# INFORMED CONSENT DOCUMENT

Project Title: **A Phase I Study to Assess the Safety, Reactogenicity and Immunogenicity of Two Quadrivalent Seasonal Influenza Vaccines (Fluzone® or Flublok®) With or Without One of Two Adjuvants (AF03 or Advax-CpG55.2) in Healthy Adults 18-45 Years of Age**

**Principal Investigator:** **Patricia Winokur**

**Research Team Contact:** **Deb Pfab**

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

## WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are in good health and between the ages of 18 to 45 years.

The purpose of this research study is to assess the safety, reactogenicity (reactions at the injection site and overall side –effects) and effectiveness of either the 2018-2019 seasonal Fluzone or Flublok given without or with one of two adjuvant formulations. An adjuvant is a substance that may cause the body to produce more antibodies when it is given with a vaccine. The two adjuvants being evaluated in this study are AF03 and Advax-CpG55.2. The adjuvants are investigational and have not been approved or licensed by the US Food and Drug Administration (FDA). Fluzone and Flublok are quadrivalent influenza vaccines (QIV) for the 2018-2019 season and are licensed and approved by the FDA.

Influenza is a common acute viral respiratory illness. Seasonal flu in the U.S. causes an estimated 100,000 to 600,000 hospitalizations and up to 50,000 deaths annually. Use of vaccines is the primary means for preventing the flu. Current licensed inactivated (virus is dead) influenza vaccines are good for preventing flu but are less effective than desirable. Several approaches have been used to increase the effectiveness of the flu vaccines including the use of adjuvants. Adjuvants can reduce the dose needed to achieve a good immune response and improve the antibody responses to the flu vaccines.

## HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 125 people will provide consent for this study, with about 30 people randomized (enrolled) into the study conducted by investigators at the University of Iowa. Up to 240 people are expected to be enrolled nationwide.

## HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study your involvement will last for approximately 12 months. The following visits/procedures will take place:

- A screening visit which will take about 1 ½ hours.
- An enrollment/vaccination visit which will take about 2 ½ hours.
- A vaccination visit at Day 90 where you will receive next season's flu vaccine. This visit will take about 1 ½ hours.
- Seven study visits which will take about 30 minutes each.
- A blood draw at each study visit. The total amount of blood collected in the study will be approximately 27 tablespoons. The maximum amount drawn at a single study visit will be about 7 tablespoons.
- Women who are able to become pregnant will be required to have a urine pregnancy test at the screening visit and/or at least 24 hours prior to the first study vaccination.

## WHAT WILL HAPPEN DURING THIS STUDY?

The follow up study visits will take place at the University of Iowa Hospitals and Clinics VTEU area, which is located on the third floor of the General Hospital. The two vaccination visits will take place at the Clinical Research Unit which is on the second floor of the General Hospital.

### Screening Visit

At the screening visit, you will be given information about the study and asked to read this informed consent. After you have read the consent and your questions have been answered, and you have had time to think about whether to participate in the study and if you wish, discussed it with your family, friends or doctor, you will be asked to sign this consent agreeing to take part in the study.

If you agree to take part in the study, the following will be done:

- You will be asked about your complete medical history including any medications you are taking or have recently taken
- You will be asked if you have received the 2018-2019 seasonal flu vaccine and non-seasonal flu vaccines including investigational ones
- You will have your temperature, pulse and blood pressure taken. We will measure your height and weight.
- You will have a physical examination.
- We will draw blood from a vein in your arm for laboratory tests. One of the tests will check for inflammation. If the test results are too high, you will not be able to continue in the study.
- Women who are able to become pregnant must use an acceptable method of birth control for at least 30 days before your study vaccination until at least 60 days after your study vaccination. You will have a urine pregnancy test at the screening visit and/or within 24 hours prior to receiving the study vaccination. If your pregnancy test is positive, you will not be able to continue in the study.

