NCT06316973

IRB APPROVED
AS MODIFIED
Feb 05, 2024

PARTICIPANT INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

TITLE:	A Phase 1a, Randomized, Double-Blind, Placebo-Controlled, Single Center Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of CS-1103 Following Single, Ascending Intravenous Dose Administration in Healthy Participants
PROTOCOL NO.:	CS-1103-01 WCG IRB Protocol #20240083
SPONSOR:	Clear Scientific, Inc.
INVESTIGATOR:	Steven G. Hull, M.D., FCCP, FAASM Dr. Vince Clinical Research 7401 W. 91st Street Overland Park, KS 66212 United States
STUDY-RELATED PHONE NUMBER(S):	(913) 333-3000 (24-hour number)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This section provides a brief summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide full details.

Why is this study being done?	You are being asked to take part in a first-in-human research study which will look at an investigational drug, CS-1103, that is being developed to lower the level of methamphetamine in the human body. An investigational drug is a drug that has not been approved by the Food and Drug Administration (FDA). Your participation in this study is voluntary.
Who is being asked to take part in this study?	You are being asked to take part in this research study because you are a healthy adult and have expressed an interest in participating in clinical research. Approximately 40 participants will take part in this research study.
How long will you have to be in this study?	If you qualify and decide to participate in the research study, your total participation is expected to last up to approximately 37 days (approximately 5 weeks). The study will have: • A screening period of up to 28 days before the in-house period to confirm whether you are qualified to participate • An in-house period for 4 days (3 nights) at the clinical research site • A clinic follow-up visit 5 days after being released from the clinical research site
What will happen to you during this study?	If you qualify and decide to participate in the research study, you will receive one dose of either CS-1103 or placebo (a substance that looks like the study drug) by intravenous (IV) infusion (a slow injection into a vein). For the purposes of describing the study, the term “study drug” will be used to discuss both CS-1103 and placebo. Study staff will closely monitor your health and perform various safety tests while you are in the clinical research site, such as taking your blood pressure, pulse rate, and ECG (measurement of the electrical activity of your heart). The complete list of procedures can be found later in the form.

What are the risks for being in this study?	CS-1103 has not been studied in humans. The following are some of the potential risks for this study based on studies in rats and dogs: • Allergic or hypersensitivity reaction, including redness of the skin, hives, puffy eyes, and loose stools. • Renal (acute kidney or bladder) injury • Injury at the intravenous injection site The complete list of risks can be found later in the form. For your safety, you should be honest about your health history.
Will blood be taken during this study?	During this study, blood samples will be collected from you. The maximum amount of blood drawn during the study will be approximately 450 mL (about 1.9 cups). Additional blood samples may need to be taken to monitor your health if the study staff find it necessary. The site standard is to draw via direct venipuncture (single needle-stick in a vein). In rare cases, a catheter may be used for a minimal number of blood sample collections. In these rare cases, this would add approximately 1 mL of blood that will be discarded prior to any blood samples taken from a catheter. Risks associated with having blood samples taken can be found later in the form.
Will being in this study benefit you?	This study is for research purposes and is not intended to treat any symptoms or illness. Therefore, there will be no direct benefit to you for being in this study. By taking part in this study, you may be helping others by providing important information about the study drug(s) and by contributing to medical knowledge.
What alternatives do you have to being in this study?	No therapeutic or other health benefits will result from participating in this study, so your only alternative is to not participate in this study.
Will you be paid for being in this study?	If you complete the screening process for this study, you may receive up to $250.00. If you qualify and decide to participate in the research study, follow all study requirements and clinical research site rules, and complete all required study visits, you may be compensated up to $3,500.00.

DETAILED RESEARCH CONSENT

What is the purpose of this form?

You are being invited to take part in a research study. A person who takes part in a research study is called a research participant, subject or volunteer. A research study is a scientific way to investigate, improve or develop new methods of health care. Research studies are designed to answer specific questions about how to prevent, diagnose, or treat diseases and disorders.

The purpose of this form is to give you important information about this study to help you decide if you want to participate. It describes the purpose of this study, the study procedures, the possible risks, and provides information about your rights as a research participant.

This form may contain words or procedures you do not understand. Please read this form carefully and take the time to ask the study staff as many questions about the study as you would like. You can also discuss this research study with other people such as your family, friends, or personal doctor.

Your participation is entirely voluntary, and you can change your mind and leave the study at any time. If you choose to leave the study at any time, your regular medical care and legal rights will not be affected, and you will not lose any benefits to which you would otherwise be entitled. If you decide to participate in this study, you will be required to sign and date this informed consent form. You cannot take part in this research study until you sign and date this form. You will receive a copy of this signed and dated informed consent form to keep for your records.

What should you know about this study?

- The study staff will explain this research study to you.
- This form summarizes that explanation.
- Taking part in this research study is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand this consent form or what is being explained to you about this research study, please ask questions before you decide to participate.

Why is this study being done?

