INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**ModernaTX, Inc. / "A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Dose Confirmation Study to Evaluate the Safety, Tolerability, and Immunogenicity of Zika Vaccine mRNA-1893 in Adults Aged 18 Through 65 Years and Living in Endemic and Non-Endemic Flavivirus Areas"**
Protocol Number:	**mRNA-1893-P201**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

In this document, "you" refers to the person participating in the study.

Adults aged 18 through 65 years are eligible to participate in this study. At study locations in areas where the age of majority is greater than the age of 18 or when the adult participant who has reached age of majority cannot legally consent to take part, the parent, legal guardian, or legally authorized representative of the participant will be required to sign and date this form, and the minor participant will be required to sign and date a separate form called an assent form. Should the minor participant reach the age of majority during study participation, they would then sign and date this form.

In cases of an adult who has reached the age of majority and where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant.

When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative or parent/legal guardian) who is signing and dating this form for the participant.

Advarra's Institutional Review Board (IRB) is an independent committee that reviews human participants research to help ensure the rights and welfare of research participants are protected and the research is carried out in an ethical manner.

Why are you receiving this key information?
You are being invited to take part in a clinical research study. This study is about an investigational vaccine for Zika virus (ZIKV) and is sponsored by ModernaTX, Inc.

It is important that you know:

- Your participation is your choice.
- You may or may not benefit from participating in this study. However, your participation may help others in the future as a result of knowledge gained from this study.
- You may leave the study at any time.
- If you choose not to take part, or if you leave the study, it will not harm your relationship with the study doctor or study site.

The study vaccine mRNA-1893 is still being evaluated in humans. Therefore, possible side effects of the study vaccine are not fully known. Please see the risks and discomforts section below for additional information.

This form is called an informed consent form (ICF). This ICF explains the things you will be asked to do before, during and after the study. It also explains the risks and possible benefits of the study. Please read this ICF carefully and ask any questions that might help you decide if you would like to take part in this clinical research study. If you decide that you will take part in this study, you will be asked to sign and date this ICF. A copy of this signed and dated ICF will be given to you to keep.

What is the purpose of this clinical research study?

The Zika virus (ZIKV) is passed on to humans by mosquitos or via person-to-person contact through blood, saliva and semen. Most people infected by ZIKV either have no symptoms or have a mild fever with a rash. However, some people infected with ZIKV may develop severe symptoms and in cases of ZIKV infection during pregnancy it may cause fetal damage, abortion or severe post-natal sequalae (conditions). Currently there is no vaccine to protect against ZIKV. The purpose of this study is to confirm that the investigational vaccine named mRNA-1893 is safe and able to induce an immune response (a process where your body can recognize the virus and fight the infection) that can help prevent ZIKV infection and to confirm the dosage of study vaccine that will be used in future clinical studies.

An effective vaccine will be the best protection against ZIKV infection. The mRNA-1893 study vaccine has already been evaluated in approximately 100 people in another study. Preliminary results of that study show that this study vaccine is safe and well tolerated in humans. This new study intends to evaluate safety, the ability to protect from ZIKV infection and other effects of this study vaccine in a larger number of people. This study is being conducted for research purposes only. The study vaccine used in this study does not cure any medical condition.

The mRNA-1893 study vaccine is called “investigational” because it has not been approved by the US Food and Drug Administration (FDA) or any other health/regulatory authority in the world. By participating in this study, you will help researchers to confirm the safe and effective dose of this study vaccine.

How many people will participate in this study?

A total of approximately 800 people will take part in this study at up to 15 study sites across the continental United States and Puerto Rico.

If the target number of participants have already started the study when you are about to start, you will be asked not to participate by the study site staff.

What procedures are involved?
If you decide to participate in this study, you will be asked to make a total of up to 8 visits to the study clinic. These visits will include a screening visit, a baseline visit, follow-up visits, and 3 telephone contacts, across approximately 7 months. You may also be asked to make an unscheduled visit to the study clinic if you experience any flavivirus symptoms such as rash, headache, fever, conjunctivitis (eye inflammation), joint pain, and muscle pain, or if you experience any side effects that you consider severe. The study staff will inform you if an unscheduled visit is needed.

If you wish to continue to the Extension Period in order to help us better understand the long-term safety and immunogenicity of this study vaccine, you will have an additional 3 visits to the study clinic every 6 months. The total duration of the study, including the Extension Period, will be approximately 25 months.

If you take part in this study, you will receive 2 injections of study vaccine or placebo (a medically inactive substance) on 2 different days during the study. You will receive the first shot on Visit 1 and the second on Visit 3 (approximately 28 days after the first study vaccination).

The study vaccine will be injected into the muscle of your shoulder. The study staff will observe you for at least 30 minutes after each study vaccination.

All participants will either be instructed to download an electronic diary (eDiary) application or will receive an eDiary device. You will also receive a thermometer and a ruler. At each study vaccination visit, you will be instructed to record your observations into the eDiary starting approximately 30 minutes after study vaccination. The study staff will always be there to assist you as necessary. You must record the following observations at the same time each day continuously for 7 days after the day of your study vaccination:

- Daily oral body temperature measurement using thermometer
- Pain
- Redness
- If you have swelling or rash or hardness after injection, record the area measurement (using ruler)
- Any medications apart from the study vaccine taken on the days of study vaccination and 28 days post study vaccination.

It is very important that you record your observations every day, at the same time each day. If any of your symptoms persist past 7 days, you will be asked to record your observations until they resolve, up to 28 days after your study vaccination.

Information about the study product
Vaccines serve to prepare your immune system for fighting illnesses.

Our body can produce special proteins (antibodies) to recognize viruses and other -illness causing pathogens (bacteria or microorganisms that can cause disease) and fight against them. The mRNA-1893 study vaccine is intended to help our body to produce enough antibodies against ZIKV and render the virus harmless when it infects human bodies. To date, no effective vaccine to prevent ZIKV has been approved.

The study vaccine – mRNA-1893 – is designed to prevent ZIKV infection by targeting our body's cells to produce antibodies to this virus. This study vaccine is based on a new process similar to the one developed for the COVID vaccine that is widely used to fight the SARS COVID-19 pandemic. Typical vaccines use a weakened or killed virus or a protein from the virus to stimulate the immune system. The mRNA-1893 study vaccine uses a part of the genetic information of the virus (known as messenger RNA or mRNA) to make your body produce ZIKV antibodies. This mRNA carries the code for ZIKV external proteins and is encapsulated in a novel lipid nanoparticle.

