INFORMED CONSENT

TITLE: Phase 2a Double-Blind, Randomized, Parallel Group, Dose-Ranging Study to Assess the Safety and Efficacy of Three Doses of TVGV-1 Vaccine Compared to Its Adjuvant, GPI-0100, in Subjects with Histologically Confirmed HPV Induced Cervical High-Grade Squamous Intraepithelial Lesions (HSIL)

PROTOCOL NO.: VAX 02-01

SPONSOR: THEVAX Genetics Vaccine USA, Inc.

INVESTIGATOR: Kelle Oberle, MD

TELEPHONE: (303) 763-5111 - 24-hour number
(303) 985-9100 - office number

INTRODUCTION

You are being asked to participate in a research study with a new, experimental vaccine. Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed research study. Ask questions, and be sure you get answers before going forward with the study. This consent document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you. It explains your right to withdraw from the study at any time and how your data and information will be maintained confidentially. No guarantees or assurances can be made as to the results of the study. You will be given a copy of this signed document, called the Informed Consent.

If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study.

Schulman Institutional Review Board (Schulman) has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

WHO IS DOING THE RESEARCH

The research is being conducted by the study doctor listed on page one of this document. Your study doctor is being paid by THEVAX Genetics Vaccine, USA, Inc. to conduct this study.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have been diagnosed with cervical human papillomavirus (HPV), which has led to cervical changes, including precancerous cells on the cervix.

HPV is a common sexually transmitted disease. Recent data from the Centers for Disease Control (CDC) in the USA, estimate that approximately 79 million Americans are currently infected with HPV, and 14 million persons are newly infected each year in the US (as of March 2014). Roughly 90% of HPV infections are cleared by the person's own immune system within 2 years and cause no harm. The most common symptoms or signs of HPV infection are genital warts (which are not harmful and don't cause cancer) and cervical dysplasia.

However, constant HPV infection can lead to the following:

1. Dysplasia: This means there are changes in the lining cells of the cervix. This is the first earliest form of cell changes that can be observed. The cell changes are 'pre-cancerous', which means there is a greater likelihood of cancer occurring, if left untreated. These changes can be described as low grade or high grade.

2. Premalignant: This is the next stage of dysplasia, and the cells are poised, or ready, to become cancerous, but it hasn't happened yet.

3. Malignant: Changes have caused cancer. Cervical cancer is always proceeded by high-grade cervical dysplasia.

Cervical intraepithelial neoplasia (CIN) is a general term for potentially precancerous cell changes on the cervix. It is grouped into 3 categories according to the degree of dysplasia; mild (CIN1), moderate (CIN2), and severe dysplasia (CIN3). The World Health Organization estimates that every year in the US one million new cases of HPV-related low-grade dysplasia (CIN1) occur, and 300,000 new cases of high-grade dysplasia (CIN2+) are diagnosed.

The current terms used for these types of cervical cell changes are High Squamous Intraepithelial Lesions (HSIL) for CIN2/3, and Low Squamous Intraepithelial Lesions (LSIL) for CIN1. The standard of care for people with persistent HSIL lesions is excisional (cutting; removal by surgery) or ablative (burning by laser) therapy. There have been confirmed findings that excisional treatment is associated with significantly increased risk of preterm birth. Researchers are looking for non-surgical ways to treat HSIL. One of those ways would be to develop a vaccine to treat high grade lesions. There are vaccines that work to prevent HPV infection, but are not likely to eliminate pre-existing HPV-associated lesions.

The purpose of this research study is to test the safety and effectiveness of the investigational study vaccine, called TVGV-1. The study will test the vaccine in women with high grade HPV cervical infection.

If you participate in this study, you will be followed closely by the study doctor and staff. This will require frequent visits to the clinic, blood tests and gynecological (GYN) exams and tests. This is explained in detail in the following pages. It is important to note that while you are in the study, you should not have any other GYN procedures done. You may give permission for your study doctor to discuss your care with your primary healthcare doctor (if they are not the same). At the end of the study, you will be seen by your primary healthcare provider or your study doctor for standard care that will include procedures listed in the section below, entitled 'End of Study Procedures'.

INFORMATION ABOUT THE INVESTIGATIONAL VACCINE, INVESTIGATIONAL ADJUVANT AND PLACEBO USED IN THIS STUDY

This is a research study to test a new investigational vaccine, TVGV-1 given with GPI-0100 (called TVGV-1 through the rest of the document). An investigational vaccine is one that is not approved by the United States Food and Drug Administration (FDA). The FDA is allowing this research study to be done with TVGV-1.

