Study Title:	**An Open-Label Phase II Clinical Trial Assessing the Safety, Feasibility, Efficacy and Immunological Correlates of Heterologous Prime-Boost with pBI-11 (IM) and TA-HPV (IM) Combined with Pembrolizumab as Treatment for Patients with Advanced, PD-L1 CPS≥1, hrHPV+ Oropharyngeal Cancer.**
Version Date:	**20 July 2023** **NCT05799144**
PI:	**Michael K. Gibson, M.D., Ph.D.**

Name of participant:_____ Age:_____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section.
If you do not understand something, please ask someone.

Key information about this study:
Oropharyngeal cancer is a type of head and neck cancer involving structures in the back of the throat (the oropharynx), such as the non-bony back roof of the mouth (soft palate), sides and back wall of the throat, tonsils, and back third of the tongue. Scientists have found that some strains or types of a virus called human papillomavirus (HPV) can cause oropharyngeal cancer.

The main purpose of this research study is to test whether it is safe and effective to give an investigational vaccine regimen against HPV to patients with HPV-positive oropharyngeal cancer, who are receiving standard-of-care treatment with an immunotherapy antibody called pembrolizumab.

You are being asked to participate in this research study because you are planning to start therapy with standard-of-care pembrolizumab for oropharyngeal cancer (OPC), and your study doctor feels you may possibly benefit from investigational treatment with 2 vaccine drugs called pBI-11 and TA-HPV, together with pembrolizumab.

It is hoped the investigational combination of these drugs will increase the ability of your immune system to fight your disease. In this study, the investigational strategy is to cause or enhance an immune response in the body against HPV, during which time the activity of pembrolizumab against oropharyngeal cancer associated with HPV may be strengthened.

It is unknown if this study will help you. You may have side effects from the drugs and feel worse. Your disease may or may not respond to this investigational study treatment.

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Investigational means the combination of pBI-11, TA-HPV and pembrolizumab is being tested in research studies and has not been approved as a standard treatment by regulatory health authorities, such as the U.S. Food and Drug Administration (FDA).

pBI-11 and TA-HPV are both investigational vaccine drugs. Neither pBI-11 nor TA-HPV (alone or in combination with each other; or in combination with other drugs, including pembrolizumab) is approved by the FDA. The safety and initial possible benefit of pBI-11 and TA-HPV are currently under investigation in early studies in humans.

pBI-11 is the second version of a circular DNA (plasmid) vaccine that has been tested in animals, but not yet in humans. pBI-11 is based on and structurally similar to an earlier first version investigational DNA vaccine called pBI-1, which has been administered in other clinical trials to patients with cancers associated with HPV (including patients with head and neck squamous cell carcinoma [HNSCC], and patients with cervical cancer). In animal studies, the investigational use of pBI-11 and TA-HPV was determined to be safe and well tolerated when used alone or in combination.

TA-HPV is an investigational recombinant vaccina virus derived from the Wyeth strain of vaccina virus, which was widely used for smallpox vaccination. In early-phase clinical trials, TA-HPV was safe and well tolerated when used alone or in combination with an investigational DNA vaccine .

Pembrolizumab (also known as KEYTRUDA®) is an antibody currently approved by the FDA for treatment of head and neck squamous cell cancer (HNSCC) as well as certain types of several other cancers.

pBI-11 and TA-HPV are vaccines which you will receive by separate intramuscular (IM) injections, intended for administration as “shots” into the side of your upper arm/shoulder (deltoid muscle). Pembrolizumab is an intravenous medication which you will receive by intravenous (IV) infusions into your vein.

As further discussed below, each patient in this study is scheduled to receive a total of 3 separate injections of vaccine (one injection of pBI-11 on Day 1, a second injection of pBI-11 on Day 22; and one injection of TA-HPV on Day 43). Additionally, each patient is also scheduled to receive a 30-minute intravenous infusion of pembrolizumab every 3 weeks while on study.

The length of time you receive treatment on this study will depend on the side effects you may experience, and how your disease does or does not respond to the study drugs. It is anticipated you

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may receive study treatment until you have intolerable side effects, until your disease gets worse, or for up to 2 years of treatment on this study. You also may withdraw from the study at any time.

If you have side effects, your study doctor may require you to temporarily stop taking one or more of the study drugs. If you have serious side effects, you may be required to permanently stop one or more of the drugs, or stop all study drugs and discontinue participation in the study.

In general, you will be asked to visit the clinic for a physical exam and regular check of your health, disease and performance status at the following time points:

- Physical exam every 3 weeks while on study treatment (plus an additional visit for physical exam, and routine blood and urine tests 1 week after you first start the study).
- Blood drawn and urine sample provided for routine lab work every 3 weeks while on study treatment.
- CT or MRI scanning of disease status every 9 weeks.
- All patients will be asked to have 2 tumor biopsies: 1 biopsy before starting treatment and 1 while receiving study treatment before starting Cycle 4.
- Follow-up visit (30 days after last dose) for safety.

This study receives financial support from PapiVax Biotech, Inc., which is the pharmaceutical company that makes pBI-11 and TA-HPV.

During your participation in this study, pBI-11 and TA-HPV will be provided by the study at no cost to you. Because pembrolizumab is an approved therapy for your disease, there is no need for the study to provide pembrolizumab to you; you and/or your insurance will be responsible for the cost of pembrolizumab, as well as the usual care you would receive even if you were not participating in this study.

About 54 total combined patients are anticipated to enroll in this study at Vanderbilt and approximately two additional academic medical centers in the United States.

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Detailed Information:
The rest of this document includes detailed information about this study
(in addition to the information listed above).

The main purpose of this study is to test the effectiveness (how well the drugs work), safety, and tolerability (the side effects that can be tolerated) of two investigational vaccine drugs called pBI-11 and TA-HPV, together in combination with a third drug called pembrolizumab, as possible treatment for a type of head and neck cancer called oropharyngeal cancer. Other goals of the study include learning more about how the immune system responds to the study treatment.

pBI-11 and TA-HPV are investigational drugs which have not been approved by the U.S. Food and Drug Administration (FDA). They are currently not "on the market" (available for you to buy). The safety and initial possible efficacy of pBI-11 and TA-HPV are currently under investigation in early human clinical trials. The FDA is allowing the use of the vaccine regimen in this study.

Together, the vaccine combination of pBI-11 plus TA-HPV is also called PVX7. In this study, this investigational vaccination regimen is scheduled for administration over the course of 7 weeks, consisting of two doses of the DNA vaccine pBI-11, followed by one dose of the TA-HPV vaccine.

During the initial 7 weeks of study treatment (in addition to receiving 2 doses of pBI-11 and 1 dose TA-HPV), each patient is also scheduled to receive 3 doses of pembrolizumab. After this time, the vaccination part of the study treatment will be complete. Subsequently, beginning on study Week 10, all patients may continue pembrolizumab as monotherapy (by itself) every 3 weeks for up to 2 years on the study, as long their disease does not get worse and they tolerate the study treatment.

Pembrolizumab (also known as KEYTRUDA®) is an FDA-approved prescription antibody medicine used to treat head and neck cancer, as well as several other cancers – including cancers of the skin, lung, blood (lymphoma), bladder/urinary tract, stomach, esophagus, cervix, liver, kidney, and breast. In the United States, pembrolizumab was initially approved (for melanoma) in 2014.

In head and neck squamous cell cancer (HNSCC):

- Pembrolizumab may be used with the chemotherapy medicines fluorouracil and a platinum as first treatment, when head and neck cancer has spread or returned and cannot be removed by

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surgery or treated with radiation.

- Pembrolizumab may be used alone as first line treatment, when head and neck cancer has spread or returned and cannot be removed by surgery or treated with radiation and tumor tissue tests positive for "PD-L1".
- Pembrolizumab may be used alone when head and neck cancer has spread or returned, and chemotherapy that contains platinum did not work or is no longer working.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Screening
You will have the following done within 28 days prior to enrolling in the study, in order to determine if you are a good candidate for the study:

- Review of your general medical history including information about your disease and what previous treatments you may have received.
- You will be asked about your level of activity.
- Physical exam that includes obtaining your body weight, height, and vital signs (blood pressure, heart rate, breathing rate, oxygen saturation, and temperature).
- You will be asked about and you should tell your study doctor about any problems you are having and the medicines you are taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Collection of about ¾ tablespoon of blood for routine laboratory testing (including blood counts and blood chemistry, troponin level to check your heart, thyroid levels, and ability of your blood to clot); and also blood testing for HIV (AIDS), Hepatitis B and Hepatitis C.
  - If you have active or chronic infection with HIV or Hepatitis B or C you will not be able to participate in the study. If the test results show that you are positive for HIV, Hepatitis B or Hepatitis C, the study staff will tell you the results. We will talk with you before and after testing. You should know that the study staff may be required to give your name to the Tennessee Department of Health if you test positive because this is the law. It is

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important to seek medical care if you have HIV, Hepatitis B or Hepatitis C. If you need a referral for such care, please let the study staff know.

- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Electrocardiogram (ECG) to check your heart's performance.
- Computed tomography (CT) or magnetic resonance imaging (MRI) performed within 28 days prior to your first dose of study drug will be reviewed to check the current state of your disease. This scanning may be part of your standard of care. If your most recent available scans were performed more than 28 days before you start treatment in this study, repeat scanning may need to be done just for this study and not as standard of care.
- Collection of about 6 tablespoons of blood for research.
- Obtain diagnostic tumor tissue (archival or new biopsy/resection) for testing HPV status and PD-L1 expression before the study; and of tumor tissue (new biopsy) during the study for additional research. More details, including the possibility that you may need a new biopsy during screening for this study is described below.

In order to participate in this study, all patients must have tumor tissue meeting <u>both</u> of the following characteristics:

- Positive for high-risk human papillomavirus (hrHPV^{+}) required to receive vaccination with pBI-11 and TA-HPV; and
- Positive for PD-L1 (defined as combined positive score [CPS] <u>≥</u>1 by immunohistochemistry) required to receive pembrolizumab.

To meet this tissue screening requirement, test results from a qualified laboratory must be available based on testing of:

- Archival (old) tumor tissue, from a biopsy or procedure performed prior to your first dose of treatment in this study, or
- New tumor tissue, from a biopsy or procedure performed prior to your first dose of treatment in this study (if deemed accessible and safe).

If you do not have qualifying hrHPV and PD-L1 tissue test results already documented, your archival tumor tissue (from a previous biopsy or procedure performed prior to your first dose of treatment in this study) will be requested and tested. If such tissue is not available or insufficient for testing, you will

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be asked to have a new biopsy for hrHPV and PD-L1 testing (if deemed accessible and safe). This new biopsy might be obtained through use of a computer tomography (CT) scan to find the exact location of your tumor and use a core needle to sample the tissue.

In addition to meeting the above hrHPV and PD-L1 tumor-tissue requirements during screening, all patients entering this study must also agree to provide additional new tumor tissue for additional research related to this study, from a biopsy or procedure performed ≤ 28 days prior to their Cycle 1, Day 1 visit in this study. If you already had a recent biopsy or procedure for hrHPV/PD-L1 testing in this study, you will not be required to have another new biopsy during screening for this study (as long as your documented hrHPV and PD-L1 test results meet the above entry requirements).

In order to participate in this study, you cannot donate blood or sperm or breast feed from the time of signing consent through at least 120 days after your final dose of heterologous vaccination and/or pembrolizumab.

Day 1 (Week 1/ Cycle 1, Day 1)
If you are eligible for the study, you will return to clinic to start the study treatment; the following things will be done:

- Physical exam and laboratory tests (unless already completed during screening ≤ 7 days prior to starting Day 1 study treatment):
  - Physical exam, body weight, and questions about your level of activity.
  - Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, troponin level to check your heart, and thyroid hormone levels).
  - Urine test to check your kidney function and overall health (about ¼ cup of urine).
  - If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Questions about any side effects that you are experiencing and any changes to your medications.
- Vital signs
- **pBI-11**: intramuscular (IM) injection into a muscle (such as the deltoid muscle on the side of your upper arm/shoulder).
- **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes. (Pembrolizumab will start at least 30 minutes after your pBI-11 injection).

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Day 8 (Week 2 / Cycle 1, Day 8)
One week after your first pBI-11 vaccination you will return to clinic for the following:

- Physical exam.
- Questions about your level of activity, any side effects you are experiencing and any changes to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and troponin level to check your heart).
- Urine test to check kidney function and overall health (about ¼ cup of urine will be needed).

Day 22 (Week 4 / Cycle 2, Day 1)
Three weeks after your first pBI-11 vaccination you will return to clinic for the following:

- Physical exam including obtaining your vital signs and weight.
- Questions about your level of activity, any side effects that you are experiencing and any changes to your medications.
- Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, troponin level to check your heart, and thyroid hormone levels).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- Collection of about 6 tablespoons of blood for research.
- **pBI-11**: intramuscular (IM) injection into a muscle (such as the deltoid muscle on the side of your upper arm/shoulder).
- **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes. (Pembrolizumab will start at least 30 minutes after your pBI-11 injection).

Day 43 (Week 7 / Cycle 3, Day 1)
Six weeks after your first pBI-11 vaccination you will return to the clinic for the following:

- Physical exam including obtaining your vital signs and weight.
- Questions about your level of activity, any side effects that you are experiencing and any changes to your medications.
- Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, troponin level to check your heart, and thyroid hormone levels).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- Collection of about 6 tablespoons of blood for research.
- **Pembrolizumab**: intravenous (IV) infusion into a vein over 30 minutes. (Pembrolizumab will start at least 30 minutes after your TA-HPV injection).

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- **TA-HPV**: intramuscular (IM) injection into a muscle (such as the deltoid muscle on the side of your upper arm/shoulder).
- Follow instructions provided to you for at-home care of the vaccination site and dressing after TA-HPV injection. These instructions must be followed from the time of TA-HPV vaccination and until advised by the study team that it is safe to stop (at least 3 weeks).

1. Please keep the dressing dry. While bathing, cover your vaccination site with a waterproof bandage, and do not share towels. Keep the area as dry as possible during showers and baths. If the gauze bandage gets wet, change it right away. Swimming is not permitted until the vaccination area is healed and dry. **Cover the TA-HPV injection site for 21 days with occlusive dressing (provided to you*).***
2. Avoid activities which may dislodge the dressing e.g. contact and physical sports. Wearing of clothing covering vaccine site is advised.
3. If the dressing begins to become detached for whatever reason, you should cover it with the adhesive dressing provided for this purpose. All dressing material should be placed in a ziplock plastic bag provided for this purpose and discarded in the regular trash.
4. Avoid touching the dressing or vaccination site with your fingers. If you think that you have touched the site with your fingers, then do not touch any other part of your body and immediately wash your hands thoroughly. Do not let others touch the site or items that have touched it such as bandages, clothes, sheets, or towels.
5. Handwashing is the best way to prevent transmission of the virus. Washing your hands after touching the dressing and before inserting contact lenses, dentures or before contact with any other open area of your body is essential.
6. You should avoid close contact between the vaccination site and its dressing and any other individual including your partner.
7. It is important to avoid contact with the following persons: pregnant women, anyone with a skin complaint such as eczema as well as those who have had a transplant of any kind, those who are taking long term steroid therapy or who are suffering from immunodeficiency such as AIDS, until advised by the study team that it is safe to do so.
8. You should not have contact with babies or children under the age of 1 years old. In the event that contact with such high risk persons is unavoidable/unexpected, ensure that your clothing covers the vaccination site and wash your hands before activities.
9. Change your bandage at least every 3 days. Change it sooner if it gets dirty or wet. Document any injection site and/or other adverse changes in your health in the patient diary at the time they occur and/or change in severity or go away.

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10. If you have any concerns about your dressing at any time, you should contact a member of the study team without delay.
11. Do your own laundry. Use a separate laundry hamper for clothes, towels, sheets, and other items that may come into contact with your vaccination site or pus from the site. Machine wash items that have touched the vaccination site in hot water with detergent and/or bleach.

- **If you do not follow these instructions, you can spread the TA-HPV virus to other parts of your body or to other people.**
- **If you believe the TA-HPV infection has spread within your own body beyond the injection site, you should contact a member of the study team without delay to arrange for its management.**
- **If you believe another person may have become infected with TA-HPV, you should contact a member of the study team without delay to arrange for their management.**

Day 64 (Week 10 / Cycle 4, Day 1)
Nine weeks after your first pBI-11 vaccination you will return to the clinic for the following:

- Physical exam including obtaining your vital signs and weight.
- Questions about your level of activity, any side effects that you are experiencing and any changes to your medications.
- Collection of about ½ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, troponin level to check your heart, and thyroid hormone levels).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease, scheduled to occur ≤ 7 days prior to receiving study treatment on Day 1 of Cycle 4.
- Collection of about 6 tablespoons of blood for research.
- Tumor biopsy (if accessible and safe)
- Electrocardiogram (ECG) to check your heart's performance.
- **Pembrolizumab**: intravenous infusion into a vein over 30 minutes.

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Day 85 (Week 13 / Cycle 5, Day 1)
Twelve weeks after your first pBI-11 vaccination you will return to the clinic for the following:

- Physical exam including obtaining your vital signs and weight.
- Questions about your level of activity, any side effects that you are experiencing and any changes to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and troponin level to check your heart).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- Electrocardiogram (ECG) to check your heart's performance.
- **Pembrolizumab**: intravenous (IV) infusion into a vein, over 30 minutes.

Additional Cycles:
Beginning 3 weeks after Cycle 5, Day 1 and continuing thereafter every 3 weeks (i.e., on Day 1 of each additional 21-day cycle) until you stop treatment on this study, or for up to 2 years of maximum total treatment on this study, you will return to the clinic for the following:

- Physical exam including obtaining your vital signs and weight.
- Questions about your level of activity, any side effects that you are experiencing and any changes to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and troponin level to check your heart).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).
- Electrocardiogram (ECG) to check your heart's performance.
- **Pembrolizumab**: intravenous (IV) infusion into a vein, over 30 minutes.

Every 3rd cycle:
(in addition to the above "additional cycle items", the following will also be done):

- Collection of about ¼ tablespoon of your blood for routine laboratory testing of your thyroid function.
- If you are a woman capable of becoming pregnant, you will have either a urine or blood pregnancy test.
- Computed tomography (CT) or magnetic resonance imaging (MRI) to check your disease. Re-scanning scheduled every 9 weeks (i.e., at the end of every 3rd cycle) to occur ≤ 7 days prior to initiating any pembrolizumab infusion on Day 1 of cycles 7, 10, 13, etc.

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30-Day Follow-Up:
30 days after your final treatment in this study, you have the following things done as part of follow-up:

- Physical exam.
- Questions about your level of activity, any side effects that you are experiencing and any changes to your medications.
- Collection of about ¼ tablespoon of your blood for routine laboratory testing (including blood counts and blood chemistry, and troponin level to check your heart).
- Urine test to check your kidney function and overall health (about ¼ cup of urine).

Long-term Follow-Up:
Approximately every 3 months after your final treatment in this study, you and/or your doctor's office may be contacted, for example by telephone or a clinic visit, to check on how you are doing. This will continue until one of the following occurs (whichever occurs first): study ends, you withdraw your consent, your death, or until 1 year after your final dose of treatment in this study. Additional follow-up beyond one year may occur if deemed medically necessary by your study physician.

Side effects and risks that you can expect if you take part in this study:

Risks of pBI-11

The investigational pBI-11 DNA vaccine to be used in this study has not been previously tested in humans. However, pBI-11 is similar to and based on the investigational pBI-1 DNA vaccine previously used in other clinical trials. The potential risks of pBI-11 in this trial are expected to be substantially similar to those experienced during previous pBI-1 use in other clinical trials.

In patients with cervical cancer associated with HPV, two early (phase I) studies found that intramuscular administration of pBI-1 DNA was safe and well tolerated. No dose-limiting or severe adverse events (side effects) were observed. The most common side effect of pBI-1 was transient (temporary), minimal discomfort at the injection site. Other side effects included malaise/flu-like symptoms, fatigue, and vaginal discomfort/discharge (cervical cancer study).

In a previous early phase clinical trial of 18 patients with HNSCC associated with HPV, intramuscular administration of pBI-1 DNA vaccine was also observed to be safe and well tolerated. The most common side effects observed included injection site reactions, skin rash, and muscle pain; and, less

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commonly, diarrhea, difficulty swallowing, elevated liver enzymes in blood, decreased red blood cell and platelet counts, muscle spasm, and upper respiratory infection. Adverse events (side effects) associated with intramuscular (IM) administration of pBI-1 DNA vaccine in that study are summarized below (again, the potential risks of pBI-11 are expected to be substantially similar to pBI-1):

The most common side effects associated with pBI-1 included:

in 4 of 18 patients (22%):

- injection site reaction (such as bruising and tenderness)
- muscle pain/inflammation (myositis)
- skin rash.

Less common side effects associated with pBI-1 included:

in 1 of 18 patients (5%):

- diarrhea
- difficulty swallowing (dysphagia)
- fatigue
- elevated liver enzyme in blood (AST)
- elevated liver enzyme in blood (ALT)
- upper respiratory infection
- decreased platelet count (can make it easier to bleed)
- decreased red blood cell count (can cause fatigue)
- muscle spasm
- headache.

Risks of TA-HPV

TA-HPV is an investigational recombinant vaccina virus engineered in a laboratory to express human papilloma virus (HPV) proteins, which are intended to stimulate the immune system. TA-HPV is derived from the Wyeth strain of vaccina virus, which was widely used for smallpox vaccination.

The investigational TA-HPV vaccine to be used in this study has been administered to patients in previous clinical trials, including in combination with pBI-1. (As discussed above, pBI-11 is the DNA vaccine to be used in this study; and pBI-11 is based on and similar to pBI-1. Thus, the potential risks of pBI-11 in this study are expected to be substantially similar to pBI-1 used in previous studies.)

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In a small early-phase (Phase I) clinical trial, 12 patients with cervical cancer associated with human papillomavirus (HPV) received pBI-1 and TA-HPV administered intramuscularly (into muscle), followed by surgery to treat/remove cervical cancer. In these 12 patients, the most common reported adverse events (AEs) included injection site discomfort, fatigue, lightheadedness, headache and vaginal itching. No dose-limiting or severe AEs were reported in any organ system, or at any treatment dosage.

Common side effects at the TA-HPV injection site included:

in 3 of 12 patients (25%):
- discoloration
- redness/itching (erythema/pruritis).

in 4 of 12 patients (33%):
- blister with drainage
- tenderness.

Common additional side effects also reported in patients with HPV-associated cervical cancer treated with TA-HPV and pBI-1 included:

in 4 of 12 patients (33%):
- fatigue/tiredness
- vaginal itching (pruritus).

in 3 of 12 patients (25%):
- localized pain
- lightheadedness
- headache.

in 2 of 12 patients (16%):
- vaginal infection (bacterial vaginosis).

in 1 of 12 patients (8%):
- swollen/sore lymph nodes
- rapid heartbeat
- nausea
- vomiting
- flu-like symptoms

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- fever
- postoperative vaginal bleeding
- bacterial (streptococcus B) vaginal infection
- urinary tract infection
- yeast infection
- muscle/joint pain
- vaginal discharge
- dysmenorrhea (painful menstrual period)
- rash (bumps on shoulder).

In this study, you will receive TA-HPV by an injection or shot into a muscle. However, TA-HPV has also been safely administered in other clinical studies to more than 100 people including patients with cervical cancer, by a process called skin scarification. During vaccination by scarification, skin at the vaccination site such as the upper arm or thigh is repeatedly scratched with a needle, followed by application of a liquid vaccination solution onto the scratched skin. In these patients, after administration by skin scarification, vaccinia virus replicates in the outer and middle layers of the skin (epidermis/dermis). After 3 to 5 days, a papule (small, raised bump) forms at the site, then becomes vesicular (fluid-filled) at approximately day 5 to 8, then pustular (pus-filled), and usually enlarges to reach maximum size 8 to 10 days after vaccination. The pus-filled pustule dries from the center outward and forms a scab. The scab formed typically separates 14 to 21 days after vaccination by scarification and usually leaves a pitted scar.

As discussed above, the investigational TA-HPV vaccine to be used in this study is derived from another vaccina virus (Wyeth strain), which was widely used for smallpox vaccination. Thus, it is possible the side effects and risks of the investigational TA-HPV vaccine used in this study, could have similarities to those associated with smallpox vaccination, including those discussed in the below sections.

The smallpox vaccine, from which TA-HPV is derived, is generally safe and effective, but some people do experience side effects and adverse reactions. Severe adverse reactions are more common in people who are being vaccinated for the first time and among young children (<5 years of age). Approximately one-third of adult primary vaccinees may feel sufficiently ill to miss work, school, or recreational activities, or may have trouble sleeping.

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Normal reactions to vaccinia (smallpox) vaccine include:

Injection site reactions:
- skin redness (erythema)
- itching (pruritus)
- pain
- swelling.

Constitutional symptoms:
- fatigue
- headache
- muscle aches
- chills
- nausea
- fever over 100°F (37.8°C)
- general feeling of discomfort or illness (malaise)
- satellite lesions (benign, secondary vaccinial lesions close to the central vaccination lesion).

Localized Reactions

Superinfection of the vaccination site or regional lymph nodes:
Vaccination progression and normal local reactions are difficult to distinguish from a superinfection of the vaccination site or regional lymph nodes. Secondary infections of the vaccination site are uncommon and are typically mild to moderate in clinical severity. Children and individuals who frequently manipulate and contaminate the vaccination site are at greatest risk.

Robust take:
Vaccinial cellulitis defined as >3 inches of redness with swelling, pain, and warmth at the vaccination site. The symptoms typically peak 6 to 12 days after vaccination and regress within the following 24 to 72 hours.

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Unintentional Transfer of Vaccinia Virus

Inadvertent autoinoculation:
Unintentional transfer of vaccinia virus from the vaccination site to another place on the body of the person receiving vaccination (the vaccinee). Vaccinees can transfer vaccina to their hands or other places (fomites). The most common sites are the eye and surrounding orbit (ocular vaccinia); followed by the face, nose, mouth, lips, genitalia, and anus.

Contact transmission:
A vaccinee can also spread vaccinia virus from the vaccination site (or other lesions distant from the vaccination site) to close contacts through direct contact, or through other vectors such as clothing, bedding, or bandages contaminated by vaccinia virus. Viral shedding can occur until the scab detaches from the vaccination site (or any distant lesions), revealing healthy skin underneath. Infection through contact transmission can result in the same adverse events observed after smallpox vaccination.

Ocular vaccinia:
There are different forms of ocular vaccinia: blepharitis (red, swollen, irritated, itchy eyelids, with inflammation and sometimes crusty dandruff-like flakes on the eyelashes), conjunctivitis (whites of eye appear reddish or pink due to inflammation or infection), keratitis (inflammation of the cornea causing red eyes, excess tear production, sensitivity to light, pain, and cloudy or blurred vision), iritis (swelling and irritation in the colored ring around the central pupil of the eye), or combinations thereof. Infections can be clinically mild to severe and can lead to vision loss.

Widespread Skin Side Effects
There are two groups of diffuse skin (dermatological) complications. One group is thought to be free of vaccinia virus (for example, erythema multiforme minor, Stevens-Johnson syndrome, and other nonspecific post-vaccination rashes), and a second group thought to be caused by vaccinia virus growing (replicating itself) at the site of the skin lesions. This section covers the second group.

Generalized vaccinia:
Widely dispersed (disseminated) rash with fluid-filled (vesicular) or pus-filled (pustular) bumps or blisters, and usually benign and self-limited in patients with strong immune systems. First-time vaccines (i.e. if you have not previously been given the Smallpox or Mpox vaccine) are at higher risk for generalized vaccinia than re-vaccinees. Generalized vaccinia is often more severe among persons with a poorly functioning immune system (underlying immunodeficiency) who might have been inadvertently vaccinated.

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Eczema vaccinatum:
Localized or spread of vaccinia virus throughout the body (systemic). It occurs most often in vaccine recipients who have a history of atopic dermatitis (chronic inflammation of skin, with dryness, itching, rashes and redness caused by an overactive immune system). The rash is often accompanied by fever and swollen lymph nodes (lymphadenopathy), and affected persons are frequently systemically ill. Eczema vaccinatum tends to be most severe among first-time vaccinees, unvaccinated close contacts of vaccinees, and young children. It can be fatal.

Progressive Vaccinia:
Rare, severe, and often fatal. It occurs when a vaccination site fails to heal and vaccinia virus replication persists. The skin surrounding the vaccination site becomes infected with vaccinia virus, and vaccinia lesions can occur at different sites. Lesions can appear necrotic (dead skin), fungated (wounded, ulcerated or broken skin often with a bad smell), piled-up, or well demarcated (clear edges). At the same time, bacterial superinfection also can occur. Progressive vaccinia typically occurs in persons with an underlying weakness in their immune system (humoral or cellular immune deficit).

Rare Adverse Reactions

Fetal vaccinia:
Rarely, smallpox vaccination of a pregnant woman using vaccinia can result in fetal vaccinia. Transmission to the fetus can occur any time during pregnancy. Miscarriage, stillbirth, or live birth (usually premature, followed by death); or birth of a surviving but pox-scarred infant can occur after the mother's exposure to vaccinia.

Post-vaccinial central nervous system disease:
Swelling of the brain or brain and spinal cord (encephalitis or encephalomyelitis) may occur after vaccinia infection. It is most common among infants aged less than 12 months. Clinical symptoms reflect problems in brain function (cerebral or cerebellar dysfunction) with headache, fever, vomiting, altered mental status, lethargy, seizures, and coma. No clinical criteria, radiologic findings, or laboratory tests diagnostic for these adverse reactions are known to exist.

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Cardiac Adverse Events

Myocarditis/pericarditis:
Reports of inflammatory disease of the muscle layer of the heart (myocardium), the outer layer of the heart (pericardium) or both after smallpox vaccination suggest an association between smallpox vaccination with the New York City Board of Health vaccinia strain and inflammation of the myocardium (myocarditis) and/or inflammation of the pericardium (pericarditis). Symptoms may include chest pain, shortness of breath (dyspnea), and feelings of strong, rapid or irregular heartbeats (palpitations) that range from subtle to severe.

Myocarditis and/or pericarditis in a small subset of patients is also one serious possible side effect of immune checkpoint inhibitors –such as pembrolizumab, which is a drug that you and all patients will receive in this study. There is a potential for enhanced cardiotoxicity when combing study product with Pembrolizumab.

Symptoms of myo/pericarditis typically occur within 3 months of starting treatment. A variety of symptoms, subtle to severe, might include heart rhythm problems (arrhythmias), complete heart block (normal electrical signals cannot pass between the upper and lower heart chambers), heart failure, and life-threatening inability of the heart to pump enough blood (cardiogenic shock).

While at home, you should monitor yourself for symptoms of myo/pericarditis, such as chest pain, palpitations, shortness of breath, peripheral swelling (in the arms, legs, fingers, and toes) due to fluid build-up (edema), fatigue, fainting, fever, cough, and pain when swallowing. If and when you have any of these symptoms, you should contact your study doctor and seek medical attention immediately.

Dilated cardiomyopathy and cardiac ischemia:
Reduced ability of the heart to pump blood due to stretching of the heart muscle (dilated cardiomyopathy) and lack of blood flow and oxygen to the heart muscle (cardiac ischemia) have been detected at similar times (temporal association) as smallpox vaccination, but have not been clearly shown to be caused by smallpox vaccination. Dilated cardiomyopathy is a known consequence of viral myocarditis (inflammation of heart muscle due to a virus) and can occur weeks to months after severe/sudden (acute) viral infection. The causal relation between smallpox vaccination and dilated cardiomyopathy is an unclear, but biologically reasonable possibility.

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Risks of Pembrolizumab (also known as KEYTRUDA®)

Pembrolizumab can cause serious side effects. Pembrolizumab is a medicine that may treat certain cancers by working with your immune system. Pembrolizumab can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work.

These problems can sometimes become severe or life-threatening and can lead to death.

You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your study doctor right away if you develop any new or worsening signs or symptoms, including:

Lung problems
- cough
- shortness of breath
- chest pain.

Intestinal problems
- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness.

Liver problems
- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal.

Hormone gland problems
- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat

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- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.

Kidney problems

- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite.

Skin problems

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in your mouth or in your nose, throat, or genital area
- fever or flu-like symptoms
- swollen lymph nodes.

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with pembrolizumab. Call or see your study doctor right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath, swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight

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- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising.

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include:

- chills or shaking
- dizziness
- itching or rash
- feeling like passing out
- flushing
- fever
- shortness of breath or wheezing
- back pain.

Common side effects of pembrolizumab when used alone include:

- feeling tired
- pain, including pain in muscles, bones or joints and stomach-area (abdominal) pain
- decreased appetite
- itching
- diarrhea
- nausea
- rash
- fever
- cough
- shortness of breath
- constipation.

Side effects of pembrolizumab when used alone that are more common in children than in adults include:

- fever
- vomiting
- upper respiratory tract infection

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- headache
- low levels of white blood cells
- low levels of red blood cells (anemia).

Common side effects of pembrolizumab when given with certain chemotherapy medicines include:

- feeling tired or weak
- nausea
- constipation
- diarrhea
- decreased appetite
- rash
- vomiting
- cough
- trouble breathing
- fever
- hair loss
- inflammation of the nerves that may cause pain, weakness, and paralysis in the arms and legs
- swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina
- mouth sores
- headache
- weight loss.

Before receiving pembrolizumab, tell your study doctor about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant.

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Reproductive Health/Sexual Activity and Pregnancy

Some medications have the potential to cause side effects in the reproductive system of women or men that could cause harm, including birth defects, during pregnancy. Pembrolizumab can harm an unborn baby. There has not been enough study of pBI-11, TA-HPV and pembrolizumab to fully predict the risks to pregnant women, the developing fetus, or to the breast-feeding child.

If sexually active with the ability to become pregnant or to cause pregnancy, both women and men participating in this study must agree to use effective birth control as discussed with and directed by their study doctor.

In the event of pregnancy, the study team may request additional information about the pregnancy or the outcome of the pregnancy in an effort to better understand the effects of study treatment on a pregnancy and/or the fetus.

Information for Women who could become pregnant (Women of Child-bearing Potential):

- Before starting treatment in this study, tell your study doctor if you are pregnant or plan to become pregnant.
- You will have a pregnancy test before starting treatment in this study.
- Together with your partner, you must use effective birth control during and for at least 180 days after your final dose of pBI-11, TA-HPV or pembrolizumab (whichever dose occurs last). Talk to your study doctor about birth control methods you can use during this time.
- Tell your study doctor right away if you think you may be pregnant, or if you become pregnant during treatment in this study.
- Tell your study doctor if you are breastfeeding or plan to breastfeed. It is not known if the study treatment passes into your breast milk. Do not breastfeed during study treatment and for at least 120 days after your final dose of study treatment.

Information for Men with sexual partners who could become pregnant (Partners of Childbearing Potential):

From the time you start study drug treatment until at least 120 days after your final dose of pBI-11, TA-HPV or pembrolizumab (whichever dose occurs last) you must:

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- Tell your sexual partner about your participation in this clinical trial. Together with your partner, you must use effective birth control during and for at least 120 days after your final dose of pBI-11, TA-HPV or pembrolizumab (whichever dose occurs last). Talk to your study doctor about birth control methods you can use during this time.
- Tell your study doctor immediately if your partner becomes pregnant during this clinical trial.
- Do not donate sperm for at least 120 days after your final dose of study treatment.

Risks of Procedures

Blood Collection
Risks of taking blood include pain, a bruise at the point where blood is taken, redness and swelling of the vein, infection, and a rare risk of fainting.

Intravenous (IV) Catheter
Prior to beginning pembrolizumab, your study doctor may need to insert an intravenous (IV) catheter for the delivery of pembrolizumab and to take blood samples. IV catheters can usually be placed in a hand, arm, or leg. These are known as "peripheral" IVs. IVs placed in the central circulation, like the internal jugular vein (neck) or subclavian vein (just beneath the collar bone), are known as "central lines." You should discuss this with your study doctor. For both types of intravenous cathe ter, the area will be numbed (with an anesthetic) before the catheter is inserted. During the insertion, you could feel a pinch and shortly thereafter bleeding, redness, or a bruise could develop. Rarely, an infection could occur if not kept clean. For central catheters, although rare, they can sometimes cause collapse of a lung or cause bleeding. Lung collapse is usually treated by putting a tube into your chest for a few days to allow your lung to expand. Pressure is placed on any area that might bleed.

Electrocardiogram (ECG)
An ECG is a test that measures the heart's electrical activity. You will typically be asked to lie flat on a table and several small electrode pads (like stickers) will be placed on your body. This test takes about 10 minutes. The test may cause some redness or itching where the pads are placed.