After vaccination, once this genetic material is inside the human body, the viral genetic material transforms into proteins. The immune system can detect this viral protein and produces an immune response in attempt to fight the virus. This study will help us find how long the human body can remember these viral proteins and how effectively can the human body fight if the real virus enters human body in the future.

All participants will be randomly assigned to 1 of 4 groups, with approximately 200 participants per group:

- Study Treatment Arm A: 2 doses of 30 micrograms of mRNA-1893 at Visit 1 and Visit 3
- Study Treatment Arm B: 2 doses of 100 micrograms of mRNA-1893 at Visit 1 and Visit 3
- Study Treatment Arm C: 1 dose of 100 micrograms of mRNA-1893 at Visit 3 (Visit 1 will be placebo)
- Study Treatment Arm D: 2 doses of placebo at Visit 1 and Visit 3

Placebo is a saline injection without any medicinal ingredients. Participants will be randomly assigned to receive two shots of the study vaccine at either the 30 ug or the 100 ug dose, two shots of placebo, or one shot of placebo and one shot of the study vaccine at the 100 ug dose. Neither you nor your study doctor will know which dose of study vaccine you are receiving. This is an observer-blind study. The pharmacy staff who are responsible for the preparation of the injections will know what dose you will receive.

Before any study procedures are performed, you will be asked to review, sign and date this ICF. Signing and dating this ICF indicates that you understand your involvement in the study, the risks of participating in the study, and that you agree to take part in the study.

By participating in this study, you consent to record information during the following activities.

These activities will be used to evaluate the safety and the effect of the study vaccine. The procedures and activities that will be performed during the study are described below:

Demographic and Medical History: During your first clinic visit, you will be asked to provide information about your medical history. You may be requested to get medical records from your personal doctor(s). You will be asked about all medications, including prescription medications, non-prescription (over the counter) medications, dietary supplements, vitamins, vaccinations, and herbal medications you are currently taking or may have taken recently.

Physical Examination, Height, and Weight: At your screening visit and on Days 1, 29, and 57 you will be given a physical examination and your height and weight will be recorded. At subsequent visits your weight will be measured, and you may have a physical examination if it is needed.

Vital Signs: The study staff will record your blood pressure, body temperature, breathing rate and how fast your heart is beating.

Pregnancy Test: If you are a female who can have children, you will be asked to provide a urine sample at screening to confirm that you are not pregnant. You will also be asked to provide a urine sample to confirm that you are not pregnant at the visits when you will receive a vaccination.

Birth Control: If you are a female who can get pregnant and who is sexually active, you will be asked to use birth control for at least 28 days prior to the first vaccination and for 3 months after the last vaccination. This is approximately 5 months from the time that you sign and date this ICF. Acceptable forms for birth control include barrier method (condom, diaphragm, or cervical cap) with spermicide, intrauterine device (IUD), hormonal contraceptives in the form of a pill, patch or injection, medroxyprogesterone injection (Depo-Provera®), etonogestrel implant or a male partner who has been sterilized before entry of his female partner into the study.

Blood Tests: During visits to clinic, you will be asked to provide blood samples. Your blood samples will be used for studying immunogenicity of the study vaccine and some might be used for research purposes (to understand how your body reacts to ZIKV).

The total amount of blood collected from you during your study visits will range from approximately 12 to 21 mL, which is approximately 2.5 to 4 teaspoons. Overall, approximately 93 mL (approximately 6 tablespoons) of blood will be collected over the 7 months of the study.

Some sites will also collect additional blood samples for cell-mediated immunity (CMI) testing.

More information about this testing can be found towards the end of this ICF. If you are participating in this study at a site doing CMI testing, you will also be asked to provide approximately an additional 6 tablespoons of blood on Days 1, 29, 36, 57, and 196.

Some sites will also collect additional blood samples for exploratory testing. More information about this testing can be found towards the end of this ICF. If you are participating in this study at a site doing exploratory testing, you will also be asked to provide approximately an additional 4 tablespoons of blood on Day 57.

Not all sites are participating in this additional testing.
Participating sites are doing **either** CMI testing **or** exploratory testing, **not** both.
You will **only** be asked to provide additional blood samples for the testing **your site** is participating in.

If you wish to participate in the Extension Period, additional blood samples will be collected from you.

If you are asked to make an unscheduled visit to the study clinic and you are experiencing flavivirus symptoms, an additional blood sample of approximately 2 teaspoons may be collected from you.

Vaccination: You will be given the randomly assigned study vaccine. Before vaccination, the study staff will measure your vital signs. After the study vaccination, the study staff/study doctor will ask you to stay in the clinic for around 30 minutes under observation (to check if you develop any reactions to the study vaccine). During this time, the study staff will ask questions and measure your vital signs again, 30 minutes after the study vaccination. You will receive instructions on what you should do after you leave the clinic and when you should return to the clinic.

eDiary: You will be asked to report about symptoms you might experience after each study vaccination and certain information about your health using an eDiary. This diary is an application (or "app") that will be downloaded onto your smartphone. If you do not have a smartphone, an eDiary device can be provided to you based on availability. You will be trained on how to complete the eDiary. You will have to complete the diary every day (preferably at the same time each day in the evenings) for 7 days after each of the 2 study vaccinations. If any of your symptoms persist past 7 days, you will be asked to record your observations until they resolve, up to 28 days after your study vaccination. Completion of the daily symptoms should take about 5-10 minutes each day.

To fill out the eDiary, you will also be asked to do the following:

- Look at your arm where you received the study vaccine and measure any specific reactions you may see (a ruler will be provided to you to measure injection site reactions).
- Describe reactions that are sometimes seen after the study vaccination.
- Measure your temperature (an oral thermometer will be provided to you). You must not eat or drink anything hot or cold within 10 minutes of taking your temperature.
- Note if you take any medications.
- Confirm if you have seen another healthcare provider for any illness or symptoms.

You should take no longer than 5-10 minutes to complete this assessment.

The detailed description of procedures for each study visit and telephone calls are presented below:

Visit	When	What will be done

Screening* (in-clinic)	Around 8 days before you enter the study (can be combined with Visit 1)	• You must read and understand this ICF. The study staff will answer your questions. If you wish to participate in the study, you must sign and date this ICF.
		• The study staff will collect information from you regarding:
		  • Your age, gender, ethnicity, etc.
		  • Your medical history
		  • If you are currently taking any medicines
		  • How you feel today
		• Based on your consent, the study staff will assess your eligibility, prior medications, current medications, and demographic details.
		• The study doctor or study staff will record your blood pressure, body temperature, how fast you are breathing and how fast is your heart beating.
		• A full physical examination, including height and weight measurement, will be conducted.
		• If you are a female participant of childbearing age, you will be asked to provide a urine sample for a pregnancy test.