- TVGV-1 is made up of proteins that are targeted to treat the HPV infection.
- GPI-0100 is an adjuvant, which is used to help boost the vaccine's ability to work with your immune system (which works to protect you from, or fight off diseases).
- A placebo is an inactive substance, and not meant to work with or against your immune system. The placebo is made up of the inactive components of the experimental vaccine mixed with sterile water.

Both TVGV-1 and GPI-0100 have been given together in clinical studies in humans before this study, and GPI-0100 has been used as an adjuvant in other human clinical studies. The doses of TVGV-1 are slightly different than in the earlier study. The placebo is used to control, or prove, the vaccine results. You will be randomly assigned by chance (like the flip of a coin) to receive either TVGV-1 with adjuvant, GPI-0100 adjuvant alone, or placebo (neither TVGV-1 nor GPI-0100).

The investigational vaccine, adjuvant or placebo will be given with a small needle subcutaneously (under your skin) on your front thigh area. The effects will be monitored by following you closely throughout the study, with visits to the study center and blood and cervical tests.

This study will have three groups of 17 women each in 0.6 mg, 0.9 mg or 1.2 mg cohort where:

- 12 will receive one of three doses of the vaccine TVGV-1
- 4 will receive GPI-0100 adjuvant only
- 1 will receive placebo only (neither TVGV-1 nor GPI-0100)

This is a double-blind, randomized, parallel group study. That means that no one directly involved in the study will know which vaccine group you are in, and won't know if you receive the vaccine or placebo; not the doctor, nurses or you. This information will be available at the end of the study and the study doctor can get the information if there is an emergency.

Because this is a research study, the study product TVGV-1 with GPI-0100, GPI-0100 alone or placebo will be given to you only during this study, and not after the study is over.

NUMBER OF SUBJECTS / LENGTH OF PARTICIPATION

This study is being done at several sites. About 51 female subjects, ages 18 – 55, will participate in this study. Participation in this study will last approximately 270 days. The screening process will occur during one or more visits at the study center. After you are enrolled in the study, there will be 13 study visits at the study center. You will participate in the study for approximately 43 weeks; this includes up to a 4-5-week screening period, a 4-week period for receiving the investigational vaccine, and approximately 35 weeks of observation after administration of the investigational product (TVGV-1, GPI-0100 alone, or placebo).

PROCEDURES

1. Study Explanation and Informed Consent: Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. Signing this consent document follows the study staff explanation of the study, and having all your questions answered.

   Before entering the study, you may have heard much of the background information above from your regular doctor or clinic. This is because you may have already been told you have HPV16 and high grade cervical dysplasia. This study will need confirmation of that diagnosis, through a copy of the lab report and/or doctor's note, from the previous 12 week period.

2. Screening period: Prior to the active study period, there is a four week screening period during which time baseline testing will be completed and eligibility criteria confirmed. The entry criteria will rely on the following tests and procedures being performed to determine if you qualify to take part in this study:

   - Gynecologic exam with colposcopy, which uses light and magnification to better see the cervix. The study staff may take samples of cells from the cervix with a swab or brush and/or a sample of tissue through a biopsy. The cell samples may come from the part of the cervix that meets the vagina or further in, where it meets the uterus. The tissue biopsy is collected in between those two areas. A local anesthetic may be used during the procedure.

     1. The study requires a positive HPV type 16 from cervical cells and HSIL from a cervical tissue sample within 12 weeks of entering the study.

     2. If you've had these tests done within the past 12 weeks, the study doctor may not need to repeat them. The study staff will request your permission to send the tests to a study specific lab for confirmation.

     3. If you haven't had them done in the past 12 weeks, the study doctor will take samples for cells and a small tissue sample, or biopsy. The samples are to test what type of HPV you have, and to see if the dysplasia is a low or high grade finding.

- Electrocardiogram (ECG): A painless procedure that uses electrodes attached to your chest to measure your heart's health.
- Blood and urine tests to be sure you are healthy enough to be in the study.
- Medical history and physical exam to be sure you are healthy enough to be in the study.

3. Study Enrollment: The study staff will notify you after all of the screening tests are done. If you are eligible, you may be enrolled in the study.

