Moderna Therapeutics, Inc., VAL-181388-P101, v2.0_21JUN2017

Informed Consent Form

INFORMATION TO PARTICIPANTS

NAME OF STUDY:	A PHASE 1, RANDOMIZED, PLACEBO-CONTROLLED, DOSE- RANGING STUDY TO EVALUATE THE SAFETY AND IMMUNOGENICITY OF VAL-181388 IN HEALTHY ADULTS IN A NON-ENDEMIC CHIKUNGUNYA REGION
STUDY NUMBER:	VAL-181388-P101
STUDY SPONSOR:	Moderna Therapeutics, Inc. 320 Bent Street Cambridge, MA 02141
STUDY DOCTOR (INVESTIGATOR):	PPD Optimal Research 15201 Shady Grove Road, Suite 202, Rockville, Maryland 20850 PPD PPD (24 hour)
INVESTIGATIONAL REVIEW BOARD (IRB)	Schulman IRB 4445 Lake Forest Drive Suite 300 Cincinnati, OH 45242 PPD

Why are you receiving this information?

You are being asked to consider whether you would like to participate in a clinical research study. The following information describes the study and your role as a possible participant. Please read this information carefully and do not hesitate to ask your study doctor any questions to ensure that you are able to make an informed decision as to whether to participate.

What is the purpose of this clinical research study?

Chikungunya virus infection causes chikungunya and results from a bite of an infected mosquito, characterized by a rapid onset of fever, rash, myalgia, and debilitating joint pain (polyarthralgia). It is rarely fatal, but neurological conditions such as Guillain Barre syndrome and chronic arthritis have been increasingly recognized. Currently there are no effective therapies or approved vaccines to treat or prevent chikungunya, and effective mosquito control has proven challenging, even in higher income countries. Therefore, there is a need for a safe and effective preventative vaccine.

The investigational study product, the messenger RNA (mRNA)-based vaccine (in this document referred to hereafter as "VAL-181388") is being developed for prevention of disease associated with chikungunya infection.

Informed Consent Form

The purpose of the VAL-181388-P101 study is to evaluate the safety and immunogenicity of VAL-181388, a vaccine against chikungunya, in healthy adult subjects in a region not common to (non-endemic) chikungunya. The primary objective is to characterize the safety profile of VAL-181388 versus placebo. The study will also evaluate immunogenicity (the body's immune response) by assessing serum neutralizing antibody (immune reaction) titers and serum binding antibody titers to CHIKV proteins. Blood samples will be collected for these tests at planned intervals after administration of the investigational study product VAL-181388 or placebo. You will not be informed of your immunogenicity status at the end of this study.

An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA). **In this clinical trial, the investigational drug, VAL-181388, will be administered to humans for the first time.** If you receive active study drug and not placebo (a medically inactive substance), you will receive a vaccine against Chikungunya, but you might not have a medical benefit from it.

It is expected that approximately 60 subjects will be enrolled in this study.

What procedures are involved?

If you decide to participate in this study, you will be asked to make a total of 10-13 visits to the study site over the next 13 months and will have 10 phone contacts over about 14 months. Each vaccination visit will take about 90 -120 minutes, each follow-up clinic visit will take about 60-90 minutes, and each phone contact will take about 15 minutes. There will be a total of 20-23 visits (clinic and phone contacts) as part of your participation in the trial.

The study will be done in 2 parts: dose escalation = Part A; and a one-year follow-up period= Part B. If you are eligible for the study and willing to participate, you will participate in both parts of the study. Subjects who meet the criteria for study entry will be assigned to the current dose cohort and randomly (by chance) assigned to receive VAL-181388 or placebo (a dummy substance with the appearance identical to that of the study vaccine, but with no active ingredient). All doses VAL-181388 and placebo will be administered as an intramuscular (IM) injection into the deltoid muscle (the shoulder muscle). All doses will be given on an outpatient basis by the designated un-blinded (person at study site that knows what treatment you are getting) study site personnel.