Visit 1* (in-clinic)	Day 1 (first vaccination)	*For some participants, Screening Visit and Visit 1 may be combined. Please check with study staff for additional details. *Before Study Vaccination:* The study staff will confirm your eligibility by reviewing medical history, medications review, and discussion of your health changes since the Screening Visit. You will be randomly assigned to receive study vaccine. • A physical examination will be done to check your overall health.

		• The study doctor or study staff will record your blood pressure, body temperature, how fast you are breathing and how fast your heart is beating. • • Approximately 4 teaspoons of blood will be collected to test for West Nile virus, Dengue virus and ZIKV previous infection. This blood sample will be used to help determine your body's response to the study vaccine. • If you are a female participant of childbearing age, you will be asked to provide a urine sample for a pregnancy test. *Study Vaccination:* • You will be given the first study vaccination shot. *After Study Vaccination:* • You will be provided with an eDiary to record any changes in your health, starting the day of your study vaccination, for at least 7 days, up to a total of 28 days. • Study staff will observe you for around 30 minutes after study vaccination.
Visit 2 (in-clinic)	Day 8 (7 days after the first study vaccination)	• Medication review and discussion of any changes in your health since the last visit. • Approximately 3 teaspoons of blood will be collected to evaluate how your body is responding to the first study vaccine. • The study staff will review your eDiary.
Visit 3 (in-clinic)	Day 29 (28 days after the first study vaccination [second vaccination])	*Before Study Vaccination:* • The study staff will review your medications and discuss any changes in your health since the last visit. • Approximately 3 teaspoons of blood will be collected to evaluate how your body is responding to the first study vaccine administration. • Your blood pressure, body temperature, how fast you are breathing and how fast your heart is beating will be measured. • A physical examination will be done to check overall health. • If you are a female participant of childbearing age, you will be asked to provide a urine sample for a pregnancy test. *Study Vaccination:* • The second study vaccine administration will be given to you.

		After Study Vaccination: • The site will review the eDiary with you and you will be asked to record any changes in your health, starting the day of your study vaccination, for at least 7 days, up to a total of 28 days. • Study staff will observe you for around 30 minutes after study vaccination.
Visits 4 through 6 (in-clinic)	Day 36 (Visit 4), Day 57 (Visit 5), and Day 85 (Visit 6)	• The study staff will review your medications and discuss any changes in your health since the last visit. • Approximately 2 teaspoons of blood will be collected to evaluate how your body is responding to the study vaccine at each of these visits (Visit 4, Visit 5, and Visit 6). • Your blood pressure, body temperature, how fast you are breathing and how fast your heart is beating will be recorded, if necessary. • At Visit 4, the study staff will review your eDiary. • At Visit 5 you will have a physical exam. •
Visits 7 to 9 (telephone calls)	Day 112 (Visit 7), Day 140 (Visit 8), and Day 168 (Visit 9)	• The study staff will review your medications and discuss any changes in your health since the last visit.
Visit 10 and End of Study Visit (in-clinic)	Day 196	• The study staff will review your medications and discuss any changes in your health since the last visit. • Your blood pressure, body temperature, how fast you are breathing and how fast your heart is beating will be recorded, if necessary. • Approximately 3 teaspoons of blood will be collected to evaluate how your body is responding to the second study vaccine administration. • If you wish to continue to Extension Period of this study, you will be given a separate ICF to sign and date. If you do not wish to continue to the Extension Period of this study, this will be your last visit for this study. • Return visits for the Extension Period will begin approximately 6 months after this visit. •
Unscheduled Visit		• A physical examination will be done to check your overall health. • Your blood pressure, body temperature, how fast

		you are breathing and how fast your heart is beating will be recorded, if necessary • The study staff will review your medications and discuss any changes in your health since the last visit. • If you are experiencing symptoms related to exposure to flavivirus, a blood sample (approximately 2 teaspoons) will be collected to confirm if flavivirus infection is detected.

If you are not familiar with any of these procedures, please ask your study doctor to explain how they are performed.

The results of the study of your blood samples will be used for vaccine research and development purposes only and you will not be told the results of the tests.

Some of your blood will be sent to special laboratories and tested for the response of your body's immune system to the study vaccines. Blood samples obtained in the study will be labeled with a code and will not contain any information that could identify you. The blood samples will be stored in a freezer until the tests analyzing your immune response to the study vaccine are performed. The blood samples may be stored for up to approximately 20 years by the Sponsor or designee. Additional laboratory tests may be performed in the future to further understand immune responses to the study vaccine, assay development, and immune responses across the family of flaviviruses. The future use of your blood samples may result in new discoveries that are important to the understanding of the study vaccine(s) or flavivirus disease.

You may request that your samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of ModernaTX and may be shared with other researchers as long as confidentiality is maintained. No testing of your DNA will be performed, except for participants participating in CMI testing – DNA epitopes relevant to the ZIKV-specific immune response may be investigated for research purposes to further characterize the response to the ZIKV study vaccine. You will not be told of additional tests, nor will you receive results of any of these tests.

The Sponsor may continue using the coded study data and samples after the study is over. You are allowing the Sponsor to use the information and samples in the research and development of mRNA-1893 and other drugs and diagnostics. You will not own any of the information or samples collected. Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and you will not share in this profit.

What is expected from you?
When deciding whether to participate, consider whether you are able and willing:

- To follow the study rules
- To commit the time required to keep appointments
- To tell the study doctor truthfully about your complete medical history

- To promptly report any new problems, illnesses, discomfort, or changes in medication during the study
- To complete your eDiary for 7 days following each study vaccination, including the day of study vaccination. If any of your symptoms persist past 7 days, you will be asked to record your observations until they resolve, up to 28 days after your study vaccination.

What will happen at the end of the study?
After completing all your study specific visits, you will be discharged from the study at the discretion of the study doctor.

What are the potential risks and discomforts?
The study vaccine mRNA-1893 is still being evaluated in humans. Therefore, possible side effects of the study vaccine are not fully known.

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

Redness, induration (lump under the skin)/swelling, pain at injection site, and/or fever are expected side effects of injectable study vaccines. These reactions normally do not last for more than 48 hours. Headache and general discomfort (flu-like symptoms, muscle aches, joint aches, chills, and fatigue [tiredness]) are also possible.