STUDY DAY/EVENT SCHEDULE

Visit*	Study Day	Study Event
Screening	-35	• Initial Screening visit • Blood draw for pregnancy test and for safety and research testing • Urine for pregnancy test and drug screen • ECG • GYN exam with colposcopy, biopsy and cervical cytology
Visit 1A	-7 to -5	• Urine pregnancy test • Blood draw for pregnancy test
Visit 1	0	• Urine pregnancy test • Blood draw for pregnancy test and for safety and research testing • Administration of the first investigational product dose, and 4 hour post vaccination observation • Provide diary and instructions
Visit 2	5	• Follow-up visit • Diary review • Urine pregnancy test • Blood draw for pregnancy test and for safety and research testing
Visit 3	7	• Diary review • Urine pregnancy test • Blood draw for pregnancy test and for safety and research testing • Administration of the second investigational product dose, and 4 hour post vaccination observation

Visit 4	12	• Follow-up visit • Diary review • Blood draw for safety and research testing
Visit 5A	22	• Urine pregnancy test • Blood draw for pregnancy test
Visit 5	28	• Diary review • Urine test for pregnancy • Blood draw for pregnancy test and for safety and research testing • Administration of the third investigational product dose, and 4 hour post vaccination observation
Visit 6	33	• Follow-up visit • Diary review and new diary given with instructions • Urine pregnancy test • Blood draw for pregnancy test and for safety and research testing
Visit 7	75	• Follow-up phone call, diary review
Visit 8	120	• Diary review • Urine test for pregnancy and safety • Blood draw for pregnancy test and for safety and research testing • GYN exam with colposcopy. Cells and tissue may be taken for testing, if the PI decides it's necessary
Visit 9	165	• Follow-up phone call, diary review
Visit 10	210	• Diary review • Blood draw for pregnancy test and for safety and research testing • Urine test for pregnancy and safety, ECG • GYN exam with colposcopy, with cells and tissue taken for testing

Visit 11	270	• Diary review and turn-in • ECG • Urine test for pregnancy and safety • Blood draw for pregnancy test and for safety and research testing • Through your healthcare provider: GYN exam with colposcopy with cells and tissue taken for testing • Standard of care surgical intervention, as determined by the study physician: e.g. LEEP, CKC, hysterectomy

* You may be asked to come in for additional study visits if your study doctor feels it is in your best interest.

EXPECTATIONS

If you participate in this study, you will be expected to attend each visit and complete all the procedures described below:

Medical History: A detailed history concerning your health (any diseases or health problems, surgeries and GYN information) will be done at your screening visit. This includes all of your current medications and if you previously received an HPV vaccination. It is important for your safety to be completely truthful with your study doctor about your health history.

Vital Signs: Vital signs, including blood pressure, heart rate, and body temperature will be taken at all study visits.

Physical Examination: A physical examination will be done at the screening visit, visit 11, and if at any time you have an adverse event (which is an unexpected or undesirable experience, whether or not it is due to the experimental vaccine).

Gynecologic Exam: A colposcopic examination of your cervix will be performed at screening, visits 8 and 10 for safety evaluation, and visit 11 to evaluate your response to the vaccination. During these exams, the study staff may take samples of cells from the cervix with a swab or brush and a sample of tissue through a biopsy. The cell samples will come from the part of the cervix that meets the vagina and further in, where it meets the uterus. The tissue biopsy is collected in between those two areas. A local anesthetic may be used during the procedure.

Testing will be done on these samples at both a local and a study specific laboratory. Samples sent to the study laboratory may have personally identifiable information on them, but all that information will be removed upon receipt, before the samples are evaluated. With your permission, samples remaining after testing will be saved for potential future use. Any future use of these samples will require an approved protocol; you will not be notified of the use.

I consent to having my remaining tissue samples stored for future use:

[ ] No

[ ] Yes

Concomitant Medications: You will be asked at each visit to list and reconfirm any medications other than the vaccination taken during the study, including all over the counter medications, vitamins and nutritional supplements.

Height and Weight: Body weight without coat and shoes and height without shoes will be recorded at the screening visit, visits 10, and 11.

Blood Draw: Blood samples will be drawn at the screening visit, and visits 1A, 1, 2, 3, 4, 5A, 5, 6, 8, 10 and 11 (approximately 10 – 78 mL, or 2 teaspoons – 1/3 cup). The blood tests will be done to find out if you have certain diseases, such as Hepatitis and HIV, and to check your overall health throughout the study. Some blood will be drawn for a pregnancy test in order to confirm that you are not pregnant. Some of the blood samples will be used to check to see how well your body is responding to the study vaccine. All of the samples will be identified only with your study number, and not your name.

