INFORMATION TO PARTICIPANTS

Sponsor / Study Title:	**ModernaTX, Inc. / A Phase 1, Randomized, Observer-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety, Tolerability, and Immunogenicity of Zika Vaccine mRNA-1893 in Healthy Flavivirus Seropositive and Seronegative Adults**
Protocol Number:	**mRNA-1893-P101**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Why are you receiving this key information?
You are being invited to take part in a clinical research study, sponsored by ModernaTX, Inc. Please read this consent form carefully and ask the study doctor or study staff to explain words or information that you do not clearly understand. 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 your doctor or the research center.

This form 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 form 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 consent form. A copy of this signed form will be given to you to keep.

What is the purpose of this clinical research study?
The Zika virus (ZIKV) is transmitted to humans by mosquitos or via person-to-person contact through blood, saliva and semen. For most people infected by ZIKV they either have no symptoms or have a mild fever with a rash. However, some people infected with ZIKV may develop neurological symptoms, or for pregnant women birth defects may occur. Currently there is no vaccine to protect against ZIKV. The purpose of this study is to evaluate if the investigational vaccine (study drug) named mRNA-1893 is safe and able to induce an immune response that may prevent ZIKV infection. An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). This study will be the first time mRNA-1893 is administered to humans.

How many people will participate in this study?

A total of approximately 120 people will take part in this study at up to 4 study sites.

If the target number of subjects have already started the study just as 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 8 visits to the study clinic including a screening visit and will have 13 phone contacts over about 13 months. Each vaccination visit will take about 90 -120 minutes, each follow-up clinic visit will take about 30-90 minutes, and each phone contact will take about 15 minutes. There will be a total of 21 visits (clinic and phone contacts) as part of your participation in the trial.

Information about the study product

Vaccines serve to prepare your immune system for fighting illnesses. Certain cells of the immune system produce antibodies (special protein molecules) that recognize viruses and other pathogens (bacteria or microorganisms that can cause disease) and make them harmless. The mRNA-1893 vaccine is intended to boost the immune system to produce enough antibodies against ZIKV so that in case of an infection, the virus becomes harmless. To date no effective vaccine to prevent ZIKV has been approved.

The investigational study product, the mRNA-1893 vaccine, is designed to prevent ZIKV infection. It is based on a new process, which allows for a much quicker production of the vaccine. Typical vaccines for viruses use a weakened or killed virus, or a protein from the virus to stimulate the immune system. In the case of mRNA-1893, instead of a protein from the virus, a part of the genetic information of the virus (so called messenger RNA, mRNA) is given. This mRNA is manufactured using molecular biotechnology and carries the design for the production of a viral protein. After the vaccine is given, it can be translated into the individual protein in the cell of a human being. The immune system can detect this viral protein, and produce an immune reaction and fight the virus if it enters the human body in the future.

All subjects at each dose level will be randomly assigned to either mRNA-1893 or placebo (a saline injection that contains no active ingredients) during Visit 1 and will receive the same study treatment again at Visit 5. This random assignment will be at one of the following dosage strengths: 10 µg (microgram), 30µg, 100 µg or 250 µg, or placebo. Neither you nor your study doctor will know which study treatment you receive.

Before any study procedures are performed, you will be asked to review, sign and date this informed consent form. Signing and dating this consent form 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.

The following activities will be performed to make sure you are able to take part in the study. These activities will also be used to evaluate the safety and the effect of the study vaccines. The procedures and activities that will be performed 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, and herbal medications you are currently taking and may have taken recently in the past.

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

Vital Signs: During some clinic visits your blood pressure, temperature, heart rate (beat) and breathing rate will be measured.

Pregnancy Test: If you are a female who is able to 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 is able to get pregnant and who is sexually active, you will be asked to use birth control for at least 30 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 informed consent form. Acceptable forms for birth control include barrier method (condom, diaphragm, or cervical cap) with spermicide, intrauterine device, hormonal contraceptives in the form of a pill or patch, Medroxyprogesterone injection (Depo-Provera ®), Etonogestrel implant (Nexaplanon ®) or a male partner of a female subject who has been sterilized before entry into the study.

If you are a male subject with a female partner, you must agree to practice adequate contraception from the first vaccination and through 3 months following the last vaccination. Males must also agree to refrain from donation of sperm from the time of the first vaccination through 3 months after the last vaccination.