If the study is paused for any reason, and there is a delay in giving the 2nd dose of study vaccine (VAL-181388 or placebo), you will be asked to continue with your regularly scheduled visits, except that you will not receive your 2nd dose. It is possible that you will not be given the 2nd dose at all, depending on how long the pause continues, but will still continue with all other visits. If you receive your 2nd dose after a pause, you may need to repeat at least one of these visits. If this does happen, your study doctor and nurse will give you details on what visits will need to be repeated at that time. You will be compensated for any repeated visits per the reimbursement schedule.

Part A (Dose Escalation)
In Part A, three cohorts (groups) will be enrolled sequentially, starting with 25ug. Dose escalation to the next treatment arm (50 or 100 µg) will occur after the blinded (treatment of each subject is kept hidden) Safety Monitoring Committee (SMC) has confirmed that it is safe to proceed to the next dose.

A total of 60 subjects will receive one of the following treatments based on the cohort in which is enrolling and the treatment to which they are randomly assigned (3:1 ratio or 3 chances to get study product to 1 chance of getting placebo):

- Cohort 1 (20 subjects): 25 µg VAL-181388 or placebo administered on Days 0 and 28.
- Cohort 2 (20 subjects): 50 µg VAL-181388 or placebo administered on Days 0 and 28.
- Cohort 3 (20 subjects): 100 µg VAL-181388 or placebo administered on Days 0 and 28.

Each cohort in Part A will be split into a sentinel safety group and Follow up group to ensure subject safety.

Sentinel Safety Group
The first four (4) subjects at teach dose level (sentinel safety group) will be randomly assigned to VAL-181388 or placebo in a 3:1 ratio (3 subjects receiving VAL-181388 and 1 subject receiving placebo). The Internal Safety Team (IST) will review blinded safety data through at least 7 days after vaccination to confirm that it is safe to proceed. The remaining 16 subjects in the cohort will also be randomized to a 3:1 ratio to complete the cohort.

Part B (Follow-up)
After completing Part A, subjects will be automatically enrolled into Part B, a continued blinded follow up period (one year from date of second injection) to monitor for longer-term safety and immune persistence. Safety contact will occur by telemedicine (eg, telephone, text, internet) every 28 days, and blood samples for immune persistence will be collected from each subject on Days 196 and 392 (days relative to first vaccination) of the study.

After Vaccinations
After vaccination, you will be kept under medical supervision for a minimum of 60 minutes before leaving the study site. You will receive a ruler, and a thermometer. Your temperature should be taken at the same time (preferably in the evening) for the first 7 days and at any other time you feel that you are feverish. For the first 7 days after each vaccination, you will also be requested to measure daily the intensity of any reactions at the injection site and provide information on a list of general symptoms that are commonly observed with vaccines. To collect this information, you will be given a Memory aid. A memory aid is a paper diary which will help you in recording possible adverse events and medications that will then be reviewed with the study staff at your next visit. You will also be provided with Memory Aids to help you to remember to write down any adverse events that happened to you between the clinic visits and the safety phone calls. You will be trained by the site staff on how to complete these study tools.

What is to be done during clinic visits for the PART A?

Screening Visit

Your personal data such as age, weight, height, gender and medical history will be assessed and the following assessments and procedures will be performed:

- If you agree to participate in this study, you will be required to sign this Informed Consent Form
- Physical examination
- Measurement of vital signs (including blood pressure, pulse, body temperature and respiratory rate)
- Blood samples will be taken for safety laboratory (including coagulation, test for hepatitis and HIV). The study doctor may be required by law to report the results of these tests to the local health authority.
- Collection of a urine sample for safety laboratory tests, drug screening and a pregnancy test for women.)
- Review of current medications you are taking.

After this the Investigator will assess your eligibility for this clinical trial.

Study Visit 1 (In-clinic visit, first vaccination)

You will come to the study site on study visit Day 1. After the study doctor has had a chance to review your medical history and laboratory reports from the screening visit and confirm you are still eligible to participate in the study, you to receive an injection of the investigational medicinal product or placebo. You will be observed for at least 60 minutes following each vaccination.