This study involves the use of an investigational drug called CS-1103. CS-1103 is being developed by Clear Scientific, Inc. to lower the level of methamphetamine in the human body. An investigational drug is a drug that has not been approved by the U.S. Food and Drug Administration (FDA). The purpose of this research study is to collect safety information about a single dose of this investigational drug, CS-1103, over multiple dose levels, and how well that single dose is tolerated.

This study will also evaluate the pharmacokinetics (PK) of CS-1103. PK is the study of how a drug moves through the body including how it is absorbed (taken into the body), distributed (spread throughout the body), metabolized (broken down in the body) and eliminated (removed from the body) and how the body affects the drug. The study will also look at how CS-1103 affects the heart.

This research study is being conducted at one research site in the United States. Approximately 40 participants will receive the study drug as part of this research study.

How will this study be done?
This is a placebo-controlled study, where either CS-1103 or placebo (a substance that looks like CS-1103) will be administered by intravenous (IV) infusion (a slow injection into a vein). For the purposes of describing the study, the term "study drug" will be used to include both CS-1103 and placebo.

If you are eligible to participate in this study, you will be assigned to one of the following treatment cohorts (groups) listed below. You will be randomly assigned to receive either CS-1103 or placebo. Randomly assigned means that the treatment you receive will be assigned by chance (like flipping a coin/drawing straws). You have a 1 out of 4 (25%) chance of receiving placebo in each cohort. Neither you, the investigator, nor the study staff will know whether you are receiving the CS-1103 or placebo. The clinical pharmacy staff at the clinical research site will know. In an emergency, the study staff can find out whether you were given CS-1103 or placebo if it is necessary for your medical care.

This study will include a total of 5 cohorts. You will take part in only one of the cohorts listed below. You cannot choose which study cohort you will be placed in.

Cohort	Number of Participants	CS-1103 Dose	Number of Participants Receiving CS-1103 (Active): Placebo
1	8	2.7 mg/kg	6:2
2	8	8.0 mg/kg	6:2
3	8	16.0 mg/kg	6:2
4	8	26.7 mg/kg	6:2
5	8	40.0 mg/kg	6:2

mg = milligrams, kg = kilograms

The decision to proceed to the next study drug dose level will be made by the Sponsor and Safety Committee after they review all laboratory tests, vital signs, ECG data, reported side effects and Pharmacokinetic (PK) data from the previous dose cohort(s). This is to be sure the previous dose level(s) were well-tolerated by participants. Depending on the overall results of this review, the dose for your cohort could be higher, lower, the same, or the study could be stopped. You will be informed of the dose level for your cohort prior to receiving your first dose of study drug. No dose will be higher than the maximum dose of 40 mg/kg.

Who is being asked to take part in this study?
You are being asked to take part in this research study because you are a healthy adult and have expressed an interest in participating in clinical research.

How long will you have to be in this study?
If you qualify and decide to participate in this research study, your participation is expected to last up to approximately 37 days (approximately 5 weeks).

Your participation will include:

- Up to a 28-day screening period between the Screening Visit and the in-house stay at the clinical research site
- An in-house period in the clinical research site lasting 4 days and 3 nights from Day -1 to Day 3
    - During the in-house period, 2 subjects will first receive a "sentinel" dose which means you will be dosed before other subjects: 1 subject will receive the study drug and 1 subject will receive the placebo. After a 24-hour follow-up, the investigator will review the safety and tolerability data of these subjects and the remaining subjects will receive the study drug only if the investigator decides that it is safe to continue.
    - All subjects in each cohort will come to the clinical research site at the same time regardless of whether you are part of the sentinel dosing group or part of the remaining group.
        - If you are selected to receive a sentinel dose, you will receive the study drug the day after you check in to the clinical research site on Day -1. The study staff will determine if you will be selected to receive the sentinel dose or not.
        - If you are not selected to receive a sentinel dose, you will be required to remain in-house at the clinical research site for up to 1 additional day before you will receive the study drug.
- A follow-up visit on Day 8 (5 days after being discharged from the clinical research site)

It is important for you to understand how often you will need to come to the clinical research site, how long each study visit and in-house stay will be, what tests and procedures will be performed, and what rules and restrictions you must follow in order to participate in this study.

What will happen to me during this study?

Before entering this study, you will be given information about the study and asked to read this informed consent form. After you have read the consent form, all your questions have been answered, and you have had time to think about whether you wish to participate in this study and discuss it with family, friends, or your personal doctor, you will be asked to sign and date this consent form.

You will be asked to give personal and medical information about yourself. You must be honest when you are asked about your health and medical history or you may not be allowed to participate in this study in order to protect your health, safety, and well-being.

Screening Visit

If you agree to take part in this research study, tests and procedures will be performed to determine if you are eligible to participate.

You will be asked to fast (no food or drink other than water) for at least 8 hours before these tests and procedures will be performed to ensure accurate test results. You will be given an identification wristband to wear during your visit to the research site.