Blood drawing may be associated with temporary discomfort, light-headedness, or a bruise at the needle site. In rare situations, infection may occur at the needle stick site where blood is drawn. You may be offered a numbing cream before the collection of blood samples, if available with your study doctor, but this is not guaranteed.

You may experience some side effects that have not been experienced before. This could be an allergic reaction, including severe hypersensitivity reactions or anaphylaxis. This reaction may include flushing (sudden redness of skin), rash, difficulty breathing, swelling of lips and/or tongue. Anaphylaxis is very rare and has not been seen with the vaccine you will receive in this study, but has been reported after the administration of other mRNA vaccines. Medical treatment will be given to you in case of an allergic reaction to the vaccine. It is important that you tell the study doctor about any changes in your health.

Tell the study doctor if you have a history of symptoms like anaphylaxis (sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness), or hives after receiving any vaccine including an mRNA vaccine or any components of an mRNA vaccine, or any other medicine for which you required medical help. If you have an allergy to some products, you may not be able to take part in this study after discussions with the study doctor and study staff. Serious allergic reactions can be life-threatening.

Placebo Risk: If you receive placebo (the saline water), you will not develop any antibodies following the injection and may experience similar side effects to those listed above.

There have been very rare reports of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation around the heart) in individuals receiving COVID-19 mRNA vaccines, which also use mRNA like the vaccine you would receive in this study. Although causality has not been established, the majority of the cases have been reported in young males shortly after the second dose of the vaccine. Symptoms of myocarditis or pericarditis include chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart, with onset of symptoms most commonly reported shortly after the second dose of the vaccine. Study participants should seek medical attention and also notify study site staff if any of these symptoms occur following vaccination. Although long-term follow up is limited, these are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of other mRNA vaccines.

In other studies of people receiving the study vaccines, the most common side effects are listed below. The study staff will ask you about these side effects during this study.

- Fever
- Pain at the injection site
- Redness and induration/swelling of the skin at the injection site
- Headache
- Muscle aches or pain
- Joint aches or pain
- Fatigue
- Nausea/vomiting
- Chills
- Allergic reaction

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

Are there any reproductive risks?
Women: It is not known if the study vaccine may affect an unborn child or nursing infant. For this reason, if you are breast-feeding, pregnant or plan to become pregnant, you may not participate in this study. Female participants must be either at least 1 year postmenopausal, surgically sterile (such as, hysterectomy [uterus removed], bilateral [both tubes] tubal ligation or bilateral oophorectomy [both ovaries removed]) or practicing a medically approved and highly effective method of contraception from at least 28 days before the first study vaccination through 3 months after the last study vaccination with the study vaccine. Such methods include condoms (male or female) with spermicide, diaphragm with spermicide, cervical cap with spermicide, IUD, oral or patch contraceptives, Nexplanon, Depo-Provera, or other FDA-approved contraceptive method that is designed to protect against pregnancy.

Periodic abstinence, declaration of abstinence for the duration of the study, and withdrawal are not acceptable methods of contraception. You should discuss with the study doctor your chosen method of birth control to determine if it is acceptable for your participation in this study.

Pregnancy: If you become pregnant during your participation in the study, your participation in the study may be stopped. However, you may be asked to share information about your pregnancy and birth outcome. It is important that you tell the study doctor immediately if you become pregnant during the study. The study doctor will talk with you about what you should do.

What are the advantages and disadvantages of participation in the study?
It is possible that you may not personally benefit from your participation in this study. However, by participating in this study you will provide new scientific information that will benefit other patients in the future.

Are there any alternative treatments?
Since this is not a treatment study, your alternative is to not participate.

Will you be informed if new information becomes available during the study?
Your study doctor will inform you in a timely manner of any new information learned during the study that may affect your willingness to continue your participation in this study.

Whom to contact about this study
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant and/or concerns or complaints regarding this clinical research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00051016.

What happens if you change your mind?
It is your choice if you want to be in the study. You may decide not to participate, or you can leave the study at any time. You will not be punished for leaving the study. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide to leave the study before the last study visit, please notify a member of the study staff and follow instructions. It may be helpful if you could explain your reasons. No prejudice will be shown toward you for medical care you may need or for future participation in research.

If you withdraw consent during the research study, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research study can be measured properly and to comply with the law. Data collected by the Sponsor up to the time you withdraw from the study will form part of the research study results.

In addition, your study doctor or the Sponsor may withdraw you from continuing to participate in the study, even if you wish to continue, for example:

- If you experience a severe adverse reaction;
- If you do not follow the study rules;
- If it is discovered that you do not meet the study requirements;
- If the study is cancelled; or
- For administrative reasons, including completion of enrollment.

If your participation in the study is stopped early, you may be asked to complete end of study procedures (such as a final medical examination and laboratory tests) for your own safety.

Are there any costs if you decide to participate?
The study vaccine will be made available to you at no charge and you will not be required to pay for any study procedures. You or your insurance company may be billed for any standard medical care that is not required for the clinical research study.

Is there a payment if you decide to participate?

«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***["after each visit," "annually," "bi-weekly," etc.]***

If you have any questions regarding your compensation for participation, please contact the study staff.

[OR]

You will not receive any monetary compensation for your participation in this study.

[If applicable:] We will reimburse you for the cost of ***[describe: e.g., traveling to your study visits]***. You will be reimbursed approximately ***[e.g., 2 weeks, 1 month, etc.]*** after you submit your travel receipts to the study staff.

Will you receive compensation if you are injured as a result of the study?
If you become sick or injured as a direct result of a study procedure or of study vaccine administration, you should call the 24-hour telephone contact number listed on the first page of this ICF. Additionally, appropriate medical care for the treatment of the illness or injury will be given to you. The Sponsor will pay for the reasonable and necessary costs associated with this care. Provision of medical care does not imply any fault or wrong doing on the part of Sponsor, your study doctor, or the study site.

To pay medical expenses, the Sponsor will need to know some information about you, like your name, date of birth, and Medicare Beneficiary Identifier.

This is because the Sponsor has to check to see if you receive Medicare and, if you do, report the payment it makes to Medicare.

Will the personnel involved in the study receive any payment?
The study doctor receives payment from ModernaTX, who is the Sponsor of this study.

Confidentiality
This clinical research study may be performed only by collecting and using your medical information. Your study records will be kept as confidential as possible. Only a number will be used to identify you.

You will not be personally identified in any reports or publications that may result from this clinical research study.

Because of the research goals of this study, however, your study records cannot be kept completely confidential. The Sponsor of this study is ModernaTX.