For your own safety, you need to be in good health to participate in this study. You cannot take part in this study if you:

- are pregnant, plan to become pregnant and/or breastfeed,
- have an autoimmune health condition such as thyroiditis, psoriasis and rheumatoid arthritis,
- have had the flu (diagnosed by a physician) within the past 6 months,
- have a history of Guillain- Barré syndrome (GBS) (see below),
- plan to travel outside the U.S. within 3 months after receiving your study vaccination,
- have received another experimental agent 30 days prior to this study or plan to receive an experimental agent during the 12 month study period,
- plan to donate blood within 4 months after receiving your study vaccination,
- have received or plan to receive an inactivated vaccine within 14 days before or after your study vaccination,
- have received or plan to receive a live vaccine within 30 days before or after your study vaccination,
- have received a 2018-2019 seasonal flu vaccine within 6 months before your study vaccination,
- plan to receive a 2019-2020 seasonal flu vaccine within 90 days after receiving your study vaccination.

There may be other reasons why you cannot participate in this study, which the research nurse or doctor will discuss with you.

After the screening visit, if you are eligible to participate in the study, you will be scheduled for your study vaccination visit.

**Study Visit 1 (Day 1)**

Before you are given the study vaccination, the following will take place:

- You will be asked if there have been any changes in your health and medications.
- Your temperature, pulse and blood pressure will be taken.
- If you are a woman able to become pregnant, a urine sample will be collected to test for pregnancy.
- You will have blood taken for study and lab tests.

You will be randomly assigned to receive one of the six study treatments (see table below). This means that whichever study treatment you receive will be determined purely by chance, like flipping a coin. You will have an equal chance to be randomized to each of the study treatments. Neither you nor the research team will know which study treatment you receive, but we will be able to get this information quickly if we need it to ensure your safety.

| Study Group | Study Vaccine at Visit 1, Day 1 | Adjuvant | Seasonal Vaccine at Visit 6, Day 90 |
|---|---|---|---|
| 1 | Fluzone 2018-2019 QIV | None | Fluzone 2019-2020 |
| 2 | Fluzone 2018-2019 QIV | AF03 | Fluzone 2019-2020 |
| 3 | Fluzone 2018-2019 QIV | Advax-CpG55.2 | Fluzone 2019-2020 |
| 4 | Flublok 2018-2019 QIV | None | Flublok 2019-2020 |
| 5 | Flublok 2018-2019 QIV | AF03 | Flublok 2019-2020 |
| 6 | Flublok 2018-2019 QIV | Advax-CpG55.2 | Flublok 2019-2020 |

- You will be given the study vaccine as an intra-muscular injection in the upper arm or deltoid area.
- After the vaccination, you must remain in the clinic for at least 20 minutes.
- The study staff will give you the following:
  - ✓ A memory aid with instructions for you to record any symptoms you may have on a daily basis, starting the day of vaccination and for the next 7 days.
  - ✓ A thermometer to take your daily temperature and a ruler to measure any swelling/redness at the injection site.

**Study Visits 2 (Day 2), Visit 3 (Day 8), Visit 4 (Day 29)**

- You will be asked if there have been any changes in your health and medications including if you have received a non-study flu vaccine.
- Your memory aid will be reviewed and your injection site will be examined (Visits 2 & 3)
- We will collect blood for study and/or safety tests.

**Study Visit 5 (Day 57)**

- You will be asked if there have been any serious changes in your health.
- You will be asked if you have received a non-study flu vaccine.
- We will collect blood for study tests.

**Study Visit 6 (Day 90)**

- You will be asked if there have been any serious changes in your health.
- You will be asked if you have received a non-study flu vaccine.
- We will collect blood for study tests.
- We will give you the 2019-2020 Fluzone or Flublok QIV as an intra-muscular injection in your upper arm.
  - ✓ You will receive Fluzone QIV if you received the Fluzone study vaccine at Visit 1.
  - ✓ You will receive Flublok QIV if you received the Flublok study vaccine at Visit 1.
- After the vaccination, you must remain in the clinic for at least 20 minutes.

**Study Visits 7 (Day 118), 8 (Day 180) and 9 (Day 365)**

- You will be asked if there have been any serious changes in your health.
- You will be asked if you have received a non-study flu vaccine.
- We will collect blood for study tests.

