Keck School of Medicine of USC
University of Southern California
1520 San Pablo St., Suite 3000
Los Angeles, CA 90033

Study Title: A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP, MULTI-CENTER TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF A SINGLE TREATMENT OF DAXIBOTULINUMTOXIN A FOR INJECTION IN ADULTS WITH ISOLATED CERVICAL DYSTONIA (ASPEN-1)

Protocol Number: 1720302

Principal Investigator: Danielle M. Feigenbaum, MD

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time: _____

Signature: _____
(Research Participant)

Keck School of Medicine of USC
University of Southern California
1520 San Pablo St., Suite 3000
Los Angeles, CA 90033

INFORMED CONSENT

TITLE: A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP, MULTI-CENTER TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF A SINGLE TREATMENT OF DAXIBOTULINUMTOXIN A FOR INJECTION IN ADULTS WITH ISOLATED CERVICAL DYSTONIA (ASPEN-1)

Protocol Number: 1720302

PRINCIPAL INVESTIGATOR: **Danielle M. Feigenbaum, MD**
Keck School of Medicine of USC
University of Southern California
1520 San Pablo Street, Suite 3000
Los Angeles, CA 90033

DEPARTMENT: NEUROLOGY

24-HOUR TELEPHONE NUMBER: (323) 442-8500

The study doctor wants to know if you would like to be a part of a research study. This consent form describes the study to help you decide if you want to participate. This consent form will tell you what you will have to do during the research study and the risks and benefits of the study.

If you have any questions about this consent form, or do not understand something in this consent form, you should ask the study doctor or study staff. You should discuss your participation with anyone you choose to better understand this research study and your options. You may take home an unsigned copy of this consent form for such a purpose. Do not sign this consent form unless the study doctor or study staff has answered all your questions, and you have decided that you want to be part of this research study. Your participation in this research study is completely voluntary. You have the right to say no to be in this research study, and it will not affect your normal medical care.

Participating in a research study is not the same as getting routine medical care. The purpose of routine medical care is to improve your health. The purpose of a research study is to gather information.

A company called Revance Therapeutics, Inc. (Revance), the sponsor of the research study, is paying for this research study. Revance is also paying the study doctor to conduct this research study.

WHY IS THIS STUDY BEING DONE?

Researchers want to find out if daxibotulinumtoxinA for injection, a new investigational study drug, is safe and effective for use in adults with isolated cervical dystonia (CD) and if the effects last longer than the standard toxin treatment. An “investigational drug” is a drug that is being tested and is one that has not been approved for sale.

In this research study, the investigational drug will be tested in subjects who have been diagnosed with CD and will be compared to placebo. Placebo is a substance that looks like the investigational drug but has no active drug in it.

DaxibotulinumtoxinA for injection is composed of purified botulinum toxin type A, formulated with a small protein RTP004, and will be used for injection. The placebo is identical to the investigational drug, except that it does not contain the botulinum toxin type A. This consent form refers to daxibotulinumtoxinA for injection and placebo as the “study drug.” Please ask your doctor if you have any questions about the study materials.

This research study will include about 300 adults with moderate to severe isolated CD who are 18 to 80 years old, at about 80 study centers in North America and Europe.

WHAT IS INVOLVED IN THE STUDY?

If you decide to be in this research study and the study doctor confirms that you can participate, your participation may last up to 39 weeks, including 3 weeks of screening.

You will come to the study center up to 12 times during the research study. The study staff will tell you when to come in for your study visits. It is important that you attend all your scheduled visits during your participation in the research study. You should ask the study staff how long your visits will last.

At 6 weeks, if you show no improvement or if you show worsening of your CD symptoms, and the study doctor agrees that you need a retreatment, you might be allowed to roll over into the open-label, long-term safety (OLS) research study (if eligible). If this is applicable, you will receive the consent form specific for this OLS study.

If you decide to be in this research study, you might have to stop taking your routine medication or treatment during the entire research study (including the screening period). If you stop your routine medication or treatment to be in the research study, your symptoms that are treated with your routine medications or treatments might come back or get worse.

After a screening period of up to 3 weeks, you will be assigned to a treatment group if you continue to qualify for the research study. You will receive study treatment 1 time during the research study. The study drug will be administered by injections into affected muscles around your neck.

The dose of study drug you receive will depend on the group that you will be put into after randomization at the time of your entry.

