

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

VGX Pharmaceuticals, LLC.

CELO02: ASSESSMENT OF THE PAIN AND INJECTION SITE EFFECTS OF INTRADERMAL  
CELLECTRA® ELECTROPORATION DEVICE IN HEALTHY SUBJECTS

CONSENT FORM / AUTHORIZATION (HIPAA) FOR A RESEARCH STUDY

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*24-hour emergency Number: (215) 662-6059 (ask for Infectious Diseases Fellow on call)*

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### INTRODUCTION

You are being asked to volunteer for a medical research study to test a new device for delivery of vaccinations (note that in this study no vaccinations are used, only saline). This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If all of your questions have been answered to your satisfaction and you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

This study is sponsored by VGX Pharmaceuticals. The doctor in charge of this study at this site is Pablo Tebas, MD. The study doctor is being paid by the Sponsor to conduct this research study.

You must be honest with the study doctor about your health history or it may not be safe for you to be in this study.

### WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate pain and localized injection site effects of the CELLECTRA® Adaptive Constant Current Electroporation Device after applying to the skin, also known as intradermal (ID) electroporation. The CELLECTRA® device is investigational. "Investigational" means the CELLECTRA® device being tested has not been approved by the United States Food and Drug Administration (FDA).

Electroporation is a technique in which a brief electric shock is applied to the skin. Momentary holes open up in the surfaces of the cells, allowing the entry of other materials, such as vaccines.

The CELLECTRA® device is a portable, battery powered machine with three parts: a generator, a hand held applicator, and a set of 3 needles arranged in a circle, also known as an array. For this study, salt water will be injected into the skin to make a bubble. Then the array will be placed over the bubble, approximately 1/8 inch into the skin of the back of upper arm. You will feel 2 short electrical pulses, a 3 second delay, followed by 2 more short electrical pulses.

Pain of the injection and injection site effects will be evaluated following treatment with the CELLECTRA® device.

### WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

All study visits will be conducted in the Macgregor Clinic on 3 Silverstein Pavilion in the Hospital of the University of Pennsylvania.

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**Screening Visit**

The screening visit will take place up to 30 days before the treatment day. At the screening visit, you will be asked to sign this consent form, give your health history, and tell study staff if you take any over-the-counter or prescription medicines, vitamins or herbs.

The study doctor or staff will conduct some tests to find out if you can be in the study. These tests include:

- Physical assessment (including vital signs)
- Physical measurements (includes height, weight, and body mass index)
- Have 1 tablespoon of blood drawn for a CPK test. CPK is an enzyme released by muscle tissue in response to a stimulus. We would like to see if the device affects CPK levels.
- Urine pregnancy test if you are a woman of child bearing potential

If you qualify to be in the study and you choose to be in the study, you will be scheduled to return for the treatment day.

**Entry Visit (Day 1)**

Prior to Treatment:

- Physical assessment (including vital signs)
- Update on medical and medication history since the screening visit
- 12-lead EKG to check for any conduction abnormalities of your heart
- Have 1 tablespoon of blood drawn for a CPK test.
- Urine pregnancy test if you are a woman of child bearing potential
- Instructions on how to perform the stop watch test

After these preliminary procedures, you will be given the electroporation treatment.

Immediately following the treatment and at time points 5, 15, 30 and 60 minutes after treatment:

- You will stop the stopwatch when you feel meaningful pain relief
- You will be asked to evaluate your pain by completing a questionnaire
- 12-lead EKG (conducted at the 15 minute time point only)
- You will be asked about how you are feeling and the study staff will examine the injection site.

You will be expected to stay at the study center for at least one hour after the treatment.

**Follow Up # 1 (Day 2)**

You will be asked to come to the study center and will be asked about how you are feeling and to ask about side effects noted at the site where you received the treatment. You will have 1 tablespoon of blood drawn for a CPK test.

**Follow Up #2 (Day 7)**

You will be asked to come to the study center and will be asked about any side effects you may have experienced.

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**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

About 10 people will take part in this study. The University of Pennsylvania is the only center participating in this study; all 10 participants will be enrolled here.

**HOW LONG WILL I BE IN THIS STUDY?**

The study will last about one week and will involve up to 4 required visits to the study site.

**WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?**

The study doctor may need to take you off the study early without your permission if:

- If you do not follow the study doctor's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health
- At the investigator's discretion

If you must leave the study before it is over, you will be asked to come in for a final visit.

**WHAT ARE THE RISKS OF THE STUDY?**

Below is a list of the most common side effects that may be experienced with the use of the CELLECTRA® device. If you do not understand what any of these side effects mean, please ask the study doctor or study staff to explain these terms to you.

Most common side effects:

- Tenderness, redness or swelling at the site of the injection.
- Temporary pain due to electroporation and/or at the injection site.

Rarely, contact with the high voltage current can cause severe burns.

In a similar study, this device was tested in 10 healthy volunteers, but the needles were longer, were inserted into the arm muscle and the voltage was higher. The average pain score on a scale of 0-10 was around 6, but decrease to 2 within 30 minutes. In this study, there are less needles and the needles will be inserted into your skin. Also the voltage will be lower. It is unknown if the pain will be the same or different than the previous study.

Because this device is investigational, all of its side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

**EKG**

You may have irritation, redness, and itching at the sites on your skin where the study doctor or study staff places the electrodes. You might need to shave the areas on your chest, arms, or legs where the study doctor or study staff wants to place the electrodes.

**BLOOD DRAW**

Taking blood may cause discomfort, bleeding, and bruising where the blood is drawn. Occasionally, there is swelling in the area where the needle enters the body and there is a small risk of infection. There is also a risk of lightheadedness, fainting, and blood clots.