With your permission, samples remaining after testing will be saved for potential future use. Any future use of these samples will require an approved protocol; you will not be notified of the use**.**

I consent to having my remaining blood samples stored for future use:

[ ] No

[ ] Yes

Pregnancy Testing: Women of child bearing potential will have both urine and blood pregnancy testing during screening and at visits 1A, 1, 2, 3, 5A, 5, 6, 8, 10, and 11. Women with a hysterectomy (greater than 2 months from the start of the study) or who are post-menopausal (greater than 12 months from the start of the study) will not need to have pregnancy testing.

Urinalysis: You will be asked to provide a urine sample at the screening visit and visits 8, 10, and 11 to make sure that you are healthy.

Drug Test: A urine drug test will be completed at the screening visit. If you test positive, you may not be enrolled into the study.

Electrocardiogram: An ECG is a painless procedure that uses electrodes placed on your chest to record or display your heart's electrical activity and heartbeat and it will be performed at the screening visit and visits 10 and 11.

TVGV-1, GPI-0100 alone or Placebo Injection: The dose is administered with a small needle under the skin in the front of your thigh at visits 1, 3, and 5.

Inspection of Injection Site Reactions: You will remain at the study site for up to four hours following each vaccination injection (given on visits 1, 3 and 5). Injection sites will be checked during that time and at each follow-up visit. If you have a reaction at the injection site, your study doctor may want to take a picture of it. The picture will only be identified with your study number, not your name.

Subject Diary: You will be provided with a subject diary to record any adverse events (health related problems or side effects) between study visits.

Follow up Phone Call: You will be called by the study coordinator to check for any adverse events, changes in medical history, or changes in medications for visits 7 and 9.

Unscheduled Visits: You are asked to return to the clinic for evaluation if you develop symptoms or signs of illness and need to be evaluated between scheduled visits. Additional medical history, physical examination, and lab tests may be completed if found necessary by the study doctor. The cost of unscheduled visit(s) is covered by the study sponsor. Unscheduled visits will take place at the same clinic where the study is performed.

After enrolling in the study, if you need to go to a hospital emergency room or urgent care center, inform them you are in a study and receiving an investigational vaccine. Also let your study doctor know that you went to an emergency room or urgent care center.

END OF STUDY PROCEDURE(S); VISIT 11 (STUDY DAY 270)

The effectiveness of the vaccine is measured from cervical tissue samples. The regression from High Cervical Intraepithelial Lesion (HSIL) to Low Cervical Intraepithelial Lesion (LSIL), or less, will be assessed by samples taken during the final visit. The study physician will determine if you need a definitive treatment such as LEEP, CKC or hysterectomy based on the pathological finding from a biopsy.

Your primary healthcare provider or the study doctor will do a GYN colposcopic exam in their office and follow with their usual standard of care. This is the same care you would receive if you were not in a clinical research study. Per their recommendation, your healthcare provider or study doctor may do one of the procedures explained below. Note that the costs associated with the standard-of-care are not covered by the study, unless otherwise described below.

The standard procedures are one of the following (as determined by the treating physician):

- **Loop Electrosurgical Excision Procedure (LEEP):** LEEP is one of the most commonly used approaches to treat high grade cervical dysplasia (CIN II+/III, HSIL). A thin wire that acts like a surgical knife is used to remove the abnormal tissue in the cervix. LEEP may be performed at the end of the study (9 months) as determined by the study physician. The LEEP procedure is done in your health provider's or study doctor's office. Costs for the LEEP procedure will only be covered by the study if you do not have medical insurance or if your insurance does not pay the total cost of the LEEP, the Sponsor will cover the difference. Otherwise, the costs for the LEEP must be submitted to your private medical or government insurance plan.

- **Cold Knife Conization (CKC):** Cold knife cone biopsy is a surgical procedure used to remove tissue from the cervix. This procedure removes a large, cone-shaped piece of the cervix to look for precancerous cells or cancerous material. Cold knife cone biopsy is performed under a general or regional anesthetic. The surgeon uses a scalpel or a laser to remove the cervical tissue. The CKC procedure is done in a hospital. Costs for the CKC procedure will not be covered by the study.