You will be assigned by chance in a 3:3:1 ratio to 1 of the 3 groups to receive either one of the 2 daxibotulinumtoxinA for injection doses or placebo. Placebo only looks like the real drug but it does not have any drug in it. There will be about 129 subjects assigned to Group 1, 129 subjects assigned to Group 2, and 43 subjects assigned to Group 3:

- Group 1: High-dose (250 Units of daxibotulinumtoxinA for injection)
- Group 2: Low-dose (125 Units of daxibotulinumtoxinA for injection)
- Group 3: Placebo

A Unit is a dosing measurement for botulinum toxin.

You have 3 out of 7 chances of being in Group 1, 3 out of 7 chances of being in group 2, and 1 out of 7 chances of being in Group 3. Neither you nor the study doctor will be able to select which study group you are in. You and the study doctor will not know which study group you are in. The study doctor can find out which group you are in if it is necessary to know for your health. This is called “unblinding.” However, the unblinding information may not be shared with you until everyone finishes the research study.

The dose you receive may be too low to have the best effect or so high that it causes bad side effects.

The study staff will review how you are doing for at least 30 minutes after the injections, and if you are not having problems, you will be allowed to leave the study center.

After the injection session, you must contact the study doctor immediately in the event of any abnormal symptoms, such as double-vision, muscle weakness, difficulty swallowing, breathing or speaking, or if you develop a severe rash or develop itching.

While you are in the research study, you must:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the research study at any time.

What happens when I come for study visits?

Before you can start the research study, the study doctor or study staff will talk to you about the research study. If you agree to participate, you will sign this consent form before the study doctor or study staff can begin the screening period to see if you are eligible to be in the research study.

After you sign this consent form, the study doctor or study staff will conduct the tests and procedures listed below when you come in for study visits. If you want more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

Demographic Questions: You will be asked to give personal information about yourself, such as your name, year of birth, and race.

Health and Medication Questions: You will be asked to answer questions about your health, your medical history, and the medications you take.

Vital Signs: The study doctor or study staff will check your blood pressure by putting a band around your arm (this will squeeze your arm for about a minute), check your pulse, listen to you breathe in and out, take your temperature, weight, and height.

Physical and Neurological Examinations: The study doctor will examine your body and check your reflexes, muscle strength, and coordination.

Pregnancy Test: You will not be allowed to participate in the research study if you are pregnant. If you are a woman and are able to have children, at the screening visit, a blood (serum) pregnancy test will be performed. The study doctor or study staff will tell you if the pregnancy test results are positive. If the test result is positive, you will not participate in the study. At all required visits after screening, a urine pregnancy test will be taken. If positive, you will have an additional blood test for pregnancy to confirm the result. If positive, you will remain in the study for safety follow-up. Your urine sample will be kept until this testing is complete, and then it will be destroyed.

Blood Testing: Blood samples will be collected from a vein in your arm to test for your general health and also to see if you have or are developing immunity to the study drug or the small protein, RTP004. If you are a woman and can have children, your blood will also be tested at screening, and possibly at later visits, to make sure that you are not pregnant. A total of about 95 mL of blood (about 19 teaspoons) will be taken from you during the about 10-month study period. Some of your blood will be frozen and stored until the end of the study for analysis in a secure laboratory in the United States of America, after which your blood sample will be destroyed.

Urine Testing: You will be asked to give a urine sample to do laboratory tests. Urine testing gives some information about your health.

12-Lead Electrocardiogram (ECG): An ECG is a painless test to measure the electrical activity and health of your heart. The study staff will place sticky patches on your chest and a machine will measure your heart activity.

Spirometry: Spirometry is a painless test to measure how well your lungs are working. The study staff will ask you to breath into a spirometer for your lung function to be tested.

Questionnaires, Evaluations, and Assessments: Your health and your CD signs and symptoms will be assessed by various rating scales performed by the study doctor or the study staff. You will be asked a series of questions about your physical and mental health. The study staff will check the injection site for any pain, redness or swelling and ask you about any medications you have taken or if you've had any health problems. Before treatment, you will be assessed as to whether or not you have any difficulties swallowing and this assessment will be conducted after treatment, only if you report any difficulties swallowing. You will also be asked to complete some quality-of-life questionnaires at certain study visits which may take about 30 - 60 minutes for you to complete.

Injection Site Evaluation: The sites where your doctor injected the study drug will be examined to check for any pain, redness, bruising, or swelling.