Blood Tests: During your visits to clinic you will provide blood samples. Blood samples collected during the course of this clinical trial will be sent to the Sponsor or external laboratories for further testing for both safety laboratories (kidney, liver, hematology [study of the blood] and chemistry assessments) as well as for the immune response (how your body reacts to foreign substances) to vaccination against Zika or other viruses in the same family. Results of this testing will be reviewed by your study doctor. If any results are concerning, you will be told the results of these tests and you will have further testing if needed. The total amount of blood collected from you during each visit will not exceed 33 mL, which is approximately 2 tablespoons. Overall, approximately 182 mL or 12 tablespoons of blood will be collected over 13 months of the study.

Vaccination: You will be given the study vaccine that was assigned to you by chance. After the vaccination, you will be asked to stay in the clinic for approximately 60 minutes so that the study doctor or his/her study staff can observe whether you have any reactions to the vaccine. During this time, the study staff will ask questions and measure your vital signs. The site will also provide you with instructions on what you should do after you leave the clinic and when you should return to the clinic.

Diary Card: You will be asked to report symptoms you might experience after vaccination and certain information about your health using a paper diary card. You will be trained on how to complete the diary card. The study staff will provide you with the diary card to take home with you. Bring the diary card back with you at the next visit.

To fill out the diary card, you will also be asked to:

- Look at your arm where you received the vaccine and measure specific reactions you may see (a ruler will be provided to you);
- Describe reactions that are sometimes seen after vaccination;
- Measure your temperature (an oral thermometer will be provided to you);
- Write down any medications you take;
- Describe any other types of reactions or illnesses that you may experience.

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

Visit	When	What will be done
Screening (in-clinic)	Before you enter the study	• Informed Consent review • Demographic data • Medical history review • Medication review • Vital signs • Physical examination • Blood sample collection including tests for hepatitis B and C, HIV West Nile Virus, dengue virus and Zika • Urine drug screen test • Pregnancy test (only if you are a female who is able to have children)
Visit 1 (in-clinic)	Day 1 (first vaccination)	• Confirmation that you may participate in the study after review of your medical history and laboratory reports • Medication review and discussion of any changes in your health since the last visit • Vital signs • Symptom-directed physical examination • Pregnancy test • Blood sample collection • First vaccination • Diary card will be provided to record any changes in your health starting the day of your vaccination for a total of 28 days • A 60-minute observation after vaccination
Visits 2 and 3 (telephone Calls)	1 and 2 days after the first vaccination	• Medication review and discussion of any changes in your health since your vaccination
Visit 4 (in-clinic)	7 days after the first vaccination	• Medication review and discussion of any changes in your health since the last visit • Symptom-directed physical examination • Blood sample collection • Your diary card will be reviewed
Visit 5 (in-clinic)	28 days after the first vaccination	• Medication review and discussion of any changes in your health since the last visit • Vital signs

	(second vaccination)	• Symptom-directed physical examination • Pregnancy test • Blood sample collection • Second vaccination • New diary card will be provided to record any changes in your health starting the day of your vaccination for a total of 28 days • A 60-minute observation after vaccination
Visits 6 and 7 (telephone Calls)	1 and 2 days after the second vaccination	• Medication review and discussion of any changes in your health since your vaccination
Visit 8 (In-clinic)	7 days after the second vaccination	• Medication review and discussion of any changes in your health since the last visit • Symptom-directed physical examination • Blood sample collection • Your diary card will be reviewed
Visit 9 (in-clinic)	28 days after the second vaccination	• Medication review and discussion of any changes in your health since the last visit • Symptom-directed physical examination • Blood sample collection • Your diary card will be reviewed
Visits 10,11,12, and 13 (telephone Calls)	About 2, 3, 4 and 5 months after the second vaccination	• Medication review and discussion of any changes in your health since the last visit
Visit 14 (in-clinic)	About 6 months after the second vaccination	• Medication review and discussion of any changes in your health since the last visit • Symptom-directed physical examination (if necessary) • Blood sample collection
Visits 15, 16, 17, 18 and 19 (telephone Calls)	About 7, 8, 9, 10 and 11 months after the second vaccination	• Medication review and discussion of any changes in your health since the last visit
Visit 20 (in-clinic)	About 12 months after the second vaccination	• Medication review and discussion of any changes in your health since the last visit • Symptom-directed physical examination (if necessary) • Blood sample collection • The site staff will inform you when results of your testing will be available

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 serum samples will be used for research 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 vaccine, assay development, and immune responses across flaviviruses. The future use of your blood samples may result in new discoveries that are important to the understanding of the vaccine(s) or flavivirus disease.