Tumor Biopsy
A tumor tissue biopsy is a procedure that involves removing samples of tumor surgically or percutaneously (through the skin) using a hollow "core" needle. To undergo a biopsy, you will be given

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medication to help numb the area and reduce pain. A small cut may then be made in the skin. Biopsy risks can include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.
- You may receive an injection of lidocaine to numb the area of the biopsy site. Lidocaine, a numbing drug, may burn or cause a rash, redness, or soreness where you get the shot. There is a risk that this drug may cause problems with heart rhythm.
- Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

Computed Tomography (CT)

A CT scan uses radiation (x-rays) guided by a computer to take pictures of your internal organs. The contrast solution that may be given for a CT scan may cause an allergic reaction (rare). Severe allergic reactions can be life threatening. CT contrast solution can cause kidney damage, especially if you are diabetic, dehydrated (lost body water) or elderly. CT contrast is used in scans to highlight specific parts of the body.

During CT scans, you will lie still on a table that slides into a tunnel slightly wider than your body. People who feel anxiety in confined spaces (claustrophobia) may feel uncomfortable in the narrow cylinder. If you feel uncomfortable in confined spaces, please tell your study doctor and the imaging team performing your scans. They may give you a medication in an effort to make you feel more comfortable in a confined space.

Magnetic Resonance Imaging (MRI)

An MRI is a type of scan using magnets to make a picture of the body and identify areas that could be injured or suspicious for diseases such as cancer. Some people cannot have an MRI because they have some type of metal in their body. For example, if you have a heart pacemaker, artificial heart valves, metal implants such as metal ear implants, pieces or fragments of bullets or shrapnel, chemotherapy or insulin pumps, or any other metal such as metal clips or rings, you cannot have an MRI.

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PI:	**Michael K. Gibson, M.D., Ph.D.**

During an MRI, you will lie in a small closed area usually inside a large magnetic tube. Some people are scared or anxious in small places (claustrophobic). The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs or specially designed headphones will be used to reduce the noise.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: Participating in this study may help patients with cancer get better care in the future.

Procedures to be followed:
The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood and tissue for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

Payments for your time spent taking part in this study or expenses:
During your participation in this study, PBI-11 and TA-HPV will be provided by the study at no cost to you. You and/or your insurance will be responsible for the cost of pembrolizumab. Standard medical care that you receive under this study will be billed to your insurer and/or you in the ordinary manner. You should learn before participating in this study which part of the research-related care will be free, which costs your insurer will pay for, and which costs will be your responsibility.

You will not be paid for your participation in this study.

Costs to you if you take part in this study:

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If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or the funder to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Michael Gibson at [redacted]. If you cannot reach the research staff, please page the study doctor at [redacted].

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your study doctor might take you out of the study for reasons such as:

- You are unable to tolerate the treatment, or you have a side effect which the study doctor feels should end the treatment.
- Your disease spreads or gets worse (progresses).

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- You have another serious illness or need major surgery.
- You do not follow the study doctor's instructions.
- The study doctor feels it is not in your best interest for you to continue in the study or decides to stop the study.

If you are removed from the study, the reason will be explained to you.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on 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 Web site at any time.

Clinical Trials Reporting Program.
Vanderbilt's NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI though their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may identify you: birth month/year and five-digit zip code. NCI uses the data to manage and enhance the nation's investment in cancer research.

Confidentiality:
All efforts within reason will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your information and samples will be given a code. Dr. Gibson, his staff, and other authorized people will be the only people who know your personal information.

Study data will be recorded in a Vanderbilt electronic database which is maintained by a research coordinator and data manager at Vanderbilt. The electronic database is password protected in order to help protect your identity. Your study records will be locked up in the clinical trials office.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Gibson and his staff will comply with any and all laws

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regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

At any time, you may ask to have your sample destroyed. You should contact Dr. Gibson and/or the research team to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include Vanderbilt Medical Center and its agents or contractors, study safety monitors and auditors, data managers and other agents and contractors used by the study team, researchers and study team members. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care

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or study oversight. Also, your records may be seen by people from regulatory authorities (such as the U.S. Food and Drug Administration [FDA]), auditors, and the IRB). By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the funder of the study and its agents or contractors, outside providers, study safety monitors, government agencies, and other sites in the study. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let him know by using the contact information provided in this consent form. Dr. Gibson's mailing address is:

Michael K. Gibson, M.D., Ph.D.
[redacted]

Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

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Consent for Genetic Research

A purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

Patients with similar diseases do not always obtain the same benefit from the same treatment. Therefore, a goal is to help understand why patients respond differently to treatment, and to then develop treatment that provides maximum benefit for individual patients.

As part of the study, your tumor biopsy tissue, blood and/or fluid samples will be collected to better understand your disease. It is possible that genetic testing may be conducted on some or all of this material. You are being asked for your permission to allow this.

It is possible that genetic testing on these samples could help to learn more about:

- The effect of treatment on your body
- Why some people respond to treatment and others do not
- Why some people have side effects
- The causes of the disease.

What we learn about you from research on your samples is unlikely to be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. To help prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Dr. Gibson and his staff helping with the study will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample may be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. Samples will be destroyed when no longer needed. Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the

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study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact Dr. Gibson to have your sample destroyed and no longer used for research. His mailing address is:

[redacted]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them. There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue/fluid samples may be used for current gene research in cancer related to pBI-11, TA-HPV, and/or pembrolizumab:

☐ Yes ☐ No

My blood/tissue/fluid samples may be stored/shared for future gene research in cancer:

☐ Yes ☐ No

My blood/tissue/fluid samples may be stored/shared for future gene research for other health problems (such as arthritis, heart disease, etc):

☐ Yes ☐ No

Signature: _____ Date: _____

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