Videography (optional): At the screening visit only, a digital video of your face and body may be recorded by the study doctor or study staff at the same time that you are being assessed for your cervical dystonia symptoms. The main purpose of this video is to assure that your cervical dystonia symptoms were accurately assessed and that you meet the criteria to enter the study. This video will assure that all the study doctors in the study are consistent in the way that they assess the cervical dystonia symptoms of the research study participants.

No identifying information other than your image will be associated with the video and since this video is considered research study data, your privacy and confidentiality will be protected as described in this informed consent form.

The video will be transferred through secure, password-protected medium to a secure server hosted by a third party vendor (Medidata Solutions Worldwide). The only people who will have access to the video will be the authorized staff at Medidata Solutions Worldwide and the key cervical dystonia expert doctors who will be assigned to review the video to confirm whether the study doctor conducted the cervical dystonia assessment correctly.

The video will be destroyed once the last subject in the study has completed the follow-up visit.

You can still be in the research study even if you do not want the study doctor or study staff to record a video of you.

I agree to be video recorded in this research study as described above (please check one box only).

Yes ☐

No ☐

Screening Visit (Day -21 to Day -1)
At the screening visit, you will have the following procedures and assessments done:

- Review of study procedures; informed consent and privacy authorization.
- Discussion of eligibility criteria for study entry.
- Demographics.
- Discussion of medical/surgical history.
- Discussion of history of CD/CD treatment.
- Physical and neurological examinations.
- Vital signs will be checked.
- 12-lead ECG.
- Pregnancy test (if you are a woman and can have children).
- Blood and urine testing.
- Questionnaires, evaluations, and assessments will include Columbia Suicide Severity Rating Scale (C-SSRS), Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS), Dysphagia Severity Scale (DSS).
- You will be asked about medications you are taking.
- You will be asked about any health conditions.

Baseline/Treatment Visit (Day 1)
The Baseline/Treatment Visit must be performed within 3 weeks of the Screening Visit.

At the baseline/treatment visit, you will have the following procedures and assessments done:

- Discussion of eligibility criteria for study entry.
- Physical and neurological examinations.
- Vital signs will be checked.
- Discussion of medical/surgical history.
- Discussion of history of CD/CD treatment.
- Pregnancy test (if you are a woman and can have children).
- Lung function test with spirometry.
- Questionnaires, evaluations, and assessments will include Columbia Suicide Severity Rating Scale (C-SSRS), Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS), Dysphagia Severity Scale (DSS), Cervical Dystonia Impact Profile (CDIP-58), Work Productivity & Activity Impairment, Short Form-36 (SF-36), Distant spread of toxin adverse event queries.
- You will be asked about any changes to medications or new medications you are taking.
- You will be asked about any health changes, in particular about any muscle weakness.

After qualifying for the research study, you will have additional baseline tests. If you continue to be eligible, you will receive initial study treatment administered by injections directly into affected muscles.

You will be observed at the clinic after completion of the treatment session for at least 30 minutes before you can leave (if there are no immediate safety concerns), for evaluation of injection sites, vital signs, and distant spread of toxin adverse event queries.

If you have any clinically significant or suspicious signs or symptoms after injections, you will remain with the investigator and staff for further observation and may be treated medically if necessary.

If you are not having problems, you will be allowed to leave the study center.

Follow-Up Visits
Subsequent study visits are at Weeks 2, 4, 6, 12, 16, 20, 24, 28, 32, and 36 weeks. The following procedures (all or some) will take place during the follow up visits:

- Physical and neurological examinations.
- Vital signs will be checked.
- 12-lead ECG.
- Lung function test with spirometry.
- Pregnancy test (if you are a woman and can have children).
- Blood and urine testing.
- Questionnaires, Evaluations and Assessments will include Columbia Suicide Severity Rating Scale (C-SSRS), Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS), Cervical Dystonia Impact Profile (CDIP-58), Patient Global Impression of Change (PGIC), Clinical Global Impression of Change (CGIC), Dysphagia Severity Scale (DSS), Treatment Satisfaction Questionnaire (TSQ), Work Productivity & Activity Impairment, Short Form-36 (SF-36), Distant spread of toxin adverse event queries, Injection Site Evaluation.
- You will be asked about any changes to medications or new medications you are taking.
- You will be asked about any health changes, in particular about any muscle weakness.