The following assessments and procedures will be performed:

- Physical examination (symptom-directed)
- Blood samples will be taken for safety laboratory
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- If you are female and of childbearing potential, a pregnancy test will also be performed. You will not be able to take part in this study if you are pregnant, breast-feeding or plan to become pregnant during the course of the study. If you are a post-menopausal woman, a hormone blood test may be performed to confirm your post-menopausal status.
- You will be assigned to a specific treatment group on Day 0 (randomization)
- Injection of the investigational medicinal product or placebo
- Blood samples will be taken to measure how your immune system reacts to the vaccine
- Measurement of vital signs (including blood pressure, pulse, body temperature and respiratory rate)
- You will be provided a paper Memory aid and a ruler and will be instructed on its use
- You will be asked to return with the diary 28 days post vaccination (Study Visit 4)
- Recording of discomfort and concomitant medication

Further visits to the study center:

Study Visit 1a and 1b (in-clinic visit)—sentinel safety group ONLY

On Days 1 and 2 (1 and 2 days post vaccination), safety cohort subjects will return to the study center and the following assessments and procedures will be performed:

- Vitals (temperature, blood pressure, heart rate and respiratory rate) will also be collected.
- Your memory aid provided during your last visit will received.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

Study Visit 2 (in-clinic visit)
This visit will occur about 7 days after Visit 1 and will include the following procedures:

- The study doctor will perform a physical exam.
- Vitals (temperature, blood pressure, heart rate and respiratory rate) will also be collected.
- Blood samples will be collected for labs.
- Your memory aid provided during your last visit will be reviewed.

Study Visit 3 (in-clinic visit)
This visit will occur about 17 days after Visit 1 and will include the following procedures:

- Blood samples will be collected for labs.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

Study Visit 3a (in-clinic visit) – sentinel safety group ONLY
This visit will occur about 21 days after Visit 1 and will include the following procedures:

- The study doctor will perform a physical exam.
- Vitals (temperature, blood pressure, heart rate and respiratory rate) will also be collected.
- Blood samples will be collected for labs.
- Your memory aid provided during your last visit will be reviewed.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

Study Visit 4 (in-clinical visit; second vaccination)
This visit will occur about 28 days after Visit 1 and will include the following procedures:

- Blood samples will be collected for labs.
- If you are female and of childbearing potential, a pregnancy test will also be performed. You will not be able to take part in this study if you are pregnant.
- The study doctor will perform a physical exam.
- Vitals (temperature, blood pressure, heart rate and respiratory rate) will also be collected before and after your vaccination.
- You will receive your second vaccination. Your memory aid provided during your last visit will be reviewed and collected.
- You will be provided with a new memory aid to take home and record any changes in health for the next 28 days.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

Study Visit 5 (in-clinic visit)
This visit will occur about 7 days after Study Visit 4 and will include the following procedures:

- The study doctor will perform a physical exam.
- Vitals (temperature, blood pressure, heart rate and respiratory rate) will also be collected.
- Blood samples will be collected for labs.
- Your memory aid provided during your last visit will be reviewed.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

Study Visit 6 (in-clinic visit)
This visit will occur about 17 days after Study Visit 4 and will include the following procedures:

- Blood samples will be collected for labs.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

Study Visit 7 (in-clinic visit)
This visit will occur about 28 days after Study Visit 4 and will include the following procedures:

- The study doctor will perform a physical exam.
- Vitals (temperature, blood pressure, heart rate and respiratory rate) will also be collected.
- Blood samples will be collected for labs.
- Your memory aid provided during your last visit will be reviewed.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

What is to be done during clinic visits for the PART B?

Study Visits 8-11 and Visits 13-18 (phone contacts)
Each safety contact in Part B will occur by telemedicine (e.g., telephone, text, internet). These phone contacts will occur at about 56, 84, 112, 140, 196, 224, 252, 280, 308 and 336 days after Study Visit 4. The call will take about 10 minutes and include the following:

- The study staff will ask you about your current medications and any changes in your health since the last visit.