**Early Termination Visit**

If you decide to leave the study early, we will ask you to complete a final study visit. At this visit, the following will be done:

- You will be asked about your current health and any changes in your medications or if you have received a non-study flu vaccine.
- You may have a brief physical examination based on your current health.
- We may collect blood for study or safety tests.

**Unscheduled Study Visits**

Unscheduled visits may occur for further evaluations. At these visits, the following may be done:

- You will be asked about your current health and any changes in your medications or if you have received a non-study flu vaccine.
- You may have a brief physical examination based on your health.
- You may have your vital signs taken - temperature, pulse, and blood pressure.
- We may collect blood for safety or study tests.

**Blood Storage for Future Use**

As part of this study, we are obtaining blood samples from you. We would like to study your blood in the future, after this study is over. We may not need to use all of the blood we collect for the study tests so some residual blood may be left over. The residual blood samples will be stored indefinitely at a site determined by the study sponsor, National Institute of Health (NIH). In addition to the blood samples for the study tests, extra blood will be taken specifically for future research and will be stored indefinitely at a site determined by the NIH. Each residual and future research blood sample will be labeled only with a barcode and a unique tracking number to protect your confidentiality. Personnel at the storage facility and testing lab will not know your identity, or the volunteer ID code assigned to you for the study.

The tests we might want to use to study your blood may not even exist at this time. Stored residual and future research blood samples will be used only for research purposes. The samples will not be sold or used directly for production of any commercial product. No human genetic (DNA) tests will be done on these samples. There are no benefits to you in the collection, storage and future use of your blood samples. The results of any future testing will be kept confidential in the same way as the results of other testing done for this study. Please feel free to ask the study staff any questions you may have about how your blood samples may be used.

**Please initial the statement below indicating your understanding what will happen to your residual and future research blood samples:**

_____ I understand that if I take part in this study, my residual and future research blood samples will be stored for an indefinite period and may be used for future research.

**Future Studies**

We may want to contact you in the future to ask if you would like to participate in another research study. If you agree, we would like to keep your name, address, phone number and e-mail address in our vaccine research registry. This information will be kept confidential and will not be shared with anyone outside of the research team. Agreeing to be in this study does not obligate you to participate in any of our future studies and a separate consent document would be signed for future studies. Your decision to participate in future studies will not affect your participation in this study.

Please **initial** your decision about permission for us to contact you in the future for upcoming studies:

_____ **YES**, you may contact me in the future by telephone, email or mail to inform me of upcoming studies.

_____ **NO**, you may not contact me in the future regarding upcoming studies.

**Study Results**
When the study results are available, after the study is completed (generally several months after your last visit), we will provide you with a summary, and a summary will appear on http://www.ClinicalTrials.gov. In addition, you may choose to learn your treatment assignment. Learning about study results can cause people to become upset, especially if the results are different from what you expected. If you have any questions or concerns about your results, please contact the Principal Investigator, Patricia Winokur, MD at XXX-XXXX.

Please **initial** your decision about whether you wish to receive your treatment assignment for this study:

_____ **YES**, I would like to receive my treatment assignment.

**Preferred method of contact: Email Letter Telephone I will contact you**

_____ **NO**, I would not like to receive my treatment assignment.

## WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The potential risks of participating in this trial are those related with having blood drawn, receiving an intramuscular (IM) injection, and possible reactions to Fluzone or Flublok QIV, with or without AF03 or Advax-CpG55.2 adjuvant, and breach of confidentiality.

**Risks related to Fluzone and Flublok Vaccines**
The 2018-2019 and 2019-2020 QIV vaccine formulations used in this study are licensed and approved by the FDA.

Sometimes after receiving an inactivated flu vaccine people may have flu like symptoms such as fever, tiredness, headache, nausea, muscle pain, joint pain and body aches. Also, there may be reactions at the injection site such as redness, tenderness, swelling, itching or bruising. Most of these reactions are in the first day of receiving the vaccination and disappear without treatment within 1 or 2 days. Taking ibuprofen or acetaminophen and resting may relieve these side effects.

