Official Title: Safety of Simultaneous versus Sequential Administration of mRNA COVID-19 Vaccine and Inactivated Influenza Vaccine (IIV) in Pregnant Women

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Duke University Health System

Consent to Participate in a Research Study
ADULT
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KEY INFORMATION SUMMARY

This is a research study to test the safety of receiving licensed, approved mRNA COVID-19 and influenza (flu) vaccines on the same day or one to two weeks apart in pregnant women 18 years or older. Pregnant women who plan to receive a COVID-19 vaccine and a flu vaccine during their current pregnancy will be offered participation. Participation in research studies is voluntary.

If you agree to be in this study, you will be assigned randomly (like flipping a coin) to one of two groups. Participants in Group 1 will be assigned to receive the flu vaccine on the same day they receive an mRNA COVID-19 vaccine. Participants in Group 2 will be assigned to receive the flu vaccine one to two weeks following receipt of the mRNA COVID-19 vaccine. You will answer questions about your health, vaccination history and symptoms following vaccination. You will come to the study clinic for up to 5 visits, have up to 3 phone visits, and have blood drawn up to 4 times. Participation is complete approximately 90 days after you have delivered your baby, and the study team has reviewed both you and your baby's medical charts. You will be asked to sign a medical release form for you and your baby during the study.

There are risks associated with the recommended flu and mRNA COVID-19 vaccines that are described in this document. Some risks could include pain, tenderness and swelling under the arm in the same arm as the injection/s, swelling at injection site, redness at the injection site/s, fatigue, headache, muscle pain, joint pain, chills, nausea, fever, cough or hoarseness, itching, and eyes that are sore, red, or itchy. There are also risks associated with having blood drawn.

If you are interested in learning more about this study, please continue reading below.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important

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information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

[redacted] will conduct the study. The study is funded by a contract from the Centers for Disease Control and Prevention (CDC). Portions of [redacted] and their research team's salaries will be paid by this contract.

Who will be my doctor on this study?
If you decide to participate, [redacted] will be your doctor for the study. They may be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

Why is this study being done?
Vaccines work by causing the body to make proteins called antibodies that fight infection. Vaccination is the most effective way to prevent infections such as influenza (flu) and COVID-19. Both vaccines are recommended by CDC, the Advisory Committee on Immunization Practices (ACIP) and the American College of OB/GYN during pregnancy to prevent severe flu and COVID-19 disease in mother and infant. It is acceptable for these vaccines to be administered at the same time to provide protection against both the flu and COVID-19. Administration together could potentially reduce the number of medical visits needed during pregnancy.

The purpose of this study is to learn more about the safety of administering a flu vaccine and an mRNA COVID-19 vaccine on the same day or 7-14 days apart in pregnant women 18 years or older. Our plan is to administer a COVID-19 vaccine to all participants at visit 1. About half of the participants will also receive a flu vaccine generally in the opposite arm at Visit 1. Those participants who do not receive a flu vaccine the first day will receive the flu vaccine at Visit 2, 7-14 days after Visit 1. The study team will monitor you for adverse events (symptoms and health events) throughout the study.

Up to 68 people will take part in this study at Duke and about 350 people will take part in total from all the participating sites.

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What is involved in the study?
If you agree to be in this study, you will be asked to sign and date this consent form. If you do not sign this consent form, you will continue to receive care, but not as part of this study. Refusal to participate will involve no penalty or loss of benefits.

Visit 1 Study Day 1 (Clinic Visit): Study staff will review this consent form with you as well as the study eligibility criteria to make sure you qualify. If you qualify and agree to participate in this study, you will have the following tests and procedures after you sign the consent form:

- Study staff will ask questions about your health, current medications, demographics, your flu and COVID-19 vaccination history, and any other vaccines you have received during this pregnancy.
- Study staff will take your temperature.
- A blood sample of 10 mL (approximately 2 teaspoons) will be taken to test for flu and COVID-19 antibodies. These samples may also be used for future, yet unknown, testing.
- You will be randomly (like flipping a coin) assigned to receive a flu vaccine at Visit 1 or Visit 2.
- You will receive an mRNA COVID-19 vaccine.
- You will receive a flu vaccine if you are assigned to receive both vaccinations at Visit 1.
- You will receive Vaccine Information Sheet/s (VIS) for the vaccines you receive during the study visit which will give you additional information about the vaccine/s.
- A study staff member will send you an electronic memory aid through email or text, give you 1-2 paper memory aids, thermometer, and ruler, and go over instructions for how to use these items.
- You will be monitored for 15 minutes after getting the vaccine(s) and assessed for any immediate symptoms.

Visit 1a, Study Days 1-Day 7 after Visit 1: You will complete an online or paper memory aid each day at around the same time. You will receive either electronic and/or telephone reminders for completing the memory aid. Study staff may reach out to you to collect symptoms or health events you experienced.

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If you select text messages as your preferred method of contact for the memory aid surveys, we will send you automated text messages throughout this study. To do this we use a web-based system, called Twilio, which uses your phone number to send you messages. We plan to use this feature to send text messages reminding you to complete the Visit 1 and 2 memory aids. As long as you agree and are a member of the study, we will contact you this way approximately 28 times during the study. If you change your mind about the messages or if your contact phone number changes, please contact the study team. These messages are one-way only, so you cannot reply. If you have questions or concerns about information in a message contact your study team. If you would like to stop receiving text messages, please call [redacted]

Visit 2 Study Day 8-15 (Clinic/Phone Visit): You will come into the clinic or have a visit by phone on day 8-15 depending on your group. If you are in Group 1 that received both the COVID-19 and flu vaccines at Visit 1, this visit can be done by phone. At this visit the following tests and procedures will occur:

- Study staff will ask you questions designed to make sure that the people getting flu vaccine at this visit are still able to receive it.
- Study staff will record any symptoms or health events within the first 7 days post-vaccination.
- You will be asked to update the list of current medications you are taking.
- You will be asked if you have received any vaccines outside of the study since your last study visit.
- Study staff will obtain your oral temperature or ask you to take and report your oral temperature.
- You will receive flu vaccine if you did not receive a flu vaccine at Visit 1, and you will be given a VIS and other appropriate information sheets.
- A study staff member will send you an electronic memory aid through email/text, give you a paper memory aid, thermometer (if needed), and ruler (if needed), and go over instructions for how to use these items.
- If you received a flu vaccine at this visit you will be monitored for 15 minutes and assessed for immediate symptoms.

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Visit 2a, Study Days 1-Day 7 after Visit 2: You will complete an online or paper memory aid each day at around the same time. You will receive either electronic and/or telephone reminders for completing the memory aid. Study staff may reach out to you to collect symptoms or health events you experienced.

Visit 3 Study Day 29 (Clinic Visit): You will come into the clinic on day 29 and the following tests and procedures will occur:

- Study staff will record any symptoms or health events you experienced within the first 7 days after visit 2.
- You will be asked to update the list of current medications you are taking.
- You will be asked if you have received any vaccines outside of the study since your last study visit.
- 10 mL (approximately 2 teaspoons) of blood will be drawn.

Visit 4 Study Day 36-43 (Clinic/Phone Visit): You will come into the clinic or have a phone visit on day 36 through 43 depending on your group. If you are in Group 1 that received both the COVID-19 and flu vaccines at Visit 1, this visit can be done by phone. The following tests and procedures will occur:

- Study staff will record any health events.
- You will be asked to update the list of current medications you are taking.
- You will be asked if you have received any vaccines outside of the study since your last study visit.
- 10 mL (2 teaspoons) of blood will be drawn if you are in Group 2 that received the COVID-19 and flu vaccines at two separate visits.

Visit 5 (Hospital Admission for Delivery): During your admission for the birth of your baby the following tests and procedures will occur:

- Study staff will record any health events.
- You will be asked to update the list of current medications you are taking.
- You will be asked if you have received any vaccines outside of the study since your last study visit.
- 10 mL (approximately 2 teaspoons) of blood will be drawn if feasible.

The study team will work with your care providers to have this drawn when you are having other blood drawn for part of your care (for example when

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an IV is placed). If this is not possible, a member of the study team may draw your blood for the study before you go home from the hospital.

- After the birth of your baby, the study team or your care providers will collect 5 mL (approximately 1 teaspoon) of umbilical cord blood (the blood that remains in the placenta after delivery), if feasible. This blood sample will be collected after the umbilical cord is cut so that there is no risk for the baby. This will not affect your ability to donate the remaining umbilical cord blood if you so wish.

Visit 6 90 Days following Visit 5 (Phone Visit/Chart Abstraction): Study staff will review your and your baby's medical records until your baby is 90 days old in order to complete research questions. If you do not deliver at Duke, study staff will ask you to sign a medical record release form, if not already done, for yourself and your baby and obtain these records from the health care providers where you delivered your baby. Study staff will review medical records to see if you develop any new or worsening medical problems. Study staff will also contact you over the phone and you will be asked about the following items:

- Adverse events (health events) for you or you baby.
- Current medications you are taking.
- Any vaccines you have received outside of the study since your last study visit.

You may be asked to return for an Unscheduled Visit, should you have an adverse reaction (health events) from the vaccine(s) and you need to be assessed by the study team.

Unscheduled Visits (Clinic Visit): You will come to the clinic if this visit is needed. The following tests and procedures will occur:

- Study staff will record any health events.
- You will be asked to update the list of current medications you are taking.
- You will be asked if you have received any vaccines outside of the study since your last study visit.
- Study staff will obtain your oral temperature.

Will I be given research results that may affect my medical care?

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Clinically relevant results of this research will be communicated with you. If the research with your information gives results that do have meaning for your health, the researchers will contact you and ask you if you would like to know what they have found.

How long will I be in this study?
You will be in this study for up to 12 months, depending on how far along you are in your pregnancy when you enroll and when you deliver. You can stop participating at any time without penalty. If you decide to stop participating in the study, we encourage you to talk to your doctor first.

What are the risks of the study?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Risks of Drawing Blood
The risks of drawing blood include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Risks Related to Vaccination
With every medicine, including approved vaccines, there is a chance of side effects. There may also be risks, discomforts, drug interactions or side effects from these vaccines that are not yet known. Vaccines may cause some, all or none of the side effects listed below.

Risks Related to mRNA COVID-19 Vaccination
More likely:

- pain, tenderness and swelling under the arm in the same arm of the injection
- pain, swelling (hardness) and redness at the injection site
- arm pain
- fatigue, headache, muscle pain and joint pain
- chills, nausea and vomiting
- diarrhea
- fever and feeling unwell

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Less likely:

- syncope (fainting) can occur in association with administration of injectable vaccines. If you feel dizzy or have vision changes or ringing in the ears, you should inform your doctor.
- severe pain in the shoulder and difficulty moving arm.
- Rarely, there can be a serious allergic reaction to any vaccine. These reactions can cause skin rash (hives), difficulty breathing, swelling around the mouth, throat, or eyes, a fast pulse, sweating, or loss of blood pressure, and would happen within a few minutes to a few hours after the vaccination. Medicines are immediately available to treat such an allergic reaction should you have one. A less serious allergic reaction can also occur after vaccination.
- a rare chance that an mRNA COVID-19 vaccine could cause inflammation (swelling) of the heart muscle (also known as myocarditis) or inflammation of the lining outside the heart (also known as pericarditis). These mainly occur in adolescents and young adults and usually happens within a few days after the second dose of mRNA COVID-19 vaccine. Signs include chest pain, shortness of breath, feelings of having a fast-beating, fluttering, or pounding heart. These may not be all the possible side effects of the mRNA COVID-19 vaccines. Serious and unexpected side effects may also occur.

Risks Related to Flu Vaccination

More likely:

- redness, swelling, or pain where the vaccine was given
- fever, body aches, headache, fatigue, itching
- nausea
- cough or hoarseness
- sore, red or itchy eyes

Less likely:

- syncope (fainting) can occur in association with administration of injectable vaccines. If you feel dizzy or have vision changes or ringing in the ears, you should inform your doctor.
- a small increased risk of Guillain-Barré syndrome (GBS). GBS is a rare but serious condition that can occur after certain infections or after receiving certain vaccines such as the flu vaccine.
- severe pain in the shoulder and difficulty moving arm.

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- Rarely, there can be a serious allergic reaction to any vaccine. These reactions can cause skin rash (hives), difficulty breathing, swelling around the mouth, throat, or eyes, a fast pulse, sweating, or loss of blood pressure, and would happen within a few minutes to a few hours after the vaccination. Medicines are immediately available to treat such an allergic reaction should you have one. A less serious allergic reaction can also occur after vaccination.

Risks of Delaying Flu Vaccination
There is a potential risk of a short delay in protection against the flu by delaying the flu vaccine by one to two weeks. If you develop flu like symptoms, you should consult with your health care provider. Your health care provider may order tests to see if you have the flu. If it is determined that you likely have the flu, your health care provider may prescribe medication to treat it.

Risks of Allowing Twilio to be Used for Text Message Reminders:
Many companies and applications on your smartphone commonly work with text platforms and cloud-based companies to send and receive information securely. We use Twilio to send you text messages. Text messaging does not provide a completely secure and confidential means of communication, and the messages are unencrypted. Twilio does encrypt your information on their servers, but no system can guarantee complete privacy. If they decide to share these data, it may no longer be covered under the privacy protections. Information that identifies you, such as your phone number, may be sent to and permanently kept by Twilio and their business associates. Information disclosed to these companies or their business partners may no longer be covered under the privacy protections. Because text messaging does not provide a completely secure and confidential means of communication, if you wish to keep your communication completely private, please let us know and we will communicate with you only through regular channels like the telephone or email. If you would like to stop receiving text messages, please call 919-613-9630.

Risks of Loss of Privacy:
There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take

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a break at any time during the study. You may stop your participation in this study at any time.

Unforeseeable Risks:
There may be risks, discomforts, drug interactions or side effects that are not yet known.

Are there benefits to taking part in the study?
The benefits are expected to be the same as they would be if you were receiving flu and COVID-19 vaccine as part of your usual prenatal care. The flu and COVID-19 vaccines have been shown to prevent flu and COVID-19 disease, respectively. As with any licensed vaccine, protection may not occur in 100% of vaccinated persons. However, most people develop protective antibodies against the flu and COVID-19. If you agree to take part in this study, there may be direct medical benefit to you but this cannot be guaranteed. Study participation will assure that you receive the recommended flu and COVID-19 vaccinations. Information learned from this study may also help researchers understand if it is as safe to administer the flu and mRNA COVID-19 vaccines on the same day compared with administering the vaccines on separate days in pregnant women .

What other choices are there to being in this study?
Both the flu vaccine and mRNA COVID-19 vaccines are available outside of this study. Please talk to your doctor about these and perhaps other options.

Will my information be kept confidential?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, and procedures may be reported to the CDC and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

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- representatives from the Food and Drug Administration,
- representatives and affiliates of the CDC,
- the Duke University Health System Institutional Review Board and others as appropriate.

If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you may be asked to have certain tests and/or procedures performed. Some of these tests and/or procedures may be done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. Your information may be shared with: CDC, FDA, DUHS IRB, and others who may need to review study results.

Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information

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you have shared. Other laws may or may not protect sharing of private health information.

The Centers for Disease Control and Prevention (CDC) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Will it cost me anything to be in the study?
There are no additional costs to you associated with this study. However, you or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. If your phone data plan includes charges for text messaging that you do not want to pay, discuss this with study staff.

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The study sponsor, CDC, has agreed to pay for study activities and procedures that are done only because you are in this study. Please talk with your study doctor/study team about the specific procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that they can help find a resolution.

Duke will use funding from CDC to provide the vaccines free of charge to you. If you decide to stop being in the study before it ends, your study doctor may request that you return for a checkup. They may ask you to complete the tests that would ordinarily occur when a person completes the study.

Will I be paid to be in the study?
You will receive up to [redacted] for your expenses related to your participation (parking, gas, and time). You will receive [redacted] per clinic visit, [redacted] per phone visit and [redacted] per memory aid. You will only be paid for the visits or memory aids you complete. In order to issue your payment, Duke may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

What about research related injuries?
Immediate necessary medical care is available at Duke in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact [redacted] at [redacted] during regular business hours and at [redacted] after hours and on weekends and holidays.

What if I want to withdraw from the study?
If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study

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purposes unless the data concern an adverse event (health event) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the CDC.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke including receiving the flu or COVID-19 vaccine. If you do decide to withdraw, we ask that you contact [redacted] in writing and let her know that you are withdrawing from the study. Her mailing address is [redacted]

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. Reasons why this might occur include that you are unable to return for follow-up blood draw visits, if not enough blood is able to be collected, or if you develop a new health condition that arises that prevents future participation. If you withdraw (or are withdrawn) from this study, the data and blood samples collected before the date of withdrawal may still be used and shared with other researchers and CDC. The sponsor or regulatory agencies may stop this study at any time. If this occurs, you will be notified and your study doctor will discuss other options with you.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

A description of this clinical trial will be available on https://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. You can search this web site at any time.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

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Specimen/Data Storage for Future Use

If you choose to be in this study, data collected from you that can be used for future research will be stored long-term in a repository following the completion of the study. Any personal information that could identify you will be removed or changed before files are stored in this repository for use by other researchers not associated with this study or results are made public. The removal of this information allows your data to be used without anyone knowing which person in the study it comes from.

Researchers will only be allowed to use your data and specimens if their research is approved by the lead study investigator and if they receive approval from an institutional review board. By agreeing to participate in this study, your samples will be stored for potential future use. If you do not want your samples or data to be used in future research, you should not sign this consent form.

By signing this consent form, you are agreeing to allow your data and blood samples to be kept for future research with identifying information that could link your sample to you. You are free to change your mind at any time. We ask that you contact [redacted] in writing and let her know you are withdrawing your permission for your identifiable samples to be used for future research. Her address is [redacted] At that time, we will ask you to indicate in writing if you want the unused identifiable samples destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

Your samples and data may be stored and shared for additional unspecified future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

No human genetic tests will be performed on your samples.

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Whom should I call if I have questions or problems?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact [redacted] at [redacted] during regular business hours and at [redacted] after hours and on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at [redacted] if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Participant	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time