Study Visit 12 (in-clinic visit)
This visit will occur about 168 days after Study Visit 4 and will include the following procedures:

- Blood samples will be collected for labs.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

Study Visit 18/End of Study (in-clinic visit)
This visit will occur about 364 days after Visit 4 (day of second dose of vaccine or placebo), or if you decide to discontinue from the study early and will include the following procedures:

- Blood samples will be collected for labs.
- The study staff will also ask you about your current medications and any changes in your health since the last visit.

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

How will blood samples be handled?

Blood samples collected during the course of this clinical trial will be sent to the Sponsor or external laboratories for further testing (kidney, liver, hematology and chemistry assessments). Excess serum will be retained and may be used for future research to investigate immune responses, activation of additional T-cell responses, or to aid in the further development of assays to better define the immune response. You will give a separate signature to consent for your samples to be used in for future research. There will also be samples taken that will be tested directly at the study site. Lab reports from the collected samples will be provided to the study doctor for review and further follow-up if needed. The Sponsor as well as third parties that are working with the Sponsor will investigate your samples only for the purposes specified in this clinical trial.

HIV and Hepatitis Testing
With the participation in this clinical trial you will be asked to give your consent to a blood test for HIV test, Hepatitis B test, and Hepatitis C test during the Screening Visit. The Investigator or a medical designee will inform you about the finding in a confidential, personal conversation. Your participation in the clinical trial is only possible in the case of a negative result of the HIV test and for the hepatitis tests. Positive HIV and Hepatitis (B and C) test results may be reportable to local health authorities according to local laws.

What are the time points for blood sampling?

Blood samples in Part A and Part B will be collected at following time points for

Part A
Day 0 - Collection of sample before dosing
Days 7, 17, 28, 35, 45 and 56; and Day 21 for sentinel safety group only

Additional blood samples taken at the following time points for

Part B:
Day 196 and Day 392

About a total of 215.5 mL (about 15 tablespoons) of blood will be collected during the entire course of the study.

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 report any new problems, illnesses, or changes in medication during the study
- Record your temperature once per day using the thermometer given to you and record your temperature in the Memory aid (preferably at same time in the evening) of each day for 7 days after injection. If several measurements are taken on the same day, you should record the highest temperature in the Memory aid. If you're feverish at any time within 28 days after any vaccine injection, you will record your temperature.
- Measure any injection site reactions daily using the ruler given to you and Record in the Memory Aid any injection site reaction (changes in size) and any medical conditions that may occur following any vaccine injections, including a list of events commonly seen with vaccines to record daily for the first 7 days. You will also have to record any treatments that you have taken during the study and any medical conditions from Day 0 to the next scheduled visit at Day 28 (Part A) or through Day 392 (Part B).

What will happen at the end of the study?

After the end of study visit, your study doctor will decide what medical treatment you should receive, if any; you will be discharged from the study at the discretion of the study doctor

What are the potential risks and discomforts?

The investigational product VAL-181388 is being tested for the first time in humans. Therefore, possible side effects of the vaccine are not fully known. In the pre-clinical animal studies with a similar mRNA-based vaccine targeting another virus, there was some microscopic damage seen in the livers of animals who received the vaccine. These changes were minimal and were seen with doses that are much higher than the doses that you could receive. In two ongoing human studies, with similar mRNA-based vaccines, some changes in liver blood tests were observed. These changes returned to normal on their own and were not associated with any

symptoms. If your liver blood test results are abnormal at screening, you will not be allowed to participate in the study. 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. Other possible reactions, which are also usually temporary, include fever, fatigue, chills, headache, muscle pain, and joint pain. 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.

As with any vaccine or drug, you may experience an allergic reaction or may have reactions, which have not been seen before. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

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 female subjects must be non-pregnant (confirmed by a negative pregnancy test at screening and before dosing) and non-lactating and meet one of the following criteria:

A) Post-menopausal (defined as not having a menstrual cycle for 12 consecutive months without an alternative medical cause or documented plasma follicle-stimulating hormone level in the post-menopausal range)

B) Surgically sterile [i.e., hysterectomy (uterus removed), bilateral (both tubes) tubal ligation, or bilateral oophorectomy (both ovaries removed)). NOTE: procedures and laboratory results must be confirmed in the medical record, by physical examination, or by official written confirmation of a procedure

C) If of childbearing potential, agrees to be heterosexually inactive from at least 21 days prior to enrollment and through 3 months after the final vaccination or agrees to consistently use any of the following methods of contraception from at least 21 days prior to enrollment and through 3 months after the final vaccination: condoms (male or female) with spermicide, diaphragm with spermicide, cervical cap with spermicide, intrauterine device, oral or patch contraceptives, Norplant®, Depo-Provera®, or other Food and Drug Administration approved contraceptive method which is designed to protect against pregnancy.