During the clinical development of Flublok, a subject fainted within 20 minutes of receiving the vaccine. This was thought to be related to the injection process rather than the vaccine. Another subject had a pericardial effusion which is excess fluid between the heart and sac surrounding the heart.

The following are other reactions that may occur, but these are rare:
- inflammation of a nerve or nervous system
- convulsions (seizure)
- severe allergic reactions

- fainting
- inflammation of the brain
- low platelet count
- inflammation of blood vessels
- Guillain-Barré syndrome
- autoimmune disorders

A small number of people (approx. 1 in 4 million) have immediate and serious allergic reactions to licensed vaccines called anaphylaxis. These reactions can include:

- skin rash (hives)
- swelling around the mouth, throat, and eyes
- having a hard time breathing
- fast heart rate
- fainting due to decrease in blood pressure

If these reactions occur, they can usually be stopped by the administration of emergency medications by the study staff. Most people who experience anaphylaxis recover completely. The research physician does not expect death to occur, but it does happen in extremely rare cases.

During the swine flu (H1N1) vaccine campaign of 1976, about 1 out of 100,000 people who received the swine flu shot got a serious illness called Guillain-Barré syndrome (GBS). GBS is a rare nerve disease that can range from a very mild case with brief weakness to a severe case which could leave you paralyzed. Fortunately, most people recover completely, but some people can be paralyzed for a long time. Since then, this illness has not been seen regularly with other influenza vaccines. Overall, vaccination rates have increased in the last 10 years, but the numbers of reported cases of vaccine-associated GBS have declined.

Adjuvants:
The study vaccine you receive may contain adjuvants. Rarely, people who have received vaccines with adjuvant have developed illnesses, sometimes serious, called autoimmune disease, where their immune system harms their own body. These illnesses have also developed in people who have not received these vaccines. We do not know if the study vaccines can actually cause autoimmune diseases. The makers of the study vaccines continue to follow this question closely.

**Risks related to AF03 Adjuvant**
The AF03 adjuvant is investigational. There may be risks and side effects we do not know about right now.

Over 1500 people have been in clinical trials in Europe and the U.S. evaluating inactivated, H5N1 or H1N1 flu vaccine with AF03. The data shows when people are given flu vaccines with the AF03 adjuvant, they have redness, swelling and pain at the vaccination site that occurs more often and more severely. Headaches and an overall unwell feeling were also reported. The reactions may last a little longer, but will go away with time.

**Risks related to Advax-CpG55.2 Adjuvant**
The combination adjuvant, Advax-CpG55.2 is investigational. There may be risks and side effects we

do not know about right now. The clinical experience with Advax (alone) is limited. CpG55.2 has never been tested in humans. The combination of the two adjuvants has also not been tested in humans. Trials with an adjuvant similar to CpG55.2 have shown similar reactions to those seen in subjects who received flu vaccines without adjuvants. Flu like symptoms such as fever, tiredness, headache, nausea, muscle pain, joint pain and body aches have been reported. There may be more reactions at the injection site such as redness, tenderness, swelling or bruising with an adjuvanted flu vaccine. Most of these reactions take place in the first day of receiving the vaccination and disappear without treatment within 1 or 2 days. Taking ibuprofen or acetaminophen and resting may relieve these side effects.

**For women participating in the study**

If you are a woman who is capable of becoming pregnant, we will ask you to take a pregnancy test before beginning this study and/or within 24 hours prior to the first study vaccination. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your fetus, or risks to your fetus that we did not anticipate, associated with being in the study. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child.

You should not be in this study if you are capable of becoming pregnant; you have sex with men and cannot use an acceptable form of birth control from 30 days before the study vaccination (Visit 1) until at least 60 days after you receive the study vaccination. Acceptable birth control methods include non-male sexual relationships, full abstinence from sexual intercourse with a male partner, monogamous relationship with vasectomized partner who has been vasectomized for 180 days or more and shown to be azoospermic prior to you receiving the study vaccination, barrier methods such as condoms or diaphragms/cervical cap **with** spermicide, effective intrauterine devices, NuvaRing®, tubal ligation, and licensed hormonal methods such as implants, injectables or oral contraceptives ("the pill").