The study personnel, the Sponsor and its agents and Pharmaceutical Product Development, LLC (PPD) will need to review the medical information collected from you for use in this

clinical research study in order to accurately record information for this study. In addition, in order to review the clinical research study findings, the FDA, other government agencies, and the IRB will be able to inspect and copy confidential study-related records that identify you by name. Representatives of the Sponsor and government agencies may also observe a clinical research study visit, to check that study staff are performing the clinical research study correctly.

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.

Statement of Consent

- I have read and understood the statements in this ICF.
- I have had the opportunity to ask questions and I am satisfied with the explanations provided.
- I voluntarily agree to take part in this study.
- I understand that I will receive a copy of this signed and dated written ICF.
- For women of childbearing potential: I agree to utilize an acceptable method of birth control as outlined in this ICF. Should I become pregnant during my participation in the clinical research study, I agree to provide information on my pregnancy and birth outcome as part of the safety -follow-up.
- I agree that the blood sample provided by me during this study will be used for the specific pursuits for research.

Participant	Signature	Date
Printed Name		

Parent/Legal Guardian or Legally Authorized Representative		
Printed Name	Signature	Date

Authority of Legally Authorized Representative to act on behalf of Participant (If Applicable)

- I presented the study and answered the participant's questions.
- I will give the participant a copy of this signed and dated ICF.

Presenter (Study Doctor/Delegate)	Signature	Date
Printed Name		

Consent to Use Medical Information for Future Research
I consent to the use of my coded samples for future medical or pharmaceutical research.

By inserting my initials in the box associated with "YES" below, I agree that any remaining samples collected during this study can be stored for up to 20 years and be used for exploratory research purposes:

YES	*Participant's initials*	NO	*Participant's initials*

THIS PAGE IS FOR SPECIFIC SITES PARTICIPATING IN THESE EXTRA ASSESSMENTS AND SHOULD BE DELETED IF THE SITE IS NOT PARTICIPATING.

Consent To Collect Peripheral Blood Mononuclear Cell Samples For Cell-Mediated Immunity (CMI) Assessments

The Sponsor requests your permission to collect and use extra blood for immune testing that evaluates your immune response by examining response of white blood cells (also known as -infection fighting cells) to the study vaccine. Around 6 tablespoons of extra blood will be collected on Days 1, 29, 36, 57 and 196 in the main study. Please indicate if you would be willing to provide these extra blood samples by initialing the appropriate box below.

☐ Yes, I agree to have extra blood collected as outlined, and my blood sample(s) used for white blood cell testing.

☐ No, I do not agree to have extra blood collected as outlined, and my blood sample(s) used for white blood cell testing.

_____

Study Participant
Printed Name Signature Date

_____

Parent/Legal Guardian or Legally Authorized Representative
Printed Name Signature Date

THIS PAGE IS FOR SPECIFIC SITES PARTICIPATING IN THESE EXTRA ASSESSMENTS AND SHOULD BE DELETED IF THE SITE IS NOT PARTICIPATING.

Consent to collect blood sample for exploratory research (not genetic testing)

The Sponsor requests your permission to collect and use extra blood for exploratory testing (not genetic testing). This blood volume will be used in an animal model to assess the protective efficacy of the antibodies you developed after receiving the ZIKV study vaccine. Around 4 tablespoons of extra blood will be collected on Day 57 visit. Please indicate if you would be willing to give this extra blood sample by initialing the appropriate box below.

☐ Yes, I agree to have extra blood collected as outlined, and my blood sample(s) used for exploratory testing.

☐ No, I do not agree to have extra blood collected as outlined, and my blood sample(s) used for exploratory testing.

Study Participant

Printed Name Signature Date

Parent/Legal Guardian or Legally Authorized Representative

Printed Name Signature Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

The following sections provide a specific description of how your information will be used and disclosed if you participate in this research study. By signing and dating this ICF, you are authorizing such access. If you do not sign and date this ICF to authorize access, you will not be able to participate in this research study.

The medical information that will be collected from you if you participate in the study includes:

- Information obtained from procedures to determine your eligibility to participate in the study, including a routine medical history, physical examination, and blood and urine tests.
- Information that is created or collected from you during your participation in the study, including the results of the blood and urine tests and any other procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, and/or other identifying information.

If you sign and date this ICF and participate in the study, the study personnel will be authorized to use the information described above to carry out the purposes of the research study. The study personnel will also be authorized to disclose the relevant information described above to the following parties involved in the research study:

- ModernaTX, Inc., PPD or other agents designated by ModernaTX, Inc., to collect or review study data for verification of study procedures and/or adverse event reporting.
- The IRB that oversees the research study at your site.
- Government regulatory agencies, including the FDA.
- Clinical research study recruitment company, if you were referred to the study by such a company; once your information is disclosed to the study Sponsor, its agents, the IRB/IEC or government agencies as described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by US federal privacy regulations. In addition to disclosures to the entities identified above, PPD may further electronically disclose your coded health information to others

involved in the research study, such as:

- To laboratories or offsite testing facilities for clinical tests for safety and immune responses as required by study protocols.
- To approved offsite storage facilities or cloud service providers to meet study record retention and storage requirements.
- To study Sponsor ModernaTX, Inc., who directs the medical research studies.
- To other third parties contracted by PPD and/or ModernaTX, Inc., to provide services related to studies.

The study data may be transferred to other countries for processing, including countries not covered by data protection legislation. The laws of your state may provide further protection.
While the study is in progress, your access to your study records will be temporarily suspended. You will be able to access your information when the research study is completed. You have the right to see and copy the medical information collected from you in the course of the study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation.

Study data, including your coded medical information, may be used and shared by the Sponsor. This authorization does not have an expiration. In California and any other state that requires an expiration date, this authorization will expire 50 years from the date you sign and date it unless you revoke (cancel or withdraw) sooner. In signing and dating this ICF, you authorize the use and disclosure of your information for purposes of the study at any time in the future.

You may withdraw your authorization at any time by sending a written request to the study doctor listed on page 1 of this ICF. If you withdraw your authorization, data collected prior to your withdrawal may still be processed along with other data collected as part of the study.

Normally no new information will be collected for the study database unless you specifically authorize that. However, the law does require that any side effects that you may suffer are documented and reported. To complete the study findings, your long-term health status may also be obtained from public sources.

I understand that I have the right to refuse to sign and date this authorization, which will result in my inability to participate in the study. You will receive a copy of this authorization after you have signed and dated it.