At the week 6 visit, if you show no improvement or worsening of your CD symptoms and the study doctor agrees that you need a retreatment, you can complete the research study and be eligible to rollover into the OLS research study, if you qualify.

If your CD symptoms are still being successfully treated at the week 6 visit, you will continue in the research study up to week 36.

If the study doctor determines that your CD symptoms are coming back at or after week 12, you may be eligible, upon qualifying, to rollover into the OLS research study.

If you choose to withdraw from the research study at any time, you will be asked to return to the study center to complete the final evaluation visit.

End-Of-Study Visit (EOS)
You will have an end-of-study visit post-injection at 6 weeks or later, depending on your CD symptoms. The latest time for an end-of-study visit is 36 weeks after your injection.

The following procedures will occur:

- Physical and neurological examinations.
- Vital signs will be checked.
- 12-lead ECG.
- Pregnancy test (if you are a woman and can have children).
- Blood and urine testing.
- Questionnaires, Evaluations and Assessments will include Columbia Suicide Severity Rating Scale (C-SSRS), Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS), Cervical Dystonia Impact Profile (CDIP-58), Treatment Satisfaction Questionnaire (TSQ), Work Productivity & Activity Impairment (WPAI), Short Form-36 (SF-36), Distant spread of toxin adverse event queries, Patient Global Impression of Change (PGIC), Clinical Global Impression of Change (CGIC), Dysphagia Severity Scale (DSS).
- Lung function test with spirometry.
- Injection site evaluation.
- You will be asked about any changes to medications or new medications you are taking.
- You will be asked about any health changes, in particular about any muscle weakness.

If you would like more information about which tests and procedures will be done at each study visit, ask the study doctor or study staff.

What should I know about rolling over into the OLS research study?
If you show no improvement or worsening of your CD symptoms at week 6, or after week 12, and the study doctor agrees that you need a retreatment, you might be eligible, if you qualify, to rollover into the OLS research study.

If you reach the week 36 visit, and the study doctor determines that your CD symptom have still not come back, you will be allowed to roll over but will not receive your first treatment at that time. You will be followed in the OLS research study until your CD symptoms return and you require treatment (which will be your initial OLS treatment).

If determined that you are eligible to rollover into the OLS research study, you will have up to 7 days to decide. After 7 days, if we have not heard from you, you will be considered not interested in participating in the OLS study. If you are interested in participating in the OLS study, and have decided within the 7-day roll over period, all your EOS procedures and tests will carry over as screening and baseline data for the OLS. If you decide after the 7-day window to participate, all of your screening and baseline procedures and tests will have to be redone prior to enrollment.

What else should I know about the research study procedures?

Your routine medical care might include some of the study tests and procedures. The study doctor or a member of the study staff can answer any questions you may have about which tests and procedures are not part of your routine medical care

If you do not return to the study center for follow-up visits, you will be contacted by phone to determine the reason(s) why you did not return. If you are unreachable by telephone after a minimum of 1 call on 2 different days, a registered letter will be sent requesting that you contact the study doctor.

WHAT ABOUT PREGNANCY?

If you are a woman, you cannot be in this research study if you are:

- pregnant
- planning to become pregnant during the research study
- nursing (breast-feeding) a child

If you become pregnant while on this research study, there may be risks to your unborn baby. Nobody knows what these risks are right now. Some drugs cause women to have their babies prematurely (early) or to have babies with birth defects.

If you are a woman who can have children, the study doctor will talk to you about birth control methods you must use during the research study. Some methods of birth control will not work when you are taking certain drugs (i.e. antibiotics). Be aware that you can still become pregnant even if you use an acceptable birth control method.

Acceptable methods of birth control are one non-barrier method such as established use of the oral contraceptive pill, injection, implant, patch, vaginal ring, intrauterine coil or device, tubal ligation, used in combination with a barrier meothod of contraception such as female/male condom with either cap, diaphragm, or sponge with spermicide. This provides a double barrier method of contraception. True abstinence (i.e. no heterosexual intercourse) or having a vasectomized partner is considered acceptable methods of contraception. Effective methods of contraception must be used from the start of the study, Baseline visit, to 30 days after the end of study participation.

All forms of birth control must be used according to the birth control manufacturer and your health care provider in order to prevent pregnancy.

The study doctor will require women who are able to have children and who join the research study to have a pregnancy test during the research study. A pregnancy test does not keep you from becoming pregnant.