- **Hysterectomy:** Although Loop Electrosurgical Excision Procedure (LEEP) and Cold Knife Conization (CKC) are the most common treatments for HSIL, occasionally, if a LEEP or CKC is not appropriate or the woman has additional gynecological problems, a hysterectomy may be advised by your treating physician. This surgery is performed under a general anesthetic and involves the removal of the cervix and the uterus. The hysterectomy procedure is done in a hospital operating room. Costs for the hysterectomy procedure will not be covered by the study.

RISKS, SIDE EFFECTS AND/OR DISCOMFORTS

RISKS OF TVGV-1

TVGV-1 with GPI-0100 has been used in a Phase I study to check safety in 15 healthy women. The most common adverse events were those involving the injection site including: swelling, redness, discoloration, injection site bleeding, itching, and pain. Most of the reactions were mild to moderate with one subject reporting a severe redness reaction.

RISKS OF STUDY PROCEDURES

Risks are addressed by using trained medical staff, close observation and contact with you throughout the study. You will receive a card that details your study participation and contact information for the study staff.

- Blood samples: Possible side effects from blood drawing include feeling faint, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

- ECG: Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used.

- Gynecology Exam/Colposcopic examination with Biopsy: Spotting or a small amount of bleeding is normal. Follow your study staff's instructions, but in general, if bleeding does occur, you may use sanitary pads, but not tampons. Avoid intercourse and vaginal douching or medications for at least 24 hours before and after your exam. Also, as with any surgical procedure, infection, heavier bleeding and pelvic pain may occur. If you are allergic or sensitive to iodine, please let us know.

- HIV Testing: Confidentiality, as results will be reported to the local health department.

- Drug Testing: Confidentiality

- LEEP and CKC: Infection of cervix or uterus (rare), narrowing of the cervix which can cause infertility, and higher risk of delivering a baby early.

- Anesthesia: There are potential risks with the use of anesthesia. Anesthetics are used to reduce or eliminate the amount of pain felt during certain procedures. Different doctors prefer certain anesthetics, so information about anesthesia, and its potential risks, will be shared with you by the study team or your physician.

If you receive placebo, your condition will not be treated with active medication and may become worse, stay the same or improve.

UNFORESEEN RISKS

Since the study vaccine is investigational when taken alone or in combination with other medications, there may be other risks that are unknown. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening.

PREGNANCY / BIRTH CONTROL

A recent study in both rabbits and rats was done to assess potential risks of the vaccine to a pregnant mother, the embryo/fetus or the newborn fetus. At all doses of the vaccine tested in rabbits there were no changes seen when compared to rabbits who received a placebo injection. However, in the highest dose studied in the rat there were changes in the embryo that are a risk to adversely impact embryo development. Thus, taking the study vaccine may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot participate in this study.

In order to reduce the risk of pregnancy, you must use an effective method of birth control while you are participating in this study and through one menstrual cycle after the end of the study or early withdrawal. Acceptable methods include intrauterine device (a contraceptive device fitted inside the uterus), double barrier method, or hormonal contraceptive combined with a double barrier method.

If you become pregnant during this study and for a period of 12 weeks following study discharge or withdrawal, you should notify the study doctor as soon as possible. The study vaccine will be stopped and your participation in this study will be ended. Information about your pregnancy and its outcome will be collected and used to learn more about the effects of the study vaccine on pregnancy. You will be asked to provide information about your pregnancy, delivery, and the health of your infant until the age of one month.

Payment for all aspects of obstetrical care, child-or related care will be your responsibility.

ALTERNATIVE TREATMENT

You do not have to be in this study to receive treatment of your cervical intraepithelial neoplasia (CIN). Your options can include: cryocautery (freezing of the outer cell layer of the cervix), electrocautery (heating tissue with electricity to destroy the CIN) , laser cautery (use of laser therapy to destroy CIN), LEEP or cervical conization.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

BENEFITS

It is unknown at this time if TVGV-1 has any benefits.

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. It is possible that information from the use of this vaccine may help advance knowledge for the development of a future vaccine for early cervical cancer. Results from this study may benefit others in the future.

COMPENSATION FOR PARTICIPATION

For your time and inconvenience related to your participation in this study, you will be paid for the study visits you complete according to the following schedule: $75.00 each for Visits 1, 3, 5, and 6; $25.00 each for Visits 1A and 5A; and $50.00 each for the Screening Visit, Visits 2, 4, 7, 8, 9, 10, and 11. You will be paid $50.00 for Telephone Visits and $25.00 for Unscheduled Visits. If you do not complete the study, for any reason, you will be paid for each study visit you do complete according to the schedule above. You will be paid after each visit.