Printed Name of Participant

Signature of Participant Date

Printed Name of Parent/Legal Guardian or Legally Authorized Representative

Signature of Parent/Legal Guardian or Legally Authorized Representative Date

- I have presented the study and answered the participant's questions.
- I will give the participant a copy of this signed and dated ICF.

Presenter (Study Doctor/Delegate) Signature Date
Printed Name

INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION
For Extension Study

Sponsor / Study Title:	**ModernaTX, Inc. / A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Dose Confirmation Study to Evaluate the Safety, Tolerability, and Immunogenicity of Zika Vaccine mRNA-1893 in Adults Aged 18 Through 65 Years and Living in Endemic and Non-Endemic Flavivirus Areas**
Protocol Number:	**mRNA-1893-P201**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This form contains information for those participants who wish to continue into the Extension Period of Study mRNA-1893-P201. All instances of 'extension study' in this form refer to the Extension Period of Study mRNA-1893-P201.

In this document, "you" refers to the person participating in the extension study.

Adults aged 18 through 65 years are eligible to participate in this extension study. At extension study locations in areas where the age of majority is greater than the age of 18 or when the adult participant who has reached age of majority cannot legally consent to take part, the parent, legal guardian, or legally authorized representative of the participant will be required to sign and date this form, and the minor participant will be required to sign and date a separate form called an assent form. Should the minor participant reach the age of majority during study participation, they would then sign and date this form.

In cases of an adult who has reached the age of majority and where the participant's representative gives consent, the participant should be informed about the extension study to the greatest extent possible given his/her understanding. During the course of the extension study, if the participant regains the capacity to consent, informed consent will be obtained from the participant.

When the participant cannot legally consent to take part, the pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative or parent/legal guardian) who is signing and dating this form for the participant.

Advarra's Institutional Review Board (IRB) is an independent committee that reviews human participant research to help ensure that the rights and welfare of research participants are protected and that the research is carried out in an ethical manner.

Why are you receiving this key information?
You have completed the vaccination and follow-up periods of Study mRNA-1893-P201, sponsored by ModernaTX Inc. You are being invited to take part in an extension study for mRNA-1893-P201. An extension to study mRNA-1893-P201 is planned to evaluate the long-term safety and immunogenicity of the investigational vaccine mRNA-1893 for Zika virus (ZIKV) for a maximum of 2 years post study vaccination. During that period there will be no additional study vaccine administration.

It is important that you know:

- Your participation is your choice.
- You may or may not benefit from participating in this extension study. However, your participation may help others in the future as a result of the knowledge gained from this study.
- You may leave the extension study at any time.
- If you choose not to take part or if you leave the extension study, it will not harm your relationship with the study doctor or study site.

The mRNA-1893 study vaccine is called "investigational" because it has not been approved by the U.S. Food and Drug Administration (FDA) or any other health/regulatory authority in the world. The study vaccine mRNA-1893 is still being evaluated in humans. Therefore, the possible long-term side effects of the study vaccine are not fully known. Please see the risks and discomforts section below for additional information.

This form is called an informed consent form (ICF). This ICF provides information you need to decide if you want to participate in the extension study. Please read this ICF carefully and ask any questions that might help you decide if you would like to take part in this extension study. If you decide that you will take part in this extension study, you will be asked to sign and date this ICF. A copy of this signed and dated ICF will be given to you to keep.

What is the purpose of the extension part of this clinical research study?
The purpose of this extension study is to confirm that the study vaccine mRNA-1893 is safe over time and that you are able to maintain the immune response (a process where your body can recognize the virus and fight the infection) against ZIKV infection after up to approximately 2 years of receiving the study vaccine.

This extension study is being conducted for research purposes only. The study vaccine that you received does not cure any medical condition. By participating in this extension study, you will help researchers assess the long-term safety and immunogenicity of this study vaccine.

How many people will participate in this extension study?
A total of approximately 800 people will be invited to take part in this extension study at up to 15 study sites across the continental United States and Puerto Rico. Those participants correspond to the participants enrolled in the study vaccination phase of mRNA-P201 who have received 2 vaccinations.

What procedures are involved?
You have completed approximately 6 months of follow-up after the last dose of study vaccine. If you wish to continue into the extension study, you will have 3 additional visits to the study clinic approximately every 6 months (on Days 364, 532, and 700).

You may also be asked to make an unscheduled visit to the study clinic if you experience any flavivirus symptoms, such as rash, headache, fever, conjunctivitis (eye inflammation), joint pain, and muscle pain, or if you experience any side effects that you consider severe. (for example, interfering with your usual daily activity). The study staff will inform you if an unscheduled visit is needed.

Before any study procedures are performed, you will be asked to review, sign, and date this ICF. Signing and dating this ICF indicates that you understand your involvement in the extension study and the risks of participating in the extension study and that you agree to take part in the extension study.

By participating in this extension study, you consent to record information during the following activities. These activities will be used to evaluate the safety and the effect of the study vaccine.

The procedures and activities that will be performed during the extension study are described below:

> **Physical Examination and Weight:** If needed, you will be given a physical examination, and your weight will be recorded.
>
> **Vital Signs:** If needed, the study staff will record your blood pressure, body temperature, breathing rate, and how fast your heart is beating.
>
> **Blood Tests:** During visits to the clinic, you will be asked to provide blood samples. Your blood samples will be used to study your immune response to the study vaccine, and to test for asymptomatic or symptomatic flavivirus infections. Your blood samples might also be used for research purposes (to understand how your body reacts to ZIKV).
>
> The total amount of blood collected from you during each study visit will be approximately 12 mL, which is approximately 2.5 teaspoons. Overall, approximately 36 mL (2.5 tablespoons) of blood will be collected during the extension period.

Some sites will also collect additional blood samples for cell-mediated immunity (CMI) testing. More information about this testing can be found towards the end of this ICF. If you participated in CMI testing at your study site, you will also be asked to provide approximately an additional 6 tablespoons of blood per visit during the extension period.

If you are experiencing flavivirus symptoms you may be asked to make an unscheduled visit to the study clinic, and an additional blood sample of approximately 2 teaspoons may be collected from you.