If you think you are pregnant during the research study, you must tell the study doctor immediately. If you become pregnant after treatment, you can remain in the research study but will not receive any further treatment. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with the sponsor and the University of Southern California Health Sciences Campus Institutional Review Board, a research ethics board that reviews research studies to protect the rights and welfare of research participants.

If you are a male with a partner who is able to have children, you are responsible for using an effective birth control method, such as the ones listed above. Effective methods of contraception must be used from the start of the study, Baseline visit, to 30 days after the end of study participation.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

All drugs carry a risk of side effects. Some people who have received injections of daxibotulinumtoxinA for Injection above and between the eyebrows in a prior research study reported the following side effects:

- headache in 14% of subjects
- itching at injection site in 5% of subjects
- burning sensation/pain at injection site in 6% of subjects
- eye disorders in 8% of subjects

Some people who have received daxibotulinumtoxinA for Injection for CD, in a prior research study, reported the following side effects:

- swallowing difficulties in 16% of subjects
- upper respiratory tract infection in 11% of subjects
- urinary tract infection in 11% of subjects
- injection site pain in 8% of subjects
- injection site redness in 8% of subjects
- nausea in 8% of subjects
- injection site bruising in 5% of subjects
- muscle tightness in 5% of subjects
- muscular weakness in 5% of subjects

The side effects were generally temporary but may last several weeks or longer.

Botulinum toxin, when given as directed, is expected to act at the site of injection. Reports of side effects possibly related to spreading of botulinum toxin products beyond the injection site include effects such as:

- generalized loss of strength and muscle weakness
- extreme tiredness
- double vision or blurred vision
- eyelid drooping
- loss of facial muscle movement
- hoarseness
- loss of bladder control
- shortness of breath
- difficulty in swallowing
- difficulty speaking
- death due to complication from severe problems with swallowing or breathing
- symptoms of allergic reaction (rash, itching, etc.)

At each visit (not including the screening visit), you will be asked whether you have experienced any of these symptoms that could occur with the spread of botulinum toxin.

Ask the study doctor if you have questions about the signs or symptoms of any side effects you read about in this consent form.

There may be risks associated with daxibotulinumtoxinA for injection that are not yet known. Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the research study, whether or not you think they are related to the study drug.

Could I have an allergic reaction?

Sometimes people have allergic reactions to drugs and to product ingredients. If you have a very bad allergic reaction, you could die. Some things that happen during an allergic reaction that could be a sign or symptom of a life-threatening allergic reaction (anaphylaxis) are:

- a rash
- having a hard time breathing
- wheezing when you breathe
- sudden drop in blood pressure (making you feel dizzy or lightheaded)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating
- a feeling of dread
- inability to breathe without assistance

You should get emergency medical help and contact the study doctor or study staff if you have any of these or any other side effects during the research study. Please tell the study doctor or study staff if you have any other problems with your health or the way you feel during the research study, whether or not you think they are related to the study injections.

Serious allergic reactions that can be life-threatening may occur.

If I stop using my routine medication what are the risks?

If you stop your routine medication to be in the research study, your health symptoms might come back or get worse. Please tell the study doctor or study staff right away if you have any problems when you stop using your routine medication.

What are the risks of being injected with study drug and giving blood for this research study?

The study doctor or study staff will take your blood by sticking a needle in your arm and the study doctor will administer the study drug by injecting into the neck muscles that require treatment. You may have some problems from needle injections, such as:

- It may hurt.
- You may get a bruise.

- You may feel dizzy.
- You may get an infection.

Could I have any other problems with my health if I participate in this research study?

It is possible that you could have problems and side effects from the study drug that nobody knows about yet, which could include your CD symptoms getting worse or even death.

It is very important that you tell the study doctor about all medications, vaccines, or supplements that you are taking during the research study because there may be some change in effects of any these including daxibotulinumtoxinA for injection.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

Are there any other risks?

There is a risk of loss of confidentiality of your health information that is used in this research study. You will read more about the protection of your information later in this consent form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this research study.

Some of the questions that you will be asked to answer may make you uncomfortable or upset, but they are needed as part of your participation in the research study. Please tell the study doctor or study staff if you feel uncomfortable or upset while answering questions. You have the right to refuse to answer any questions.

WILL YOUR INFORMATION BE KEPT PRIVATE?

