPATION IN THIS STUDY

As previously discussed, you may withdraw from the study at any time. You will not be asked for further information or samples. If you decide to stop participating in this study, please contact the study doctor or the study staff listed on top of this Informed Consent Form. If you decide to stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis.

Why Would The Doctor Take Me Off This Study Early?

The study doctor may need to take you off the study early without your permission if:
- the study is cancelled by the U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), or the University of Pennsylvania's Institutional Review Board (IRB).
- you are not able to attend the study visits as required by the study.

The study doctor may also need to take you off the study without your permission if:
- continuing the study may be harmful to you
- you need a treatment that you may not take while on the study

What About Confidentiality?

The greatest risk is that someone may take information from your medical records without your permission. The chances of this happening are very low. If this information becomes available, you may face discrimination when you apply for insurance or a job. You may also have similar problems if you share the information yourself or let us release your medical records.

Confidentiality and Labeling of Samples

We will label your samples with a code that only the study team can link to you. We will keep any information that can be traced back to you private to the extent permitted by law.

Information about you (such as your name, address, and telephone number) will be kept separate from the results of research tests we perform. Research information will be kept in a password-protected computer file that only the study investigators can view. If we learn anything of importance to our research from this testing, we may publish the results in a medical journal. However, you will not be identified in such an article.

When results of a University of Pennsylvania research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the University of Pennsylvania will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the University of Pennsylvania will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your University of Pennsylvania medical records. However, you should know that the Act allows release of some information from your medical record without your permission; for example, if it is required by the study sponsor, Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

HIPAA AUTHORIZATION

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might also be disclosed?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Personal and family medical history
- SSN: will be collected if it is expected you will receive more than $600 for study participation in a given year
- Current and past medications or therapies.
- Results of tests and procedures you will undergo during this research study

Why is your personal contact and health information being used?
Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?
The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?
As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- Social & Scientific Systems, Inc.: Data for this study will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be cleaned and stored at this facility until it is ready to be analyzed.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration and to the National Institutes of Health/National Institute for Allergy and Infectious Disease (NIAID), for them to evaluate the safety and efficacy of the treatments being used in this study.
- Monitors and Auditors: The study records will be assessed by a contract monitoring agency to assure that all assessments and evaluations are being conducted appropriately for the study. These persons will have access to your clinical trial medical chart for these purposes.

Regulatory and safety oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study vaccine you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Can you change your mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who

are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What Other Choices Do I Have Besides This Study?

The alternative is not to participate in this study. You can also just receive current standard of care treatment for influenza.

You have the right to agree or refuse to participate in this research. If you decide to participate and later change your mind, you are free to discontinue participation at any time. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. Refusal to participate will not affect your legal rights or the quality of health care that you may receive at this center. You will be given any new information that becomes available during your participation in the research that may affect your willingness to continue in the study.

Will I Receive Any Payment?

You will be compensated $50.00 cash for travel costs associated with coming to the outpatient study visits. You will not be compensated while you are an inpatient. The total amount of compensation for the study will vary from $50 to $300 depending on when you are discharged from the hospital.

Please note that if you receive more than $600.00 compensation in one year for participation in research studies at the University of Pennsylvania, you must provide a Individual Tax Identification number or Social Security Number for tax purposes.

What Are the Costs To Me?

There is no charge to participate in this study. The study will pay for research-related plasma, tests and assessments.

You and/or your health insurer will still be responsible for your health care costs that are not associated with participation in this research.

What Happens If I Am Injured?

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through the University of Pennsylvania, the NIH or the Federal Government. You will not be giving up any of your legal rights by signing this consent form. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

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.

Clinical Trials Listing

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results of this research. You can search this Web site at any time.

What Do I Do If I Have Questions Or Problems?

By agreeing to participate in this study, you do not waive any rights that you have regarding access to and disclosure of your records.

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.

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	Time
Participant's Legal Guardian (print) (As appropriate)	Legal Guardian's Signature	Date	Time
Name of Person Obtaining Consent (Please Print)	Study Staff Signature	Date	Time