The Screening Visit will include the following tests and procedures:

- You will be asked about your demographic information including your age, sex, race, and ethnicity
- You will be asked about your medical history including any surgical procedures you have had, your history of recreational drug use, as well as alcohol, caffeine, and tobacco use
- You will be asked about any prior and/or current medications you are taking, including prescription medication, over-the-counter medication, vitamins, and supplements
- A complete physical examination
- Vital signs defined as triplicate (taken 3 times) blood pressure, and single heart rate, oxygen saturation (level of oxygen in your blood), breathing rate, and body temperature
- Height and weight
- Your body mass index (BMI) will be calculated – This is a measure of your weight in relation to your height
- Triplicate (taken 3 times) ECG – This records the electrical activity of your heart.
- Blood and urine samples for laboratory tests
- Urine drug screen*
- Urine or breath alcohol test*
- Blood test for human immunodeficiency virus (HIV) and Hepatitis B and C*
- Blood pregnancy test for all females*
- Blood test to confirm menopausal status for females
- Complete an Anxiety Symptoms Questionnaire (ASQ) at the discretion of an investigator – A questionnaire that measures the symptoms of anxiety and how frequent and intense or bothersome they are

*These tests must be negative for you to participate in this research study.

Completing the Screening Visit does not guarantee you will be able to participate in this research study. If you test positive for any prohibited and illicit drugs or alcohol during the Screening Visit, you will not be allowed to participate in the study. The results of the screening tests and procedures will be reviewed by the study staff to determine your eligibility to participate in this research study. The study staff will contact you about the results of your Screening Visit.

<u>Clinical Research Site Check-In/Admission (Day -1)</u>
You will be required to fast (no food or drink other than water) for at least 8 hours before the Check-In Visit.

You will report to the clinical research site for admission 1 day before you receive the first dose of study drug. Upon admission to the clinical research site, you will be given an identification wristband to wear during your entire stay at the clinical research site.

You will be required to stay at the clinical research site for 4 days and 3 nights. All meals, snacks, and drinks will be provided to you during your stay at the clinical research site, but you will only be allowed to eat the food and drinks during the scheduled mealtimes. You will be allowed to drink water as needed unless specific restrictions are required. You will be informed of any specific water restrictions during the study.

If you test positive for COVID-19, or any prohibited and illicit drugs or alcohol during the Check-In Visit, you will not be allowed to participate in the study.

The Check-In Visit will include the following tests and procedures:

- You will be asked about any changes to your health, medical history, and medication use since your Screening Visit
- A brief physical examination
- Vital signs defined as triplicate blood pressure, and single heart rate, oxygen saturation, breathing rate, and body temperature
- Weight
- Triplicate ECG
- Holter Monitoring – This is a portable device that will be worn for 4 hours to record the rhythm of the heart with electrodes attached to the chest.
- Blood and urine samples for laboratory tests
- COVID-19 test*
- Urine drug screen*
- Urine or breath alcohol test*
- Urine pregnancy test for all females*
- You will be asked about any prior and/or current medications you are taking, including prescription medication, over-the-counter medication, vitamins, and supplements
- Complete an Anxiety Symptoms Questionnaire (ASQ) at the discretion of an investigator
- You will be shown how to collect your urine during the study. On Check-In Day, your urine will be collected starting from 12 hours prior to the time you are scheduled to receive the study drug

*These tests must be negative for you to participate in this study.

The results of the check-in tests and procedures will be reviewed by the study staff to determine if you are eligible to continue to participate in this study.

<u>Check-In Controlled Search</u>

To ensure that the clinical research site remains pleasant and safe for all involved, we may ask that study volunteers change into a gown. This helps to ensure that no prohibited items are brought into the clinical research site.

You will be asked to step into the dressing room, remove all clothing (including undergarments), and change into a gown. Once you have done so, study staff will verify the absence of prohibited items. If you have any questions or concerns about the nature of the search, please ask the study staff for more details. If you are uncomfortable about the search, you have the right to leave the study. Your bags and possessions will also be checked for prohibited items. Upon completion, you will change into your scrubs. Any prohibited items will be placed in your locker to be retrieved upon discharge. We appreciate your understanding and cooperation in this process.

In-House Stay (Day 1)

You will be required to fast (no food or drink other than water) for at least 10 hours before you receive the study drug.

Before you receive the study drug, the following tests and procedures will be performed:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken
- Urine samples for laboratory tests
- Triplicate ECG
- Holter Monitoring – This will be worn for 24 hours starting one hour prior to dosing
- Vital signs defined as triplicate blood pressure, and single heart rate, oxygen saturation, breathing rate, and body temperature
- Injection Site Assessment – The injection site will be examined for redness and swelling prior to the injection
- Your urine will continue to be collected
- A blood sample will be collected for PK (study of how the study drug moves through the body) testing
- Complete an Anxiety Symptoms Questionnaire (ASQ) at the discretion of an investigator

You will then receive a one-time infusion of the study drug over a period of approximately 10 minutes.

During the infusion, the following tests and procedures will be performed:

- Vital signs defined as single blood pressure, heart rate, oxygen saturation, breathing rate and body temperature

You will be required to fast (no food or drink other than water) for at least 4 hours after you receive the study drug. After the 4 hours, you will be served standard meals and drinks.

After the infusion, the following tests and procedures will be performed:

- Your urine will continue to be collected in a container until 48 hours post-dose.
- Blood samples will be collected for PK testing 15 times throughout the day.
- Single ECGs will be performed 2 times throughout the day
- Triplicate ECGs will be performed 5 times throughout the day
- Vital signs defined as single blood pressure, heart rate, oxygen saturation, breathing rate, and body temperature will be taken 2 times throughout the day
- Vital signs defined as triplicate blood pressure, and single heart rate, oxygen saturation, breathing rate, and body temperature will be taken 6 times throughout the day
- Complete an Anxiety Symptoms Questionnaire (ASQ) 3 times throughout the day at the discretion of an investigator
- Injection Site Assessment – The injection site will be examined for redness and swelling 7 times throughout the day

In-House Stay (Day 2)
The following tests and procedures will be performed at approximately 24 hours from the time you received study drug:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken
- Blood and urine samples for laboratory tests
- Triplicate ECG
- Holter Monitor will be removed
- Vital signs defined as triplicate blood pressure, and single heart rate, oxygen saturation, breathing rate, and body temperature will be taken 2 times throughout the day
- A brief physical examination
- Injection site assessment
- Blood samples will be collected for PK testing 2 times throughout the day
- Your urine will continue to be collected in a container until 48 hours post-dose.

Discharge Day (Day 3)
The following tests and procedures will be performed at approximately 48 hours from the time you received study drug:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken
- Triplicate ECG
- Vital signs defined as triplicate blood pressure, and single heart rate, oxygen saturation, breathing rate, and body temperature
- A brief physical examination
- Injection site assessment
- A blood sample will be collected for PK testing
- Your urine collection will end at this time

Following the Day 3 procedures, you will be discharged from the clinical research site if an investigator determines it is medically acceptable for you to leave.

You will be informed by the study staff when you will be required to return to the clinical research site for your Follow-Up Visit.

Follow-Up Visit (Day 8)
You will report to the clinical research site for your Follow-Up Visit on Day 8. You will be given an identification wristband to wear during your visit to the research site.

The Follow-Up Visit will include the following procedures:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken since your last visit to the clinical research site
- A complete physical examination
- Weight

- Vital signs defined as triplicate blood pressure, and single heart rate, oxygen saturation, breathing rate, and body temperature
- Triplicate ECG
- Blood and urine samples for laboratory tests
- Urine pregnancy test for all females

Once you have completed the Follow-Up Visit, your participation in the study will end unless you experience a change in your health that needs continued monitoring.

Early Termination

At any time, the study staff may decide it is in your best interest to remove you from the study for your safety, welfare, or the integrity of the study, or you may decide on your own that you no longer wish to participate in the study. If you leave the study early for any reason, the study staff will request to have the following procedures performed before you leave the clinical research site:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken
- A complete physical examination
- Weight
- Vital signs defined as triplicate blood pressure, and single heart rate, oxygen saturation, breathing rate, and body temperature
- Triplicate ECG
- Blood and urine samples for laboratory tests
- Urine pregnancy test for all females

Once the above procedures have been completed, your participation in the study will end unless you experience a change in your health that needs continued monitoring.

Unscheduled Visits

You may be asked to return to the clinical research site at other times outside of the visits listed above if you have a reaction or illness or if the study staff feels it is necessary for your health and safety. If you are asked to return to the clinical research site for an unscheduled visit, some or all the tests and procedures outlined above may be performed. The study staff will determine what procedures will be conducted after reviewing any symptoms that you are experiencing.

Additional Controlled Searches

At any time during your participation in the study, you may be required to undergo a controlled search by designated study staff if the study staff have reason to believe you are in possession of any prohibited items. During the controlled search, you will be required to remove all clothing including undergarments and put on a gown in order to have your clothes and person checked for any prohibited items that may have been brought into the clinical research site. Any possessions you bring into the clinical research site may be subject to controlled search as well.

Additional Drug and Alcohol Testing

You may be required to undergo additional drug and/or alcohol testing at any time while in the clinical research site. If the study staff suspects you are using drugs and/or alcohol, and you test positive for either drugs or alcohol, you will not be allowed to continue to participate in the study.

What are my restrictions during the study?

In order to participate in this research study, you will need to avoid the following medications, dietary items, substances, and activities for the specified timeframes listed in the chart below:

Restricted Medication, Food, Substance or Activity:	**Timeframe of Restriction:**
Water/Fluid	Will be restricted until at least 1 hour after dosing of study drug
Fasting (no food or drink other than water)	At least 10 hours prior to dosing of study drug and until at least 4 hours after dosing
Strenuous Activities, such as exercise, weightlifting or sports	At least 72 hours (3 days) before the Screening Visit, 72 hours (3 Days) before admission until discharge from the clinical research site and 72 hours (3 Days) before the Follow-Up Visit
Low level physical activity	On days when Holter monitoring is being taken, participants are restricted to a low level of physical activity and should refrain from any activities likely to stimulate or excite them (e.g., video games, stimulating movies, or television shows, etc.). Additionally, participants should refrain from using hand-held electronic or electrical devices (e.g., cell phones, hair dryers, etc.) as these have a potential to interfere with ECG signals.
Alcohol	At least 48 hours (2 days) prior to dosing of study drug until the Follow Up Visit.
Caffeine or other xanthine-containing products (for example, coffee, tea, cola, caffeine-containing sodas, chocolate, or energy drinks)	At least 7 days (1 week) prior to dosing of study drug until the Follow Up Visit.
Poppy seeds, red wine, grapefruit or grapefruit-containing foods or beverages, Seville oranges or Seville orange-containing foods or beverages, pomelos, exotic citrus fruits, fruit juices	At least 7 days (1 week) prior to admission into the clinical research site until the Follow-Up Visit
Smoking and/or the use of tobacco or nicotine-containing products	At least 30 days (1 month) prior to dosing of study drug until the Follow Up Visit.
Recreational drug use	From the Screening Visit until the Follow Up Visit.

Prescription or non-prescription medication (except for oral contraceptives), topical medications, over-the-counter medications or herbal remedies or supplements	At least 14 days (2 weeks) prior to dosing of study drug until the Follow Up Visit, unless the Investigator and Sponsor agree the medication will not interfere with the study.
Other investigational drugs or products	At least 30 days (1 month), or 90 days (3 months) for a biologic, prior to dosing of study drug until the Follow Up Visit.
Donation or loss of blood or blood products of 500 mL or more	At least 56 days prior to the Screening Visit until at least 90 days (3 months) after the last dose of study drug.
Donation or loss of blood plasma or plasma products	At least 7 days (1 week) prior to the Screening Visit until at least 90 days (3 months) after the last dose of study drug.
Male contraception	Must agree to use a condom with spermicide or abstain from heterosexual intercourse from the Screening Visit until at least 90 days (3 months) after the last dose of the study drug.
Sperm donation	From the Screening Visit until at least 90 days (3 months) after the last dose of study drug.

How long procedures may take and the length of time for any restrictions is an estimate and may be longer than expected.

What are my responsibilities for being in this study?

If you choose to participate in this study, you will have the following responsibilities for the protection of your safety and well-being throughout the study.

- Understand all information listed in this consent form and ask questions about anything you do not understand
- Tell your personal doctor about your participation in the study if you choose to do so
- Be able to keep with the study schedule and arrive on time for all scheduled study visits
- Complete all scheduled visits required for the study
- Complete all unscheduled visits if needed for follow-up on your health and safety
- Follow all study procedures and instructions provided by the study staff
- Follow all rules of the clinical research site
- Tell the study staff of any changes in your health including any illnesses, injuries, side effects, or any problems that occur during your participation in the study
- Tell the study staff of any new medications (prescription or over-the-counter), vitamins, or supplements you begin taking after signing this consent form
- Inform the study staff if you decide you no longer want to be in this study. If you leave the study early, you will be asked to complete the early termination procedures described in this form

During your participation in this clinical research study, we will contact you via text messaging for study eligibility, appointment reminders, and other study-related information. This will be our main form of communication with you, so it is important that we have your current cell phone number. You can opt out at any time and we will contact you via phone call or email instead. If your contact information changes at any time, please call our office at 913-333-3000 to provide us with this new information.

What are the risks of being in this study?

By participating in this study, you will receive study drug. Participating in a clinical research study involves some unforeseeable risks or side effects that could occur.

CS-1103 Risks

This study is the first human experience with CS-1103. Since CS-1103 has not been studied in people, it is not known what side effects may occur. The possible side effects that may happen in this study are based on animal studies conducted with relevant doses of CS-1103. Animal studies have been performed using various doses of CS-1103 to try and predict what type of side effects may occur in people who receive doses of CS-1103. However, animal studies do not always predict how humans will respond to the study drug. All participants in this study will be watched very carefully for side effects and safety monitoring.

Based on the studies with rats and dogs, the risks associated with using CS-1103 at the planned doses in this study include the following:

- Allergic or hypersensitivity reaction, including redness of the skin, hives, puffy eyes, and loose stools within the first five minutes of administration, and resolved within 1-3 hours after the dose.
- Renal (acute kidney or bladder) injury
- Injury at the intravenous injection site

Placebo Risks

A placebo is a substance that looks like the study drug but does not contain any active drug or ingredients. Researchers use a placebo to see if the study drug works better or is safer than not taking anything. A placebo is unlikely to cause side effects.

Allergic or Hypersensitivity Reactions Risks

At the dose range to be examined in this study, there is a risk of allergic or hypersensitivity reactions occurring. The symptoms of allergic or hypersensitivity reactions can include:

- Rash
- Flushing (warmness over the face/neck/upper chest)
- Hives
- Blisters
- Itchiness or irritation
- Difficulty breathing and/or wheezing
- Changes in blood pressure
- Swelling around the mouth, throat, and eyes
- Fast heart rate
- Sweating and/or
- Anaphylaxis

Allergic and hypersensitivity reactions can be serious and/or life threatening and can sometimes lead to death. You will be monitored closely during the administration of the study drug and while you are at the clinical research site for the potential of allergic and hypersensitivity reactions. If you feel any side effects, you should seek treatment and contact the study staff immediately. It is important to tell the study staff of any side effects you experience. If it is an emergency or if you cannot contact the study staff, you should call 911 immediately.

Renal Injury Risks

Renal injury also known as acute kidney or bladder injury occurs when the blood flow to the kidney is blocked causing a sudden reduction in the ability of the kidney to filter waste products from the body. In animal studies, renal injury included mild damage to parts of the kidney in dogs and mild damage to the bladder in rats. These injuries were observed above the dose range to be examined in this trial. Although not expected at the dose range in this trial, there is still the potential for damage to these organs. During the conduct of the study and follow-up visit, your renal function will be monitored closely. The symptoms of renal injury can include:

- Swelling of the legs, ankles, and feet
- Fatigue
- Loss of appetite
- Nausea
- Chest pain

Intravenous (IV) Injection Risks

Intravenous injections are injections of substances into a vein and directly into the bloodstream. In this study, all participants will receive CS-1103-01 through an IV infusion. Risks associated with IV injections may include the following:

- Redness
- Pain
- Bruising
- Bleeding
- Infection
- Irritation or discomfort at the injection site
- Vein irritation from the substances being given
- Local swelling due to the IV substance accidentally entering the tissue rather than the vein
- Blood clots, which may cause inflammation, swelling, or pain
- Nerve damage
- Air embolism (sudden blocking of blood flow) if an air bubble (or air bubbles) enters the vein
- An abnormal increase in blood volume

Injection Site Reaction Risks

Injection site reactions including bruising, rash, itching, and pain are common with injections under the skin. There is also the possibility of necrosis or thrombosis occurring at the site of the injection. Necrosis occurs when blood flow to cells or body tissue is blocked, such as from an injury, resulting in the death of the cells or body tissue. Thrombosis occurs when a blood clot forms within a blood vessel blocking the blood flow to cells or body tissue. Symptoms of injection site necrosis or thrombosis can include:

- Increased or persistent pain and discomfort at the injection site
- Weakness
- Swelling
- Tenderness
- Numbness or tingling sensation
- Blisters, wounds, or sores
- Skin that feels hot or cold to the touch
- Whitening of the skin at the injection site
- Blotchy, red skin at the injection site
- Bluish or purple skin discoloration at the injection site
- Skin sloughing which is when skin falls away from the tissue underneath

Electrocardiogram (ECG) Risks

Electrocardiogram (ECG) is a test that records the electrical activity of your heart. Small sticky pads called electrodes will be placed on your body. There is no pain related to an ECG, but the electrodes may be cold when applied and may cause skin irritation such as redness or itching when removed. In some areas, it may be necessary to shave your body hair so the electrodes can be placed on your body. Irritation from shaving could also occur. Female participants may not be allowed to wear a bra for the ECG.

Holter Monitoring

A Holter monitor is a small, wearable device that records the rhythm of your heart. It is used to detect or determine the risk of irregular heartbeats know as arrythmias. Small sticky pads called electrodes will be placed on your body. There is no pain related to wearing a Holter monitor, but the electrodes may be cold when applied and may cause skin irritation such as redness or itching when removed. In some areas, it may be necessary to shave your body hair so the electrodes can be placed on your body. Irritation from shaving could also occur. Female participants may not be allowed to wear a bra during while wearing the Holter Monitor.

Some devices may interrupt the signal from the electrodes to the Holter monitor. You may be asked to avoid devices such as microwave ovens, cellphones, and portable music players while you are wearing the Holter monitor. You will not be allowed to shower while wearing the Holter monitor as well.

Pulse Oximetry Risks

Pulse oximetry measures the amount of oxygen in your blood by placing a sensor on your finger. The sensor may cause some discomfort while being worn.

Fasting Risks
Fasting could cause dizziness, headaches, stomach discomfort, or fainting.

Blood Draw/Sample Risks
During the study, you will have blood drawn from a vein using either single needle-sticks or through an intravenous (IV) catheter. An intravenous catheter is a small plastic tube that is temporarily inserted into your vein with a needle to make it easier for multiple blood samples to be taken without having a needle stick each time. You may have an IV catheter in place for several hours during each day.

The maximum amount of blood drawn during the study will be 450 mL (about 1.9 cups). In rare cases, a catheter may be used for a minimal number of blood sample collections. In these rare cases, this would add approximately 1 mL of blood that will be discarded prior to any blood samples taken from a catheter. A standard blood donation at a blood collection center is about 500 mL (about 2 cups) taken once every 56 days (2 months). Additional blood samples may need to be taken to monitor your health if the study staff find it necessary.

Risks associated with having blood samples taken during the study may include the following:

- Lightheadedness, dizziness, or fainting
- Redness
- Pain
- Bruising
- Bleeding
- Infection
- Nerve damage
- Blood clots, which may cause inflammation, swelling, or pain

Blood Pressure Measurement Risks
During the study, your blood pressure will be measured. Temporary discomfort and bruising may occur from the repeated inflation of the blood pressure cuff. Your blood pressure may be required to be taken while you are sitting or lying down. You may experience lightheadedness or fainting upon sitting up or standing.

HIV and Hepatitis Testing Risks
To participate in this study and if any person is exposed to your blood, you must have your blood tested for the human immunodeficiency virus (HIV) and hepatitis viruses.

HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). A positive HIV test result means that you have been exposed to the virus and are infected. It does not mean that you have AIDS or that you will necessarily become sick with AIDS in the future. It may take weeks or months after becoming infected with HIV for the test to be positive. There are treatment options available for people who have HIV.

You may choose not to take these tests. However, if you decide not to take these tests, you cannot participate in this study. If you take these tests, your test results will be kept confidential subject to reporting positive test results to local health authorities as required by law. However, this cannot be guaranteed, and it may be possible for a court of law to obtain your health and study records without your permission.

If any of these tests are positive, a confirmation test may be performed. If you test positive for either HIV or hepatitis, you cannot participate in this study. You will be notified by the study staff if you test positive for either HIV or hepatitis and will be provided information on further medical care. Positive test results must be reported by the clinical research site to the local health authorities.

The risks for HIV and hepatitis testing can include psychological and social risks. Positive test results can lead to restrictions in freedom of travel to certain countries as well as possible prejudices in job employment, insurance eligibility, housing, and other forms of discrimination.

COVID-19 Risks

Coronavirus disease (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus can spread from an infected person's mouth or nose in small liquid particles when they cough, sneeze, speak, sing, or breathe. Some people who are infected may not have any symptoms while some people can have mild to severe symptoms that may even be life-threatening.

Extra precautions may be taken to minimize your exposure to COVID-19 including but not limited to COVID-19 testing at check-in, indigo lighting in designated areas to disinfect and kill viruses, bacteria, and microorganisms that cause disease, mandatory masks for participants and study staff, social distancing, and extra hand washing. Despite these precautions, there is still a risk of exposure to and developing COVID-19 while you are in the clinical research site.

Symptoms of COVID-19 may include, but are not limited to:

- Cough
- Shortness of breath or difficulty breathing
- Fever or chills
- Tiredness
- Muscle or body aches
- Headache
- Sore throat
- Sudden loss of taste or smell
- Congestion (feeling "stuffed up") or runny nose
- Nausea or vomiting
- Diarrhea

If you experience any of these symptoms during the study, please tell the study staff immediately.

If you have COVID-19, you may have other symptoms besides those listed above. Just because you develop any of these symptoms does not mean you have COVID-19. The study staff will check if your symptoms require further isolation, treatment and/or, additional COVID-19 testing. Additional restrictions in the clinical research site such as limited movement through the site and meals served at bedside, may be put in place in the event a large outbreak occurs.

If you test positive for COVID-19 at any point during the study, you may be removed from further participation in the study. However, if your symptoms are mild, you may be asked to isolate within the clinical research site and continue until you are discharged after you complete all of the study procedures. Positive test results must be reported by the clinical research site to the local health authorities. COVID-19 tests may cause temporary nasal discomfort.

Risks of Loss of Confidentiality

Total privacy cannot be guaranteed and there is always a chance that despite the best efforts of 6 the study staff, your personal and medical information may be inadvertently released or 7 improperly accessed by unauthorized individuals. It is possible for someone to use that 8 information to discriminate against you when you apply for insurance or employment.

Unknown/Unforeseeable Risks

In addition to the risks mentioned above, there may be other risks that are unknown at this time, and you may experience side effects or discomforts that are not listed on this form.

If you experience any side effects or health concerns, you should tell the study staff immediately. If you do not tell the study staff about any side effects or health concerns you may experience, you may harm yourself by being in this study. If it is an emergency or if you cannot contact the study staff, you should call 911 immediately.

Reproductive Risks

The effects of the study drug on the reproductive system, embryo, fetus, or nursing infant are unknown at this time. Therefore, it is very important that you do everything within your power not to have your female partner become pregnant/father a child for 90 days following the last dose of study drug.