Your identity will be protected as required by law and according to any policies the study center or sponsor may have. Be aware that your study records (which include your medical records, your signed consent form, and other information) will be shared as needed for the research study. For example, the US Food and Drug Administration (FDA), Health Canada, the European Medicines Agency (EMA), the sponsor, and the University of Southern California Health Sciences Campus Institutional Review Board, may look at your study and medical records.

While participating in this research study, the study doctor and study staff will replace your name with a code that identifies you. Your study information and your blood and urine samples will have a code instead. The list that matches the code with your name will be stored separately at the study center.

You should ask the study doctor or study staff about how long your blood samples might be kept. If you change your mind about being in the research study later, be aware that your samples may or may not be withdrawn from the research, depending on the sponsor's policies. You can ask the study doctor or study staff about this.

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.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

The study drug may improve your CD symptoms, but there is no guarantee that being in this research study will help you. Your CD symptoms might not get better or may even get worse while you are in this research study. Information from this research study might help researchers to come up with new tests or medications to help others in the future.

WHAT OTHER OPTIONS ARE THERE?

You do not have to be in this research study to get help for your CD. The study doctor will talk to you about other things you can do for CD, including injections of botulinum toxin outside of the research study. The study doctor will discuss the advantages and disadvantages and risks and benefits of these alternatives with you. In addition, you may discuss your options with your primary healthcare provider.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

Site will use the Greenphire ClinCard solution to provide the Subject reimbursement, Subject caregiver reimbursement, and reimbursement for pre-approved travel costs in the amount of up to USD 150.00 per visit, including unscheduled visits. This allowance is intended to offset the Subject's actual travel costs, including but not limited to lodging, meals, and parking that are incurred as a result of Subject participation and has been approved by the Sponsor and IRB/IEC, as reflected in the Informed Consent Form.

WHAT ARE THE COSTS?

The study will pay for all research tests and procedures. You and/or your health plan/insurance will not be billed for tests and procedures that are done in this research.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. The sponsor will pay for the treatment if your injury is the result of your participation in the study, use of the study drug/device, and properly-performed research procedures.

However, by signing this form you have not given up any of your legal rights.

WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?

If the study doctor learns of any new information that might change your mind about continuing in the research study, the study doctor or study staff will tell you about it in a timely manner. The study doctor will also tell you if new approved treatments become available for your CD. You may be asked to sign a new consent form if this occurs.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this research study is voluntary (your choice). You can decide not to be in the research study, and you can change your mind about being in the research study at any time. There will be no penalty to you, and you won't lose any benefits to which you are otherwise entitled. Your routine medical care at this study center will not change if you decide not to be in the research study. If you want to stop being in the research study, tell the study doctor or study staff.

CAN YOU BE REMOVED FROM THE STUDY?

The study doctor or sponsor can remove you from the research study at any time, even if you want to stay in the research study. This could happen if:

- The study doctor or study staff believes it is best for you to stop being in the research study.
- You do not follow directions about the research study.
- The sponsor stops the research study for any reason.

If you stop being in the research study early, the study doctor or study staff may ask you to complete the final evaluation visit. To help you leave the research study safely, the study doctor may ask you to participate in more tests.

If you do not show up for the final visit, the study doctor or study staff will try to reach you by telephone and, if unsuccessful, by letter.

If you leave the research study, the study doctor and study staff will still be able to use your information that they have already collected.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Danielle Feigenbaum, M.D. at (323) 442-5710 (during business hours) with any questions, concerns, or complaints about the research or your participation in this study. If you need to reach the study doctor after business hours call (323) 442-8500 and ask the operator to page Danielle Feigenbaum, MD. You can also reach the study helpline at 1-800-989-7751. If you feel you have been hurt by taking part in this study, please contact Danielle Feigenbaum, M.D. at (323) 442-8500. If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-442-0114 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Fax: 323-224-8389 or email at irb@usc.edu).

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the Institutional Review Board at 1640 Marengo Street, Los Angeles, CA 90033.

You will get a copy of this consent form.

Keck School of Medicine of USC
University of Southern California
1520 San Pablo St., Suite 3000
Los Angeles, CA 90033

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

_____	_____	_____	_____
Name of Research Participant	Signature	Date	Time

I have personally explained the research to the participant using non-technical language. I have answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

_____	_____	_____	_____
Name of Person Obtaining Informed Consent	Signature	Date	Time

A witness is required when: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form. If no witness is needed, leave this signature line blank.

Name of Witness	Signature	Date Signed