Periodic abstinence (e.g., calendar, ovulation, symptothermal, post ovulation methods) 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, data 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 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. In addition, you must continue to use contraception methods and refrain from sperm donation for 90 days after the final vaccination dose.
Periodic abstinence, declaration of abstinence for the duration of the study, 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 benefit from your participation in this trial. However, by participating in this study you will be making a contribution towards improving vaccines for adults.

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.

Who can you contact with further questions?

You may ask questions about this consent form or the study at any time (before or during the course of the study). If you have additional questions, or experience a research-related injury, contact the study doctor using the details provided in the table on the first page of this information sheet.

If you have a complaint or question about your rights as a research subject, you may contact the Schulman IRB in writing or by phone using the details provided in the table on the first page of this information sheet. This is a group of scientific and non-scientific individuals who review research studies with the safety and welfare of research subjects in mind to help protect the rights of research subjects.

What happens if you change your mind?

Your participation in this study is voluntary. You do not have to take part, and you may stop your involvement at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to leave the study before the last study visit, tell the study doctor and follow the instructions given. 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.

In addition, your study doctor or the sponsor may withdraw you from the study without your consent for your own safety, even if you wish to continue to participate, 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 competitive enrollment - the target number of subjects has entered the study.

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?

You will receive payment for participation in this study. You will receive [amount per visit] for each visit. If you do not complete the study, your payment will be paid for each study visit you do complete.
You will be paid after each visit.

If you have any questions regarding your compensation for participation, please contact the study doctor at the telephone number listed on page one of this consent document.

Will you receive compensation if you are injured as a result of the study?

If you are injured because of your participation in this study, treatment for the injury will be made available through Dr. Stephen Bart and Optimal Research. The sponsor will pay the costs of this treatment not paid by your medical insurance. No other payment is available from the sponsor or the study doctor in the event of injury. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document, accepting medical care or accepting payment for medical expenses.

Will the personnel involved in the study receive any payment?

The investigator receives payment from Moderna Therapeutics, Inc. Moderna Therapeutics, Inc. is the sponsor of this study.

Primary Care Physician / Specialist Notification

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ I do not have a primary care physician/specialist.

_____ The study doctor is my primary care physician/specialist.

What will happen to your data?

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 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) and other regulatory agencies may review your medical records. 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 this consent form, you are authorizing such access. If you do not sign 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 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:

- Moderna Therapeutics, PPD or other agents designated by Moderna Therapeutics, to collect or review study data for verification of study procedures and/or adverse event reporting.
- The Institutional Review Board (IRB) or Independent Ethics Committee (IEC) 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, for analytical purposes and so they may be compensated.

Once your information is disclosed to the study sponsors, 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 Moderna Therapeutics, who directs the medical research studies.
- To other third parties contracted by PPD and/or Moderna Therapeutics, 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 50 years from the date you sign it unless you revoke (cancel or withdraw) it 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 affects you may suffer are documented and reported. To complete the study findings, your long term health status may also be obtained from public sources.

Informed Consent Form

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 have the right to refuse to sign this authorization, which will result in my inability to participate in the study
- I understand that I will receive a copy of this signed and dated written consent form

Subject		
Printed Name	Signature	Date

- Additional consent to the use of excess serum for future research at the discretion of the Sponsor.

□ I consent to the use of excess samples to be used as described in this informed consent.
□ I do not consent to the use of excess samples to be used as described in this informed consent.

Subject		
Printed Name	Signature	Date

Person Conducting the Informed Consent Discussion		
Printed Name	Signature	Date