The study sponsor will pay the costs for the standard-of-care colposcopy with biopsy procedure if that biopsy is determined to be HSIL positive (a study specific criteria). This assumes that you consent to be in the study and have met all study criteria. This means the sponsor will cover the co-pay cost for someone with insurance, or the full cost for someone who does not have insurance, if the previously stated criteria are met. 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.

CONFIDENTIALITY

Records of your participation in this study will be confidential, except when sharing the information required by law (e.g. health department and positive blood tests for hepatitis or HIV), or as described in this Informed Consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

Specific data will be obtained while you are participating in this study, and will be entered into a database. The information is coded under a subject identifier number, not your name. The database is password protected and available only to study personnel. Paper records, including this consent form, will be maintained separately and only be available to study staff and personnel from the FDA and IRB (as listed in the paragraph above).

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

COMPENSATION FOR INJURY

If you are injured as a result of the study vaccine or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third party coverage. There are no plans to provide other compensation beyond that which is listed in this informed consent document. 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.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

COSTS

There will be no charge to you for your participation in this study. The study vaccine, study-related procedures, and study visits will be provided at no charge to you or your insurance company. LEEP will be performed according to standard clinical practice at your health provider's office, and the procedure cost is not covered by the study, unless you do not have medical insurance or if your insurance does not pay the total cost of the LEEP, the Sponsor will cover the difference. Otherwise, the costs for the LEEP must be submitted to your private medical or government insurance plan. CKC or hysterectomy will be performed according to standard clinical practice at your local hospital, and the procedure cost is not covered by the study.

EMERGENCY CONTACT / IRB CONTACT

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

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Schulman Institutional Review Board, 4445 Lake Forest Drive – Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you
- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled
- For administrative reasons, including competitive enrollment - the target number of subjects has entered the study
- Pregnancy or breastfeeding
- Imprisonment
- At the request of the FDA (Food and Drug Administration) and/or IRB (Institutional Review Board)

If you leave the study for any reason and you have received the study drug prior to withdrawal, the study doctor will ask you to complete all procedures for study follow up at Day 270 (Visit 11) for your safety.

PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION

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.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

CONSENT FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. **Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance**

AUTHORIZATION TO USE AND DISCLOSE

PROTECTED HEALTH INFORMATION

During your participation in this research study, the study investigator and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study documents. The study investigator will keep this personal health information in your study-related records (that we will refer to as "your study records"). In addition, the study doctor may obtain, and include in your records, information regarding your past, present and/or future physical or mental health and/or condition. Your study investigator may ask you to sign a separate authorization to obtain some or all of your medical records from your doctor. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization". Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study investigator and staff to use your PHI to conduct this study.

By signing this Authorization, you also are agreeing to allow the study investigator to disclose PHI as described below:

- The sponsor of this study, THEVAX Genetics Vaccine USA, Inc. and anyone working on behalf of the sponsor to conduct this study. The sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the sponsor. The sponsor may, however, look at your complete study records that identify you. In addition, the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct.

- The Institutional Review Board ("IRB") may have access to your PHI in relation to its responsibilities as an Institutional Review Board.

- The Study Monitor or other authorized representatives of the sponsor may inspect all documents and records required to be maintained by the Site Investigator including medical records (at office, clinic or hospital) and pharmacy records for all the subjects in this study.

- This study will use an SMC, a Safety Monitoring Committee, which is an independent group of experts that advises the Sponsor and the Site Investigators in monitoring subject safety. This committee is external to the Sponsor, composed of at least 2 or 3 voting members. The SMC will have access to your unblinded (treatment assignment) data if there are concerns that arise during the study.

- If you receive medical treatment at a facility that is separate from the study investigator's office while you are in this study, your insurance company may have access to your PHI.

The study investigator or sponsor may disclose your PHI to the United States Food and Drug Administration ("FDA") or similar regulatory agencies in the United States and/or foreign countries.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some or all of your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study investigator stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this study.

You will receive a copy of this Authorization after you have signed it.

Please indicate your preference below:

□ I hereby authorize the use and disclosure of my information for the sub-study as described above.

□ I do not authorize the use and disclosure of my information for the sub-study as described above.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of the Person Obtaining the Authorization

_____ _____
Signature of the Person Obtaining the Authorization Date

FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness* Date

*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the subject. **Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance**