UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: A Phase I Safety and Immunogenicity Trial of IHV01 in HIV-1 Uninfected Volunteers

Study No.: HP-00065547

Principal Investigator: Charles Davis, Jr., M.D. (410) 706-4608

Sponsor: Institute of Human Virology

You are being asked to take part in a research study, participation is voluntary. You qualify because you are a healthy person without HIV infection. Many people around the world acquire HIV infection every year and there is no cure for this infection. Infection with many viruses is prevented by giving people vaccine. Currently, there is no vaccine to prevent HIV but we would like to test a new experimental vaccine against HIV. Before you decide if you want to be a part of this study, we want you to know about the study. This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You may ask questions at any time. It is your own choice to take part in this study. Your regular medical care will not be affected by joining this study. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

PURPOSE OF STUDY

The purpose of this study is to test how safe a new experimental vaccine against HIV is when given to healthy people. It will also test how well this experimental vaccine turns on the body's defense system (immune response) against the HIV virus. This vaccine is called "full length single chain" or "FLSC".

FLSC is a protein vaccine that looks like the structure created when the HIV virus binds to a protein on your white blood cells called CD4. This vaccine is not made from live HIV or from HIV-infected cells. There is **NO** chance that these vaccines have live HIV virus. Therefore, you absolutely **CANNOT** get HIV infection from this vaccine. FLSC will be given with alum. Alum is a substance that is commonly used in vaccines that are approved by the U.S. Food and Drug Administration (FDA) to make the body respond better to the vaccine. As FLSC has never been given to people before, the FDA has reviewed the vaccine and approved its use in this study. In this study, you will either receive FLSC or a placebo. You will receive a total of 4 injections into your upper arm muscle.

You are being asked to participate in this study because you are a healthy person without HIV infection. To participate in this study, you must be healthy and without cancer, Hepatitis B, Hepatitis C, and HIV infection. You also must be at low risk for getting infected with HIV (for example, you do not use intravenous (IV) drugs or you do not have unprotected sex with multiple partners).

How many people will take part in this study?
You will be one of 180 people asked to join this study, in order to ensure 60 finish the study.

Where will the study be conducted?
The study will be done at the University of Maryland Baltimore, Institute of Human Virology.

PROCEDURES

The study will be explained to you. After you agree to join this study and have signed this form, you will complete a screening visit to see if you are eligible to participate in the study. If you qualify for the study, you will receive 4 injections (shots) at week 0, 4, 8, and 24 of either FLSC or placebo. The placebo does not have active ingredients. The injection you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what injection you get. You will have a one in four chance of being given the placebo.

You will need to visit the study staff 15 times over 1 year (including the screening visit) as well as speaking to them over the phone 1-2 days after each injection. Each study visit will last approximately 30 minutes but the initial visit, final visit, and the injections visits will last approximately 60 minutes. The phone call will take approximately 10 minutes. At the scheduled study visits, you will have blood drawn for laboratory testing as described below. Over the entire study duration (about 1 year), you will have about 75 tablespoons of blood drawn. All study activities including the immunizations and blood draws are research activities. The details of the visits are described below:

If you are a woman of childbearing potential, you will have blood collected for a pregnancy test. The pregnancy test must be negative for you to enroll in the study. A urine pregnancy test will be performed prior to each injection (week 0, 4, 8, and 24) and at the end of the study. A negative pregnancy test will be required prior to each injection. You may also request a urine pregnancy test at any other time during your participation in the study. If you think you are pregnant you must notify study personnel immediately.

Screening Visit: 3 days to 4 weeks before the first immunization.
You will be asked for your complete medical history including: allergies, medications, past and present illnesses, and review of systems and, if needed, for consent to obtain medical records of HIV serostatus (i.e., whether you have antibody against HIV), medical/psychiatric illnesses, and substance abuse. By signing this consent form, you are giving consent for study personnel to

review your medical records for the above information. A complete physical examination, including vital signs, temperature, weight and height will be performed.

Blood tests for safety labs and immune system studies will be performed. Some blood will be stored for future tests. These tests are listed in the study flow sheet (see page 5 of this consent form) and will include an HIV test, Hepatitis C and Hepatitis B tests (viruses that can affect your liver), as well as a CD4 cell count(a type of white blood cell that helps fight off infection). Urine will be collected for urinalysis. In women, a serum human chorionic gonadotropin (HCG) assay (pregnancy test) will be performed.

Approximately 5 tablespoons of blood will be drawn at this visit. This visit will last approximately 60 minutes.

Immunization Visits: Weeks 0, 4, 8, and 24.
A follow-up medical history since the previous visit will be obtained along with a brief physical examination, if needed. A urine pregnancy test will be performed (female volunteers) prior to each injection. Blood for safety labs and immune system studies, including blood that will be stored for future tests, will be obtained.

The study vaccine will be injected into your shoulder muscle. You will be observed for 30 minutes after the injection with vital signs taken every 15 minutes. You will be given a thermometer and instructions on how to take your own temperature at home. You will also be given a diary and instructions on how to record reactions to the injection and your temperature for 7 days following the injection. You will bring the completed diary back on your next visit at which time it will be reviewed with you by study personnel.

Approximately 4-6 tablespoons of blood will be drawn at these visits. These visits will last about 60 minutes.

Follow-up Phone contact by study nurse: 24-48 hours after each immunization
The study coordinator/nurse will call you 1 to 2 days after you receive each injection to check and make sure you are not having any problems or side effects to the injection.

This phone call will last about 10 minutes.

Follow-up Visits: Weeks 2, 6, 10, 12, 16, 26, 28, 36, and 42.
A follow-up medical history since the previous visit will be obtained along with a symptom-directed physical examination. Blood for safety labs and immune system studies, including blood that will be stored for future tests, will be obtained. Your diary will be reviewed with you on the week 2, 6, 10, and 26 visits. Any changes in any conditions you may have, and changes in any medication you are taking will be reviewed and written down at each visit. If you stop taking the study injections (FLSC or placebo) for any reason, you will be asked to return to the study site for all study visits or withdraw consent from study participation.

Approximately 4 tablespoons of blood will be drawn at each of these visits except for visits at week 12 and 28 where you will have approximately 6 tablespoons of blood drawn at each visit. These visits will last approximately 30 minutes.

End of Study visit: Week 48

A follow-up medical history since the previous visit will be obtained along with a complete physical examination. Blood for safety labs and immune system studies, including blood that will be stored for future tests, will be obtained. A urine pregnancy test will be performed (females) and urine for urinalysis (everyone) will be collected at the week 24 visit. Any changes in any conditions you may have, and changes in any medication you are taking will be reviewed and written down at each visit. This visit could occur earlier than week 48 if you decide to stop participating in the study or have to be withdrawn from the study. Approximately 7 tablespoons of blood will be drawn. This visit will last approximately 60 minutes.

STORAGE OF BLOOD AND FUTURE TESTING

A portion of the blood drawn at some study visits will be frozen and stored for future clinical tests and research studies, including tests of antibodies and how your cells respond to proteins. It is possible that some of this blood will be used for tests not directly related to this study. Samples will be stored with a coded number at the Institute of Human Virology. Only the researchers will have access to them. Some samples may have studies done through Bill and Melinda Gates Foundation affiliated laboratories such as the Vaccine Research Center at NIH; the Duke Human Vaccine Center, Durham, North Carolina; Harvard's Ragon Institute, Boston, Massachusetts; Dartmouth University, Hanover, New Hampshire; and the Fred Hutchinson Cancer Center, Seattle, Washington as these laboratories have the most expertise in performing the needed research tests. All samples sent to these labs will only have the coded number on them and no personal information. These tests may not be done for several months, and it is possible these studies may never be performed. Research results will not be communicated directly to you or your provider.

You may call the IHV at 410.706.1684 any time in the future and withdraw your consent for future testing of the stored samples. These specimens will not be destroyed if you withdraw from the study. Information gathered from the results of these specimens may be published in the medical literature; however, your identity will remain confidential.

Please note and initial below whether you agree to the use of your extra blood.

_____ _____ I **AGREE** to have my blood stored and used for future research.
Initials Date

_____ _____ I **DO NOT agree** to have my blood stored and used for future research.
Initials Date

STUDY SCHEDULE

You can see below the schedule for this study:

STUDY VISIT	**0**	**01**		**02**	**03**		**04**	**05**		**06**	**07**	**08**	**09**		**10**	**11**	**12**	**13**	**14**[3]
STUDY DAY	**-30 TO –3**	**0**	**1-2**	**14**	**28**	**29-30**	**42**	**56**	**57-58**	**70**	**84**	**112**	**168**	**169-170**	**182**	**196**	**252**	**294**	**336**
STUDY WEEK	**-4 TO 0**	**0**		**2**	**4**		**6**	**8**		**10**	**12**	**16**	**24**		**26**	**28**	**36**	**42**	**48**
Informed Consent	X																		
Immunization		**X**			**X**			**X**					**X**						
Complete Medical History and Physical Examination	X																		X
Interval Medical History and Directed Physical Examination		X		X	X		X	X		X	X	X	X		X	X	X	X	
Phone Interview			X			X			X					X					
Dispense diary		X			X			X					X						
Monitor Adverse Events		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood for Screening Labs: CBC with diff Serum Chemistry, LFT's PT/PTT Hepatitis B Surface Antigen Hepatitis C Antibody[1] CD4 cell count HIV-1 RNA PCR HIV-1 ELISA/Western blot	X																		X
Pregnancy Test (serum)	X																		
Pregnancy Test (urine)		X			X			X			X		X						X
Urinalysis	X																		X
Blood for Safety Labs: CBC with diff Serum Chemistry, LFT's CD4 cell count HIV-1 RNA PCR[2]		X		X	X		X	X		X	X	X	X		X	X	X	X	
Blood for Serologic Assays/Serum storage	X	X		X	X		X	X		X	X	X	X		X	X	X	X	X
Blood for Cellular Immune Response Assays	X	X		X	X		X	X		X	X	X	X		X	X	X	X	X
Total blood volume(ml)	75 ml	64 ml	X	64 ml	84 ml	X	64 ml	84 ml	X	64 ml	84 ml	64 ml	90 ml	X	64 ml	94 ml	64 ml	64 ml	102 ml
Approximate Visit Duration (minutes)	60	60	10	30	60	10	30	60	10	30	60	30	60	10	30	30	30	30	60

Footnotes: All study activities are for research not clinical care.

1. If positive Hepatitis C antibody and documentation of negative Hepatitis C PCR can be provided, the volunteer may enroll
2. HIV RNA PCR will be performed at the screening and end of study visit. Blood will be stored for the PCR at subsequent visits but the assay will not be performed unless there is a concern for acute infection.
3. Visit 14 procedures will also be carried out in the case of early withdrawal/discontinuation.

STUDY VISIT	**0**	**01**		**02**	**03**		**04**	**05**		**06**	**07**	**08**	**09**		**10**	**11**	**12**	**13**	**14[3]**
STUDY DAY	**-30 TO –3**	**0**	**1-2**	**14**	**28**	**29-30**	**42**	**56**	**57-58**	**70**	**84**	**112**	**168**	**169-170**	**182**	**196**	**252**	**294**	**336**
STUDY WEEK	**-4 TO 0**	**0**		**2**	**4**		**6**	**8**		**10**	**12**	**16**	**24**		**26**	**28**	**36**	**42**	**48**
Immunization		X			**X**			**X**					**X**						
Blood for Screening Labs: CBC with diff Serum Chemistry, LFT's, PT/PTT CD4 cell count HIV-1 RNA PCR	X																		X
Blood for Safety Labs: CBC with diff Serum Chemistry, LFT's CD4 cell count HIV-1 RNA PCR[2]		X		X	X		X	X		X	X	X	X		X	X	X	X	
Pregnancy Test (serum)	**3 ml**																		
CBC with diff	**3 ml**	**3 ml**		**3 ml**	**3 ml**		**3 ml**	**3 ml**		**3 ml**	**3 ml**	**3 ml**	**3 ml**		**3 ml**	**3 ml**	**3 ml**	**3 ml**	**3 ml**
Serum Chemistry, LFT's,	**3 ml**	**3 ml**		**3 ml**	**3 ml**		**3 ml**	**3 ml**		**3 ml**	**3 ml**	**3 ml**	**3 ml**		**3 ml**	**3 ml**	**3 ml**	**3 ml**	**3 ml**
PT/PTT	**3 ml**																		3 ml
HIV-1 RNA Quantitative PCR[2]	**5 ml**	**5 ml**		**5 ml**	**5 ml**		**5 ml**	**5 ml**		**5 ml**	**5 ml**	**5 ml**	**5 ml**		**5 ml**	**5 ml**	**5 ml**	**5 ml**	**5 ml**
HBsAg, Hep C Ab	**5 ml**																		
HIV-1 ELISA/Western blot	5 ml												5 ml						5 ml
CD4 cell count	**3 ml**	**3 ml**		**3 ml**	**3 ml**		**3 ml**	**3 ml**		**3 ml**	**3 ml**	**3 ml**	**3 ml**		**3 ml**	**3 ml**	**3 ml**	**3 ml**	**3 ml**
PBMC stored	30 ml	30 ml		30 ml	50 ml		30 ml	50 ml		30 ml	50 ml	30 ml	50 ml		30 ml	50 ml	30 ml	30 ml	50 ml
Serum stored	15 ml	20 ml		20 ml	20 ml		20 ml	20 ml		20 ml	20 ml	20 ml	20 ml		20 ml	30 ml	20 ml	20 ml	30 ml
Total blood volume(ml)	75 ml	64 ml	X	64 ml	84 ml	X	64 ml	84 ml	X	64 ml	84 ml	64 ml	90 ml	X	64 ml	94 ml	64 ml	64 ml	102 ml

Total Study Blood Volume (over 48 weeks): 1125 ml

Footnotes:

2. HIV RNA PCR will be performed at the screening and end of study visit. Blood will be stored for the PCR at subsequent visits but the assay will not be performed unless there is a concern for acute infection.

3. Visit 14 procedures will also be carried out in the case of early withdrawal/discontinuation.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?
If you take part in this research, you will have to follow study visits and instructions from the study staff:

- Follow the instructions given to you.
- Tell your doctor or study staff about any changes to your health or new medicines.
- Tell your doctor or study staff if you want to stop being in the study at any time.
- Tell your doctor or study staff if you think you are pregnant.

POTENTIAL RISKS/DISCOMFORTS:
Risks with Immunization
You may experience minor pain and/or bruising at the injection site of the immunizations. Localized bleeding or bruising, irritation, infection, light-headedness and/or fainting may, but rarely occur.

In receiving FLSC or placebo, you may experience pain at the injection site for up to 48-72 hours. Other possible reactions are rash at the injection site, muscle aches, fever, chills, diarrhea, abdominal pain, nausea, headache, fatigue or flu-like symptoms. As with all vaccines or drugs, you could also have an allergic reaction (rash, hives, or even difficulty breathing) which could be serious or even life-threatening. This is why you will be watched for 30 minutes after each immunization. Allergic reactions can occur whether you receive the actual vaccine or the placebo. If you have any of these reactions it does not mean you received the actual vaccine. These side effects usually don't last long and people usually don't need to be treated for them.

Alum is a substance containing aluminum hydroxide and saline (a salt water solution) that helps to stimulate your immune system. It is currently, and has in the past, been used in many of the licensed vaccines available around the world. You may experience pain at the injection site, rash, muscle ache, fever, or flu-like symptoms when you receive an injection of alum. Similar symptoms may be noted when you receive an injection of the placebo, saline (salt water).

If you are assigned to the FLSC group, this means that you will be receiving the experimental HIV vaccine. As such, your body's defensive response to the virus may be different from a person who has never been vaccinated. This would make it very hard for you to take part in any future HIV vaccine trials. Also, because your blood test may show presence of infection fighting proteins (antibodies) against HIV-1, you would not be permitted by a blood bank to donate blood in the future.

Risks from a Partial Positive HIV Antibody Response
The FLSC vaccine may cause the formation of proteins that block HIV (antibodies). This means you will likely have a positive screening blood test for HIV. You are not actually infected, because the vaccine does not contain HIV. Rather, and in your case, a positive antibody test only means that your immune system responded to the FLSC vaccine. The Principal Investigator will provide you with a letter/card that explains your participation in the study if you ask for it.

You should know that there are potential legal and social implications to a positive HIV-1 antibody test. Difficulty may be encountered in obtaining life insurance, donating blood, traveling to other countries, gaining employment, and during hospitalization. Other tests should be able to distinguish between the positive antibody test that develops following immunization with this vaccine and true HIV infection. However, the investigators in this study can make no guarantee that a positive HIV antibody test in the future will not be used against you. If your screening test for HIV is positive, you will be given a letter/card at the end of the study that will describe the antibody response you have had to the vaccine. This should be sufficient evidence for doctors and other persons concerned with your health matters to understand that your antibody response is the result of vaccination and is not a true HIV infection. However, the doctors who are involved in the FLSC study can make no guarantee that others reviewing this data will do so correctly. If any antibody response to HIV develops it is not known how long a person will remain positive by the standard HIV test.

Theoretical Risks of Immunization with FLSC
There is a theoretical risk that the infection fighting proteins (antibody) that are formed as a result of this vaccine may actually make it easier for HIV to infect you if you are ever exposed to the virus (for example, sex or drug use). While this occasionally has occurred with other viruses, this has not been the case in persons having received HIV-1 vaccines similar to those used in this study.

As the FLSC protein is designed to look like the structure that occurs when the HIV virus binds to a protein on the human cell called "CD4", it is possible that antibodies to a structure on your CD4 cells could develop. This could possibly cause your CD4 cell count to decrease, which could weaken your immune system. However, we do not believe that this will happen, as studies done in the past giving human CD4 to people did not cause any changes in the CD4 count. We will be monitoring your CD4 cell count closely in this study to look for this effect.

Risks of drawing blood
Drawing blood may cause pain, bleeding, and bruising where the blood is drawn. Sometimes, there is swelling in the area where the needle enters the body, and there is a very small risk of infection. There is also a risk of lightheadedness, fainting, and blood clots.