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**ARE THERE RISKS RELATED TO PREGNANCY?**

It is not known whether the CELLECTRA<sup>®</sup> device used in this study can harm unborn babies. If you are having sex that could lead to pregnancy, you must agree not to become pregnant. If you are a woman of reproductive potential and choose to have sex, you must use a type of birth control listed below for the 7 days you are participating in the study:

- Condoms (male or female) with or without a spermicidal agent
- Diaphragm or cervical cap with spermicide
- IUD
- Hormone-based contraception

You cannot be in the study if you are pregnant or breastfeeding. It is not known whether the study device is safe for breast fed babies. Therefore if you are breastfeeding a child then it may not be safe for you to participate in the study. A pregnancy test can be wrong. The effects of the study device on an unborn baby are unknown. If you become pregnant during the study, notify the study doctor at once.

If you are pregnant or become pregnant during the study, the study device may involve risks to the unborn baby, which are currently unforeseeable.

**ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?**

You may receive the benefit of information about your health and a chance to be in a research study that may help others. There are no additional benefits.

**WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?**

Since this study is for research only, the only other choice would be not to be in the study.

**WHAT HAPPENS IF I CHOOSE NOT TO JOIN THE RESEARCH STUDY?**

The decision to join a study is up to you (voluntary). If you choose not participate in the study there will be no penalties or loss of benefits.

**WHAT ABOUT CONFIDENTIALITY?**

By signing this Consent/Authorization Form you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the processing of this study.

**What personal health information is collected and used in this study, and also might be shared?**

Personal health and contact (phone number, address) information collected as part of this study is recorded in your clinical trial chart. This record is separate from your medical chart. Data collected for the study is reported to the study team on a case report form, which includes the information listed below, but not your name or other identifying information. Results of

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laboratory tests or study procedures will be copied and sent to your primary care physician by name, at your request only.

Personal health information that is collected and will be disclosed to the agencies listed on the following page as part of this research study is:

- Demographics (Race, Gender)
- Signs and symptoms you experience while on the study
- Current and past medical diagnoses; allergies
- Current and past medications and therapies
- Information from a physical exam: weight, blood pressure, heart rate, temperature
- Data from laboratory tests (pregnancy tests)
- Data from EKG test
- Data from study questionnaires

**Why is your personal health information being used?**

Personal contact information, such as phone number and address, will be used only by clinical trial staff to get in touch with you while you are participating in this study. Your health information and results of tests and procedures are being collected as part of the research study and for the advancement of medicine and clinical care. The Principal Investigator will use the results to monitor your safety and ability to tolerate the study medications.

**Which of our personnel may use or disclose your personal health information?**

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and other University staff associated with this study;
- The University of Pennsylvania Institutional Review Boards (the Committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine work force who may need to access your information in the performance of their duties, for example, to provide treatment, to ensure the integrity of the research, accounting or billing matters, etc.

**Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive your personal health information?**

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- Pharmaceutical Sponsors: Drug companies (VGX Pharmaceuticals) who supply the CELLECTRA<sup>®</sup> device for the study will have access to safety information.
- Government Agencies: Data from this study will be made available to the Food and Drug Administration for them to evaluate the safety and efficacy of the treatments being used in this study.

Study staff will inform you if there are any changes to this list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by federal privacy protection regulations.

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In all disclosures outside the University of Pennsylvania Health System or School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier, unless disclosure of the direct identifier is required by law. Personal health information will be disclosed by a unique code number. Only study staff can break the code and identify you to your code.

**How long will the University of Pennsylvania Health System and the School of Medicine be able to use or disclose your personal health information?**

Your authorization for use of your personal information for this specific study does not expire. This information may be stored in a database (research repository). However, the University of Pennsylvania Health System and the School of Medicine may not re-use or re-disclose your personal health information collected for this study for another purpose other than the research described in this consent form unless you have given written permission to the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care will not be included in your medical record unless you want them to be sent to your primary care provider. You will need to complete a medical records release of information to allow us to provide study data to your doctor.

**Will you be able to access your records?**

You will be able to request access to your medical record when the study is completed. During your participation in the study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know the information to best treat you. You will have access to your medical record and study information that is part of that record when the study is over. The Investigator is not required to release to you research information that is not part of your medical record.

**Can you change your mind?**

You may withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at 502 Johnson Pavilion. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

**WHAT ARE THE COSTS TO ME?**

The study evaluations and assessments will be provided for free.

**WILL I RECEIVE ANY PAYMENT?**

You will receive a maximum of \$250 for your participation in the study if you attend all visits. This compensation will be given as cash according to the following schedule: \$50 for screening; \$75 for Day 1; \$50 for Day 2; \$75 for Day 7. You will NOT be compensated for visits you do not attend.

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**WHAT HAPPENS IF I AM INJURED?**

If you have a medical emergency during the study you may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available from the University of Pennsylvania. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

**WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?**

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. You will be treated the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you would like the results of the study, let the study staff know.

**WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-615-4321)
- Clinical Trials Unit (215 349-8092)

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

**SIGNATURE PAGE FOR STUDY**

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below.

\_\_\_\_\_  
Participant's Name (print)

\_\_\_\_\_  
Participant's Signature and Date

\_\_\_\_\_  
Participant's Legal Guardian (print)  
(As appropriate)

\_\_\_\_\_  
Legal Guardian's Signature and Date

\_\_\_\_\_  
Study Staff Conducting  
Consent Discussion (print)

\_\_\_\_\_  
Study Staff Signature and Date