

**STUDY TITLE:** A TriAal of the Safety and Immunogenicity of the COVID-19 Vaccine (mRNA-1273) in Participants with Hematologic Malignancies and Various Regimens of Immunosuppression, and in Participants with Solid Tumors on PD1/PDL1 Inhibitor Therapy

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Cohort: Affected participants  
Consent Version: April 16, 2021

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**WHO DO YOU CONTACT ABOUT THIS STUDY?**

*[Include the site PI and study coordinator's names, numbers and email addresses]*

**KEY INFORMATION ABOUT THIS RESEARCH**

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at [insert site]. This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at [insert site]. is your choice.

You are being asked to take part in this study because you have solid tumor or blood cancer and your doctor feels as though you may be able to help in a study looking at a possible COVID-19 vaccine.

The purpose of this study is to test safety and efficacy of an experimental study vaccine using mRNA-1273 that may protect cancer patients from a viral infection called the coronavirus disease (also called, "COVID-19").

The mRNA-1273 study vaccine is intended to boost the immune system to produce enough antibodies against coronavirus; so, in case of an exposure, the virus does not cause illness.

The use of mRNA-1273 study vaccine in this study is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat COVID-19 in participants having solid tumor or blood cancer. However, the FDA has given us permission to use mRNA-1273 vaccine in this study.

If you had an allergic reaction after being vaccinated in the past or if you are allergic to any product(s), then you must tell the study doctor or study staff before you decide to sign and date this informed consent form. Some symptoms of allergic reactions are rash; wheezing and difficulty breathing; dizziness and fainting; swelling around the mouth, throat, or eyes; a fast pulse; or sweating. If you have an allergy to some products, then you may not be able to take part in this study.

If you decide to join this study, here are some of the most important things that you should know that will happen:

You will receive an injection of the mRNA-1273 vaccine into a muscle in your arm on Days 1 and 29 and will be followed through 12 months after the second vaccination. The second dose of vaccine will be administered preferably in the same arm used for the first dose.

After you enroll in the study, in-person clinical visits will occur on Day 1, 29, 36, 57 209, and 394. These visits will take about 4-6 hours.

Follow-up phone calls will occur at about day 8 after the first vaccination.

The total length of your participation in this study is about 13-14 months.

For women able to become pregnant, pregnancy tests will be done at screening and before each vaccine dose. If you are found to be pregnant prior to the first dose, you will not be able to participate in this study. If you become pregnant after the first dose, you will be removed from the study.

You may experience side effects from taking part in this study. Some can be mild or very serious, temporary, long-lasting, or permanent, and may include death. Examples of some of the side effects that you may have include fever, headache, muscle pain, fatigue, chills, underarm gland swelling on the side of the vaccination, shivering and nausea.

You will be seen regularly during the study. You will have clinical and laboratory tests to see how you are doing and to assess your disease. We will also collect required samples from you (such as: blood and saliva) for both clinical and research purposes.

Just as we do not know what side effects you might have, we cannot know if you may benefit from taking part in this study. If you do not benefit, this study and the results from our research will help others in the future.

You are free to stop participating in the trial at any time. If you decide to stop, the study doctor may ask you to agree to certain tests to make sure it is safe for you to stop.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with [insert site], staff, and with your family, friends, and personal health care providers.

## **IT IS YOUR CHOICE TO TAKE PART IN THE STUDY**

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

## **WHY IS THIS STUDY BEING DONE?**

This is a research study. The purpose of this research study is test safety and efficacy of an experimental study vaccine that may protect people from a viral infection called the coronavirus disease (also called, “COVID-19”).

We are asking you to join this research study because you have solid tumor or blood cancer and this vaccine might serve to prepare your immune system for fighting and preventing infection from COVID-19.

Certain cells of the immune system produce antibodies (special proteins) that recognize viruses and other pathogens (things that cause disease) and make them harmless. The mRNA-1273 study vaccine is intended to boost the immune system to produce enough antibodies against SARS-CoV-2; so, in case of an infection, the virus does not cause illness.

The mRNA-1273 study vaccine is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat COVID-19. The FDA has allowed the mRNA-1273 vaccine to be used under its emergency use authorization (EUA).

## **WHAT WILL HAPPEN DURING THE STUDY?**

### **Before you begin the study**

If you decide to take part in this study, you will be asked to provide information about your medical history and following assessments will be done to determine if you are eligible to participate in the study.

- Informed consent review
- Medical history review (including any medications you take)
- Physical examination (including vital signs)
- Pregnancy testing (blood or urine): If you are pregnant prior to the first dose, you will not be able to participate in this study.
- Routine blood tests (such as those to check blood counts and organ function)

### **During the study**

If you are found to be eligible to take part, we will work with you to get you scheduled to come to the clinic for the first vaccine. We will repeat following assessments if they were not performed within 1 week of first vaccine. We will tell you if there were any changes that may mean you cannot get the vaccine:

- Medical history review (including any medications you take)
- Physical examination (including vital signs)
- Pregnancy testing (blood or urine)
- Routine blood tests

The following will then occur if you are able to receive the vaccine and after you receive it:

- You will receive an injection of the mRNA-1273 vaccine into a muscle in your arm on days 1 and 29 and will be followed through 12 months post after the second vaccination. The second dose of vaccine will be administered preferably in the same arm used for the first dose.
- After you enroll in the study, In-person clinical visits will occur on Day 1, 29, 36, 57, 209 and at day 394. These visits at clinical center will take approximately about 4-6 hours.

- A follow-up phone call will occur on day 8 after the first vaccination.
- The total length of your participation in this study is approximately about 13-14 months.
- The visits where you will receive your study vaccine at clinical center will take approximately 4-6 hours.
- For women of childbearing potential serum pregnancy test will be done at Day 29 before the second dose.

### **Additional research testing**

In addition to the tests that we will conduct to determine whether you are having side effects or if you are responding to the study therapy, we will also collect samples from you for purposes of research only. The samples are being done to look at the effects of therapy on your immune system and markers of tumor activity. Unless noted otherwise below, the blood and saliva samples will be collected on days 1, 29, 36, 57, 209 and 394.

The samples included for these studies include:

- Blood (maximum 1.3 cup total including all time points)
- Saliva (at the above; maximum 1 teaspoon total including all time points)

### **Long-term follow-up visits**

You will be asked to return to the clinic approximately on day 57 (after 28 days after the second vaccination) for a safety visit. At the safety visit, we will perform a physical exam, including vital signs, draw blood for clinical and research assessments and ask you about any symptoms you have experienced and about medications you are taking.

About 6 months after your first vaccination (on day 209) you will visit the clinical center where we will draw blood for research assessments and ask you about any symptoms you have experienced and about medications you are taking.

About 12 months after the second vaccination (on day 394), you will visit clinical center where we will draw blood for research assessments and ask you about any symptoms you have experienced and about medications you are taking. This will be your end of study visit and you will be taken off study.

### **Early Termination Visit**

If you stop the study early (before the day 394 visit), you will be asked to return to the clinic for an early termination visit if it is feasible. This visit should occur as soon as possible after you decide to stop.

At this visit, the study doctor/study team will do the following:

- Perform a complete physical examination and medical history
- Record your vital signs (blood pressure, heart rate, body temperature, and breathing rate) and body weight

### **HOW LONG WILL THE STUDY TAKE?**

The total length of your participation in this study is about 13 months.

## HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have about 60 people participate in this study at [insert site]. About 120 people will take place at all sites.

## WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

The pharmaceutical collaborator and manufacturer of this vaccine, Moderna, Inc., conducted a large Phase 3 trial of the study vaccine which began in July 2020. In November 2020, the data from the trial were analyzed by Moderna and reviewed by an independent group of safety experts. It was determined that this study vaccine was approximately 94% effective at preventing COVID-19 (this also called "vaccine efficacy"). This means that for every 100 people exposed to the virus, the study vaccine should prevent about 94 of them from getting sick with COVID-19.

If you receive two doses of the mRNA-1273 study vaccine as part of the study, we believe that you may have the benefit of protection against getting sick with COVID-19. However, it is important for you to understand there are some limitations and aspects of the study vaccine that we are still trying to learn more about which are listed below:

- The study vaccine is not 100% effective and a few people who have received the study vaccine have still gotten sick with COVID-19.
- We do not know yet if people who received the study vaccine and became infected can still carry the virus and pass it to other people around them.
- If you only receive one dose of the mRNA-1273 study vaccine during the study, you might have some level of protection but likely not as much as those who received two doses. We have not fully studied how well the study vaccine works with just one dose, and we think the best protection against becoming sick with COVID-19 starts about two weeks after receiving your second dose.
- Cancer patients undergoing active treatment were not included in the Moderna-sponsored Phase 3 trial of the study vaccine. As a result, we do not know how your cancer or treatment for your cancer will affect your body's ability to protect you from COVID-19 even with the potential benefit of the vaccine. Your cancer itself or the treatment for your cancer might suppress your immune system's response to the vaccine. Lastly, we do not know for how long our study vaccine protects you from getting sick, which means your protection could wear off at any time, and we do not know when this might happen.

Therefore, even after you receive the study vaccine, we strongly encourage you to still follow all instructions from your study doctor and local guidance around limiting your exposure to the virus (for example, social distancing, mask wearing, and handwashing).

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

The lists below show the most common and the most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

### **mRNA-1273 Vaccine**

The mRNA-1273 vaccine is being studied in several ongoing studies in the United States. The first study (also called “Phase 1”) was started in March 2020, the second study was started in May 2020 (also called “Phase 2”) and as noted above, the third study (also called “Phase 3”) was started in July 2020.

Multiple dose levels of the study vaccine, including the one to be used in this study, are being evaluated in these studies. To date, over 15,000 adult subjects have received at least 2 doses of the mRNA-1273 study vaccine on the trials that have been conducted to date.

There have been no serious side effects observed or reported by subjects in these studies. The majority of side effects that are reported by subjects to date have been mild to moderate in severity. There may be possible side effects of the study vaccine that are not fully known.

If you choose to take part in this study, you are at risk for the side effects listed in this section. You should discuss these with the study staff and if you choose, with your regular doctor. You will be monitored for risks and side effects throughout your participation in the study. You should contact the study doctor if you think you are having side effects or experiencing a change in your medical condition.

If you had an allergic reaction after being vaccinated in the past or if you are allergic to any product(s), then you must tell the study doctor or study staff before you decide to sign and date this informed consent form. Some symptoms of allergic reactions are rash; wheezing and difficulty breathing; dizziness and fainting; swelling around the mouth, throat, or eyes; a fast pulse; or sweating. If you have an allergy to some products, then you may not be able to take part in this study.

Serious allergic reactions can be life- threatening.

In other studies of people receiving similar study vaccines like mRNA-1273, the most common side effects are listed below. You will be asked about these side effects during this study.

- Fever
- Pain at the injection site
- Redness and hardness of the skin at the injection site
- Headache
- Muscle aches or pain
- Joint aches or pain
- Fatigue (tiredness)
- Nausea/vomiting
- Chills
- Under arm gland swelling on the side of study vaccination

Most of these side effects occurred within the first few days after study vaccination and went away within a few days. Not everyone has had these side effects and those who experienced them did not necessarily experience them after every dose. These side effects were usually reported as mild or moderate and not severe.

Brief increases in some laboratory tests were noted in previous clinical studies with similar mRNA vaccines. These increases were observed without physical symptoms or signs, and generally returned to levels observed before study vaccination. The significance of these observations is unknown.

You may have emotional stress if you experience any of the side effects listed above or from keeping to the study visit schedule. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may stop taking part in the study at any time.

## **Other risks**

### **Are there risks if you become infected with the coronavirus after getting study vaccine?**

To date, Moderna have observed that there have been fewer cases of severe COVID-19 in participants who received the mRNA-1273 study vaccine. This continues to reassure us currently that the study vaccine does not increase your risk for severe illness. We will continue to monitor this closely and let you know if that changes.

## **Risks of study procedures**

### **Blood collection**

Side effects of blood draw include pain and bruising in the area where the needle was placed, lightheadedness, and rarely, fainting. When large amounts of blood are collected, low red blood cell count (anemia) can develop.

### **Saliva collection**

There is no risk associated with this procedure.

### **What are the risks related to pregnancy?**

If you are able to become pregnant, we will ask you to have a pregnancy test before starting this study. You will need to practice an effective form of birth control before starting study treatment, during study treatment, and for 30 days after the second vaccine dose (the restricted period). If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. You must tell the study doctor if your birth control method fails during the restricted period. If you think or know you have become pregnant during the restricted period, please contact the study team as soon as possible. If you become pregnant on study you will be removed from the study and should follow up with your home obstetrics/gynecological (OB/GYN) doctor.

If you are a sexually active person with a partner able to become pregnant, it is important that your partner not become pregnant during the restricted period. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become pregnant during the restricted period, please contact the study team as soon as possible. If you and your partner plan for your partner to become pregnant after the restricted period, please discuss this with the study team.

## **WHAT ARE THE BENEFITS OF BEING IN THE STUDY?**

You might not benefit from being in this study.

However, by taking part, you will help to provide new scientific information that will benefit participants in the future.

### **Are there any potential benefits to others that might result from the study?**

In the future, other people might benefit from this study because new scientific information that will benefit participants in the future

## **WHAT OTHER OPTIONS ARE THERE FOR YOU?**

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could choose to take part in a different study, if one is available.

## **DISCUSSION OF FINDINGS**

### **New information about the study**

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study or information we have learned from other scientists doing similar research in other places.

### **Return of research results**

You will not receive any results from research tests.

## **EARLY WITHDRAWAL FROM THE STUDY**

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease worsens or comes back during treatment you may not be well enough to receive both vaccine doses
- if you have side effects from the treatment that your doctor thinks are too severe
- if you become pregnant
- if the mRNA-1273 vaccine may become unavailable
- if new information shows that another treatment would be better for you
- if you do not follow the study rules
- if the study is stopped for any reason

In this case, you will be informed of the reason therapy is being stopped.

After therapy is stopped, we would like to see you for a safety visit 394 days after your first dose of vaccine.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines,

information collected on you up to that point may still be provided to ModernaTX, Inc. or designated representatives.

## STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

## Will your specimens or data be saved for use in other research studies?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding infection of COVID-19 in participants with solid tumor or blood cancer. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

## Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be

able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

### **How long will your specimens and data be stored by the NIH?**

Your specimens and data may be stored by the NIH indefinitely.

### **How Long Will Your Specimens and Data be Stored by the [insert site]?**

Your specimens and data may be stored by the [insert site] [describe time period, e.g., possibly indefinitely, for no longer than XX months/years].

### **Risks of storage and sharing of specimens and data**

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

### **PAYMENT**

#### **Will you receive any type of payment for taking part in this study?**

You will not receive any payment for taking part in this study.

### **REIMBURSEMENT**

#### **Will you receive reimbursement or direct payment by [insert site] as part of your participation?**

*State here whether this study offers compensation (e.g., check payments, gift cards, or other items) for participation (e.g., time and inconvenience). If compensation is offered, state the type, amount and timing.*

[Insert details here]

## COSTS

### Will taking part in this research study cost you anything?

*If appropriate, state which study agent(s), tests, or procedures are provided free of charge.*

*We recommend that investigators utilize an insurance coverage analysis of the study to ensure that billable and non-billable costs are appropriately identified. In most cases, all non-billable research costs should be covered by the study and provided free of charge to all participants.*

*Outline any other pertinent financial impact or support.*

*Make sure that you have committed funding for all costs identified as covered by the study. Make sure that all procedures listed as covered by the study align exactly with what is described in the protocol.*

[Insert details here]

## CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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. You can search this Web site at any time.

## CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

*Local sites should insert their institution's confidentiality and privacy language in this section.*

[insert text here]

### Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor Center for Cancer Research (CCR)
- Qualified representatives from ModernaTX, Inc., the pharmaceutical company who produces mRNA-1273 vaccine

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

### **Certificate of Confidentiality**

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

### **Privacy Act**

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

### **POLICY REGARDING RESEARCH-RELATED INJURIES**

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care will be provided by the NIH, the NIH Clinical Center, or the Federal Government.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing

COVID-19 countermeasures. Because this study is covered by the PREP Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program. This is a program set up by the United States Government. Information about this program can be found at <https://www.hrsa.gov/cicp/about/index.html> or by calling 1-855-266-2427.

## **PROBLEMS OR QUESTIONS**

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the site Principal Investigator, [Name], [Email address],[Telephone number]. *Other researchers you may call are: [Name], at [Telephone number].* For questions about your rights while in this study, call the (\*insert name of organization or center\*) Institutional Review Board at (\*insert telephone number\*).

## **CONSENT DOCUMENT**

Please keep a copy of this document in case you want to read it again.

*Insert the local site signature section.*