If you become pregnant during this study, please contact Deb Pfab at XXX-XXXX as soon as possible.

**Risks related to blood draws**

Having your blood taken from your arm can cause temporary discomfort, bruising and fainting with a rare risk of infection.

**Risks with confidentiality**

Subjects will be asked to provide personal health information (PHI). All attempts will be made to keep this PHI confidential within the limits of the law. However, there is a chance that unauthorized persons will see the subject's PHI. All study records will be kept in a locked file cabinet or maintained in a locked room at the VTEU area. Electronic files will be password-protected. Only people who are involved in the conduct, oversight, monitoring, or auditing of this trial will be allowed access to the PHI that is collected. Any publications from this trial will not use information that will identify subjects by name. Organizations that may inspect and/or copy research records maintained at the VTEU site for quality assurance and data analysis include groups such as the IRB, NIH and the FDA.

## WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study. You will be receiving a seasonal flu vaccine

in this study at Study Visit 1; however the timing of the study is designed to happen at time when influenza virus is unlikely to be circulating. All participants will receive a dose of 2019-2020 QIV at Study Visit 6 which may provide protection from the flu in the fall/winter season of 2019-2020.

There may be benefits to society through the improvement of our understanding of these two adjuvants and how they affect the immune response to seasonal influenza vaccine.

## WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study. You/your health insurance company will remain responsible for your regular medical care expenses that are not part of this study.

## WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

Total amount of compensation will be $XXX, if all study visits are completed. Compensation is outlined below:

- 1 screening visit - $XX
- 2 vaccination visits - $XX each
- 7 clinic study visits - $XX each
- Unscheduled study visit - $XX
- Parking passes will be provided to cover all parking expenses at each study visit

## WHO IS FUNDING THIS STUDY?

National Institute of Health (NIH) is funding this research study. This means that the University of Iowa is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

## WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.

- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.
- NIH or the Federal Government has no plans to provide long-term medical care or financial compensation for research related injuries.

## WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- the U.S. Food and Drug Administration,
- NIH,
- ICON (study monitoring group),
- auditing departments of the University of Iowa, and
- The University of Iowa Institutional Review Board (a committee that reviews and approves research studies).

To help protect your confidentiality, we will use ID numbers on research data. The data will be stored in locked offices when not in use. Only research team members who are involved in the conduct, oversight or auditing of this study will have access to the research data. Electronic data will be stored in password protected computers and websites. For this study, each blood sample will be labeled with a barcode and a unique tracking number to protect your confidentiality. Personnel at the central storage and testing lab will not know your identity or the volunteer ID assigned to you for the study. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

To help us protect your privacy, we have received a Certificate of Confidentiality from NIH. The certificate says that the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this certificate cannot be disclosed to anyone else who is not connected with the research unless:

- There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings).
- You have consented to the disclosure, including for your medical treatment.
- The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

As noted above, disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the FDA.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The University of Iowa Hospitals and Clinics generally requires that we document in your medical record chart that you are participating in this study. The information included in the chart will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

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

## WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, the National Institute of Health, Technical Resources International (TRI) (pharmacovigilance group), ICON, and the Emmes Corporation (data coordinating center).

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Patricia Winokur, University of Iowa, Department of Medicine, Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

## IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

### What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to permit the study staff to contact you to follow up on any reactions you may have had and to collect blood samples, if possible.

### Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

### Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers [or the study sponsor] might decide to end your participation in this research study earlier than planned. This might happen because you are not following study-related directions or a serious reaction occurs or because the entire study has been stopped.

## WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Deb Pfab at XXX-XXXX.** If you experience a research-related injury, please contact: Pat Winokur, MD at XXX-XXXX. If it is an emergency during the evening, night or weekend or holiday you call XXX-XXXX and tell the hospital operator you are a research subject of Dr. Winokur in Infectious Diseases.

If you have questions, concerns, or complaints about your rights as a research subject or about a research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____ _____
(Signature of Subject) (Date)

**Statement of Person Who Obtained Consent**

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)