Detailed descriptions of the procedures that will happen at each study visit for all participants are presented below:

Visit	When	What will be done
Visit 11 (in-clinic)	Day 364	• If needed, a physical examination will be done to check your overall heath. Your weight may also be measured. • If needed, your blood pressure, body temperature, breathing rate, and how fast your heart is beating will be measured before starting any study procedures. • A blood sample will be collected to evaluate how your body is responding to the study vaccine as well as to test for asymptomatic flavivirus infection • The study staff will review your medications and discuss any changes in your health since the last visit.
Visit 12 (in-clinic)	Day 532	• If needed, a physical examination will be done to check your overall heath. Your weight may also be measured. • If needed, your blood pressure, body temperature, breathing rate, and how fast your heart is beating will be measured before starting any study procedures. • A blood sample will be collected to evaluate how your body is responding to the study vaccine as well as to test for asymptomatic flavivirus infection. • The study staff will review your medications and discuss any changes in your health since the last visit.
Visit 13 and End of Extension Study Visit (in-clinic)	Day 700	• If needed, a physical examination will be done to check your overall heath. Your weight may also be measured. • If needed, your blood pressure, body temperature, breathing rate, and how fast your heart is beating will be measured before starting any study procedures. • A blood sample will be collected to evaluate how your body is responding to the study vaccine as well as to test for asymptomatic flavivirus infection. • The study staff will review your medications and

		discuss any changes in your health since the last visit. • This will be your last visit for this extension study.
Unscheduled Visit		• If needed, a physical examination will be done to check your overall heath. Your weight may also be measured. • If you are experiencing symptoms related to exposure to flavivirus, a blood sample (approximately 2 teaspoons) will be collected to confirm if flavivirus infection is detected.

If you need to know more about any of these procedures, please ask your study doctor to explain how they are performed.

The results of the study of your blood samples will be used for vaccine research and development purposes only, and you will not be told the results of the tests.

Some of your blood will be sent to special laboratories and tested for the response of your body's immune system to the study vaccines. Blood samples obtained in the study will be labeled with a code and will not contain any information that could identify you. The blood samples will be stored in a freezer until the tests analyzing your immune response to the study vaccine are performed. The blood samples may be stored for up to approximately 20 years by the Sponsor or designee. Additional laboratory tests may be performed in the future to further understand immune responses to the study vaccine, assay (test) development, and immune responses across the family of flaviviruses. The future use of your blood samples may result in new discoveries that are important to the understanding of the study vaccine(s) or flavivirus disease.

You may request that your samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of ModernaTX, Inc. and may be shared with other researchers as long as confidentiality is maintained. No testing of your DNA will be performed, except for participants participating in CMI testing – DNA epitopes relevant to the ZIKV-specific immune response may be investigated for research purposes to further characterize the response to the ZIKV study vaccine. You will not be told of additional tests, nor will you receive the results of any of these tests.

The Sponsor may continue using the coded study data and samples after the extension study is over. You are allowing the Sponsor to use the information and samples in the research and development of mRNA-1893 and other drugs and diagnostics. You will not own any of the information or samples collected. Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed), and you will not share in this profit.

What is expected from you?

When deciding whether to participate, consider whether you are able and willing:

- To follow the extension study rules
- To commit the time required to keep appointments
- To promptly report any new problems, illnesses, discomfort, or changes in medication during the study

What will happen at the end of the extension study?
After completing all your study specific visits, you will be discharged from the extension study at the discretion of the study doctor.

What are the potential risks and discomforts?
The study vaccine, mRNA-1893, is still being evaluated in humans. Therefore, possible long-term side effects of the study vaccine are not fully known.

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

Blood drawing may be associated with temporary discomfort, light-headedness, or a bruise at the needle site. In rare situations, infection may occur at the needle stick site where blood is drawn. You may be offered a numbing cream before the collection of blood samples, if available with your study doctor, but this is not guaranteed.

Please seek treatment immediately and tell the study doctor and study staff if you have any symptoms during the study.

Are there any reproductive risks?

If you become pregnant during your participation in the extension study, you will be asked to contact the study doctor immediately and asked if you would agree to share information about your pregnancy follow up and birth outcome.

What are the advantages and disadvantages of participation in the extension study?
It is possible that you may not personally benefit from your participation in this extension study. However, by participating in this extension study, you will provide new scientific information that may benefit other patients in the future.

Are there any alternative treatments?
This is not a treatment study. You may choose to not participate.

Will you be informed if new information becomes available during the extension study?
Your study doctor will inform you in a timely manner of any new information learned during the study that may affect your willingness to continue your participation in this extension study.

Whom to contact about this study
During the extension study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00051016.

What happens if you change your mind?
It is your choice if you want to be in the extension study. You may decide not to participate, or you can leave the extension study at any time. You will not be punished for leaving the extension study. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide to leave the extension study before the last study visit, please notify a member of the study staff and follow instructions. It may be helpful if you could explain your reasons. No prejudice will be shown toward you for medical care you may need or for future participation in research.

If you withdraw consent during the research study, the study doctor and relevant study staff will not collect additional personal information from you, although any personal information that has already been collected will be retained to ensure that the results of the research study can be measured properly and to comply with the law. Data collected by the Sponsor up to the time you withdraw from the study will form part of the research study results.

In addition, your study doctor or the Sponsor may withdraw you from continuing to participate in the extension study, even if you wish to continue, for example:

- If you experience a severe adverse reaction;
- If you do not follow the study rules;
- If it is discovered that you do not meet the study requirements;
- If the study is cancelled; or
- For administrative reasons, including completion of enrollment.

If your participation in the study is stopped early, you may be asked to complete end of study procedures (such as a final medical examination and laboratory tests) for your own safety.

Are there any costs if you decide to participate?
You will not be required to pay for any extension study procedures. You or your insurance company may be billed for any standard medical care that is not required for the clinical research study.

Is there a payment if you decide to participate?

«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***["after each visit," "annually," "bi-weekly," etc.]***

If you have any questions regarding your compensation for participation, please contact the study staff.

[OR]

You will not receive any monetary compensation for your participation in this study.

[If applicable:] We will reimburse you for the cost of ***[describe: e.g., traveling to your study visits]***. You will be reimbursed approximately ***[e.g., 2 weeks, 1 month, etc.]*** after you submit your travel receipts to the study staff.

Will you receive compensation if you are injured as a result of the extension study?
If you become sick or injured as a direct result of a study procedure, you should call the 24-hour telephone contact number listed on the first page of this ICF. Additionally, appropriate medical care for the treatment of the illness or injury will be given to you. The Sponsor will pay for the reasonable and necessary costs associated with this care. Provision of medical care does not imply any fault or wrong doing on the part of Sponsor, your study doctor, or the study site.

To pay medical expenses, the Sponsor will need to know some information about you, like your name, date of birth, and Medicare Beneficiary Identifier.

This is because the Sponsor has to check to see if you receive Medicare and, if you do, report the payment that it makes to Medicare.