Blood samples will be collected for HIV (the virus that causes AIDS), hepatitis B and hepatitis C testing during your screening visit to determine your eligibility for participation. The study doctor may be required by law to report the result of these tests to the local health authority.

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, or changes in medication during the study
- Complete your Diary Card in full and return the completed Diary Card to the study staff after completion at your scheduled visits.

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 drug mRNA-1893 is being tested for the first time in humans. Therefore, possible side effects of the 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 or experiencing a change in your medical condition.

Following injectable vaccines, redness, swelling, pain, tenderness, and/or fever, may occur. These reactions normally last no more than 48 hours. Headache and malaise (general discomfort or illness), muscle aches, joint aches, chills, and feeling tired have also been reported in ongoing studies with similar vaccines.

Blood drawing may be associated with temporary discomfort, light-headedness, or a bruise at the needle site. Infection may occur at the needle stick site where blood is drawn, but this is very rare.

If you had an allergic reaction after being vaccinated in the past, or if you are allergic to any product you must tell the study doctor or study staff before you decide to sign and date this informed consent form. If you have an allergy to some products, you will not be able to take part in this study. Serious allergic reactions can be life-threatening.

In other studies of people receiving vaccines, 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
- Sweating
- Nausea/Vomiting
- Chills
- Rash

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 treatment 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 subjects 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 30 days before the first vaccination through 3 months after the last vaccination with the study drug. Such methods include: condoms (male or female) with spermicide, diaphragm with spermicide, cervical cap with spermicide, intrauterine device (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 trial, your participation in the study may be stopped. However, information about your pregnancy may be collected. It is important that you tell the study doctor immediately if you or your partner becomes pregnant during the study. The study doctor will talk with you about what you should do.

Men: It is not known if the study treatment may affect your sperm or an unborn child. For this reason, you must use an acceptable method of birth control from the time of first vaccination until 3 months following the last vaccination. In addition, you must agree to refrain from donation of sperm from the time of first vaccination until 3 months following the last vaccination. Periodic abstinence, declaration of abstinence, and withdrawal are not acceptable methods of contraception.

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 taking part, you will provide new scientific information that will benefit other patients in the future.

Ask the study doctor for your estimated recovery time from the study treatment or procedures done during your participation in this study.

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 Investigator 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 subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  PPD
- or call **toll free**: PPD
- or by **email**: PPD

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

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. You may receive standard treatment and no prejudice will be shown towards you for medical care or participation in future research.

If you do withdraw consent during the research project, 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 project can be measured properly and to comply with law. Data collected by the sponsor up to the time you withdraw will form part of the research project 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 drugs 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 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 properly administered investigational study product, you should call the 24-hour telephone contact number listed on the first page of this consent form. 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 wrongdoing on the part of sponsor, your study doctor, or the study center.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). 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, Inc., Inc. who is the Sponsor of this study.

Confidentiality
This 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 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, Inc., 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 study in order to accurately record information for this study. In addition, in order to review the study findings, the U.S. Food and Drug Administration (FDA), other government agencies, and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. Representatives of the Sponsor and government agencies may also observe a study visit, to check that study staff are performing the study correctly.

Statement of Consent

- I have read and understand the statements in this informed consent form
- 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 consent form
- For Men: I agree to utilize an acceptable method of birth control with my partner as outlined in this informed consent AND agree to not donate sperm from the time of first vaccination until 3 months after the last vaccination.
- For Women of childbearing potential: I agree to utilize an acceptable method of birth control as outlined in this informed consent. Should I become pregnant during my participation in the trial 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.

Subject Signature Date
Printed Name

- I presented the study and answered the subject's questions
- I will give the subject a copy of this signed and dated Informed Consent

---

Presenter (Investigator/Delegate) Signature Date
Printed Name

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 consent form, you are authorizing such access. If you do not sign and date this form 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 exam, 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 form 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 Institutional Review Board (IRB) that oversees the research study at your site.
- Government regulatory agencies including the Food and Drug Administration (FDA).

- Clinical trial 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 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 for pharmaceutical research purposes related to this study. This authorization will expire in 50 years from the date you sign it unless you revoke (cancel or withdraw) sooner. In signing this form, 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 investigator listed on page one of this informed consent. 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 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 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 Subject

_____ _____

Signature of Subject Date

- I have presented the study and answered the subject's questions
- I will give the subject a copy of this signed and dated Informed Consent

_____

Presenter (Investigator/Delegate) Signature Date
Printed Name