Risks of loss of confidentiality
There is always a risk for loss of confidentiality. This risk will be minimized by assigning you a special study code number to refer to all your information and blood samples. We will also keep your research records in a secure area and keep all study information private. Electronic data will be password-protected. We will only give out information listed in the Health Insurance Portability and Accountability Act (HIPAA) form if absolutely necessary. The HIPAA form is a document stating which part of your personal health information you will allow to be used and who will be allowed to use it.

Other Risks
There may be risks in this study which are not yet known.

It is important to immediately report any of the above mentioned side effects and/or any side effects you may have to the study doctor or coordinator.

ARE THERE RISKS RELATED TO PREGNANCY?
The effects that this injection/vaccine may have on a developing baby or the development of your ovum (eggs) are unknown. You may not participate in this study if you are pregnant, breastfeeding, or intend to become pregnant during the study. It is recommended that you use two types of birth control (for example, oral contraceptives, diaphragm, cervical cap, or female condom) during sexual intercourse or your partner should use a condom.

WHAT IF I BECOME PREGNANT DURING THIS STUDY?
If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are not known. There have been no studies of FLSC in pregnant women. If you become pregnant while on this study you will be stopped from further immunizations in the study. You will continue to be followed by the study doctor until the end of your pregnancy.

Breastfeeding
It is not known whether the study drug passes through the breast milk and may cause harm to your baby. You must not breast-feed if you are in this study.

POTENTIAL BENEFITS
There is no guarantee that you will receive direct benefit from your participation in this study. FLSC is experimental and has no proven benefit, but it has the potential to stimulate your immune system to provide antibodies against HIV. However, your participation in this study will provide important information about the safety and usefulness of this and similar vaccines to prevent HIV.

ALTERNATIVES TO PARTICIPATION
This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS
The study procedures like study visits with the doctor and staff, health check-ups, and blood tests, will be done for free. The sponsor will supply the study vaccine.

Should injury occur due to participating in this research study, the study personnel will help you seek appropriate medical care and treatment. It is possible that taking part in this study may lead to added costs to you and your insurance company. In some cases, it is possible that your

insurance company will not pay for these costs because you are taking part in a research study. We will not pay for these extra costs.

PAYMENT TO PARTICIPANTS
Compensation will be provided to cover travel and expenses. You will be compensated as follows:

Screening Visit: $125
Blood draw Visits $125
Vaccine Visits: $200
Phone Call Visits: $25
Final Visit if complete all visits: $350

There are 15 total visits and 4 phone call visits for a total of $2500 if you complete all of the study visits. You will be responsible for reporting this income to the Internal Revenue Service (IRS) if you receive $600 or more in a calendar year.

CONFIDENTIALITY AND ACCESS TO RECORDS
We will do everything we can to protect your privacy and personal information (including research study and medical records). We will store research data in a secure place in a locked office/cabinet and password-protected computer in the Institute of Human Virology. We will only let people who have a need to review this information see it. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Efforts will be made to limit access to your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization, the Food and Drug Administration, Profectus Biosciences, and the Bill and Melinda Gates Foundation.

The data from this study may be published, but you will not be identified by name. People from the institution where the study is being conducted may be allowed to see sections of your medical and research records related to the study. However, everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.

To help us protect your privacy, we will obtain a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: suspected child abuse or intent to hurt yourself or others.

If you test positive for HIV or Hepatitis B, the results will be reported as required by state law. This does not include partial positive HIV antibody responses as indicated in the "*Risks from a Partial Positive HIV Antibody Response"* section above.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Charles Davis Jr., M.D., at 410-706-4608 during the day or 301-775-7618 at night.

If you withdraw from this study, there will be no adverse consequences (physical, social, economic, legal, or psychological) from your decision. If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether we can collect data from your routine care. If you agree, this data will be handled the same as research data.

You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

CAN I BE REMOVED FROM THE RESEARCH?

The study doctor, Charles Davis, can decide to remove you from the study at any time. You could be removed from the study for reasons related to you (for example, not following the study directions, an illness occurs that would interfere with the results of the study, or you have a serious reaction during the study).

Also, the entire study could be stopped by the study doctor, Institutional Review Board, the facility where the study is carried out, a Data Safety Monitoring Board, Profectus Biosciences (the company that makes the vaccine) or the University of Maryland. The study doctor will tell you about this, and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. **If you incur uninsured medical costs, they are your responsibility.** The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members

of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
620 W. Lexington Street, Second Floor

Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____	_____
Investigator or Designee Obtaining Consent Signature	Witness
Date:_____	Date:_____