Will the personnel involved in the study receive any payment?
The study doctor receives payment from ModernaTX, Inc., who is the Sponsor of this study.

Confidentiality
This clinical research extension study may be performed only by collecting and using your medical information. Your study records will be kept as confidential as possible. Only a number will be used to identify you.

You will not be personally identified in any reports or publications that may result from this clinical research extension study.

Because of the research goals of this extension study, however, your study records cannot be kept completely confidential. The Sponsor of this study is ModernaTX, Inc.

The study personnel, the Sponsor and its agents and Pharmaceutical Product Development, LLC (PPD) will need to review the medical information collected from you for use in this clinical research extension study in order to accurately record information for this extension study. In addition, to review the clinical research extension study findings, the FDA, other government agencies, and the IRB will be able to inspect and copy confidential study-related records that identify you by name. Representatives of the Sponsor and government agencies may also observe a clinical research extension study visit, to check that study staff are performing the clinical research study correctly.

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.

Statement of Consent

- I have read and understood the statements in this ICF related to the study extension.
- I have had the opportunity to ask questions, and I am satisfied with the explanations provided.
- I voluntarily agree to take part in this extension study.
- I understand that I will receive a copy of this signed and dated written ICF.
- For women of childbearing potential: Should I become pregnant during my participation in the clinical research study, I agree to provide information on my pregnancy and birth outcome as part of the safety -follow-up.
- I agree that the blood samples provided by me during this extension study will be used for the specific pursuits for research.

_____

Participant Signature Date
Printed Name

_____

Parent/Legal Guardian or Legally Authorized Representative
Printed Name Signature Date

_____
Authority of Legally Authorized Representative to act on behalf of Participant (If Applicable)

- I presented the study and answered the participant's questions.
- I will give the participant a copy of this signed and dated ICF.

_____

Presenter (Study Doctor/Delegate) Signature Date
Printed Name

Consent to Use Medical Information for Future Research
I consent to the use of my coded samples for future medical or pharmaceutical research.

By inserting my initials in the box associated with "YES" below, I agree that any remaining samples collected during this study can be stored for up to 20 years and be used for exploratory research purposes:

YES	*Participant's initials*	NO	*Participant's initials*

THE BELOW INFORMATION IS FOR SPECIFIC SITES PARTICIPATING IN THESE EXTRA ASSESSMENTS AND SHOULD BE DELETED IF THE SITE IS NOT PARTICIPATING.

Consent To Collect Peripheral Blood Mononuclear Cell Samples For Cell-Mediated Immunity (CMI) Assessments

The Sponsor requests your permission to collect and use extra blood for immune testing that evaluates your immune response by examining response of white blood cells (also known as infection -fighting cells) to the study vaccine. Around 88 ml (approximately 6 tablespoons) of extra blood will be collected at each of the 3 extension study visits. Please indicate if you would be willing to provide these extra blood samples by initialing the appropriate box below.

☐ Yes, I agree to have extra blood collected as outlined and my blood sample(s) used for white blood cell testing.

☐ No, I do not agree to have extra blood collected as outlined and my blood sample(s) used for white blood cell testing.

_____

Study Participant

Printed Name Signature Date

_____

Parent/Legal Guardian or Legally Authorized Representative

Printed Name Signature Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

The following sections provide a specific description of how your information will be used and disclosed if you participate in this research study. By signing and dating this ICF, you are authorizing such access. If you do not sign and date this ICF to authorize access, you will not be able to participate in this research study.

The medical information that will be collected from you if you participate in the extension study includes:

- Information that is created or collected from you during your participation in the study, including the results of the blood tests and any other procedures performed during the study.
- Information contained in your underlying medical records related to your medical history and treatment.

The above information may identify you by name, address, telephone number, social security number, health plan number, study number, date of birth, dates relating to various medical procedures, and/or other identifying information.

If you sign and date this ICF and participate in the extension study, the study personnel will be authorized to use the information described above to carry out the purposes of the research study. The study personnel will also be authorized to disclose the relevant information described above to the following parties involved in the research study:

- ModernaTX Inc., PPD, or other agents designated by ModernaTX Inc., to collect or review study data for verification of study procedures and/or adverse event reporting.
- The IRB that oversees the research study at your site.
- Government regulatory agencies, including the FDA.
- Clinical research study recruitment company, if you were referred to the study by such a company; once your information is disclosed to the study Sponsor, its agents, the IRB/IEC (Independent Ethics Committee) or government agencies as described above, there is a potential that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations. In addition to disclosures to the entities identified above, PPD may further electronically disclose your coded health information to others involved in the research study, such as:
    - To laboratories or offsite testing facilities for clinical tests for safety and immune responses as required by study protocols.
    - To approved offsite storage facilities or cloud service providers to

meet study record retention and storage requirements.
- To study Sponsor ModernaTX Inc., who directs the medical research studies.
- To other third parties contracted by PPD and/or ModernaTX Inc., to provide services related to studies.

The study data may be transferred to other countries for processing, including countries not covered by data protection legislation. The laws of your state may provide further protection.

While the extension study is in progress, your access to your study records will be temporarily suspended. You will be able to access your information when the research study is completed. You have the right to see and copy the medical information collected from you in the course of the study for as long as that information is maintained by the study personnel and other entities subject to federal privacy regulation.

Study data, including your coded medical information, may be used and shared by the Sponsor. This authorization does not have an expiration. In California and any other state that requires an expiration date, this authorization will expire 50 years from the date you sign and date it unless you revoke (cancel or withdraw) sooner. In signing and dating this ICF, you authorize the use and disclosure of your information for purposes of the study at any time in the future.

You may withdraw your authorization at any time by sending a written request to the study doctor listed on page 1 of this ICF. If you withdraw your authorization, data collected prior to your withdrawal may still be processed along with other data collected as part of the study.

Normally no new information will be collected for the study database unless you specifically authorize that. However, the law does require that any side effects that you may suffer are documented and reported. To complete the study findings, your long-term health status may also be obtained from public sources.

You will receive a copy of this authorization after you have signed and dated it.

I understand that I have the right to refuse to sign and date this authorization, which will result in my inability to participate in the study.

Printed Name of Participant

Signature of Participant Date

Printed Name of Parent/Legal Guardian
or Legally Authorized Representative

Signature of Parent/Legal Guardian Date
or Legally Authorized Representative

- I have presented the study and answered the participant's questions.
- I will give the participant a copy of this signed and dated ICF.

Presenter (Study Doctor/Delegate) Signature Date
Printed Name