Females

Females who are pregnant, planning to become pregnant or breastfeeding, or are capable of becoming pregnant are not eligible to participate in this research study. A pregnancy test will be performed during screening, at check-in to the clinical research site and at the Follow-Up Visit. If you become pregnant during this research study, you must inform the study staff immediately. If you do become pregnant during the study, your pregnancy will be followed through to the outcome of the pregnancy.

Females must meet one of the following criteria to be in this study:

- Be post-menopausal meaning you have had no menses for at least 12 months. This will be confirmed by a blood test during screening.
- Have been surgically sterilized by one of the following procedures:
    - hysterectomy (removal of the uterus)
    - bilateral oophorectomy (removal of the ovaries), or
    - bilateral salpingectomy (removal of the fallopian tubes)

Males
Males with a female partner of child-bearing potential must not father a child during the course of this study. If your female partner becomes pregnant during this study, you must inform the study staff immediately. Your female partner may be asked for permission to collect information about the pregnancy and its outcome by signing a separate consent form.

Even if you use birth control during the study, there is a chance your partner could become pregnant. If your partner becomes pregnant during the course of the study, the study drug may involve unforeseeable risks to the unborn baby.

The only certain way for your partner to not get pregnant is to not have sex. If you choose to have sex, you must agree to use one of the types of birth control listed below. Males must also agree to not donate sperm from screening until at least 90 days after receiving the last dose of study drug.

Males must meet one of the following criteria to be in this study:

- If your partner is of child-bearing potential, you must agree to use one of the acceptable birth control methods listed below beginning from screening until at least 90 days after receiving the last dose of study drug.

Types of Birth Control
You must agree to use at least one of the types of birth control listed below:
Males
• Use of a male condom with spermicide • Abstinence from heterosexual intercourse (Not having sex)

If at any time during the study you or your partner becomes pregnant, you must tell the study staff immediately. You or your partner may be asked for permission to collect information about the pregnancy and its outcome by signing a separate consent form. The study staff may ask you, your partner and/or the doctor who will be taking care of you or your partner during the pregnancy to provide information on the progress of the pregnancy and its outcome. This is to ensure the safety of you, your partner, and the unborn child. You and your partner are not required to provide this information.

Will you be informed of new information relating to this study?
During this study, if any new information, findings, or changes to the way this study will be conducted becomes available that may affect your willingness to continue to participate in the study, you will be informed in a timely manner (both verbally and in writing).

Will being in this study benefit you?
This study is for research purposes and is not intended to treat any symptoms or illness. Therefore, there will be no direct benefit to you for being in this study.

By taking part in this study, you may be helping others by providing important information about the study drug(s) and by contributing to medical knowledge.

What alternatives do you have to being in this study?
No therapeutic or other health benefits will result from participating in this study, so your only alternative is to not participate in this study.

Will it cost you anything to be in this study?
There will be no cost to you to participate in this study. The study drug and all supplies, tests, procedures, and visits required for this study will be paid for by the study sponsor, Clear Scientific, Inc. Dr. Vince Clinical Research will receive payment from the sponsor to run this study.

Will you be paid for being in this study?
You will receive payment for your time and travel associated with being in this study.

If you qualify and decide to participate in the research study, follow all study requirements and clinical research site rules, and complete all required study visits, you may be compensated up to $3,500.00. If you do not complete the study, you will be paid for the visits you do complete based on the following breakdown:

Visit	**Per Day**
Screening	$250
Day -1 Check-In	$500
Day 1 In-House Stay	$500
Day 2 In-House	$500
Day 3 Discharge	$0
Day 8 Follow-Up Visit	$250
Completion Payment	$1,500
Total	**$3,500**

Any scheduled payments for a visit that occur on an evening, weekend or holiday will be paid on the next business day following the visit.

The Screening Visit will be compensated in the amount of $250.00 paid approximately 1 to 2 business days following the visit (excluding weekends and holidays).

The Day -1 Check-In visit will be compensated in the amount of $500.00 paid on Day 1.

The Day 1 through Day 2 In-House stay will be compensated in the amount of $1,000.00 ($500.00 per overnight stay) paid at Discharge on Day 3.

If you are not selected to receive a sentinel dose, you will be required to remain in-house at the clinical research site for 1 additional day before you will receive the study drug. You will be compensated an additional $500.00 ($500.00 per overnight stay) for this additional day paid on Day 3. The study staff will determine whether you will receive the sentinel dose or not.

The Day 8 Follow-Up Visit will be compensated in the amount of $250.00 paid at the end of the visit.

If you complete all visits listed above within the scheduled timeframe, you will receive the completion amount of $1,500.00. Your participation in the study is not completed until you have met all end of study requirements and the study staff has reviewed and cleared you of all study procedures and no further follow-up is required. The completion amount will be issued within 14 days (2 Weeks) of the last study visit on Day 8 when you have met all requirements for study completion and no further follow up is required.

Payments will typically be issued in the form of a reloadable card. If payment is unable to be issued in the form of a reloadable card, payment may also be issued in the form of cash, check, or gift card at the discretion of the study staff.

You may be required to return to the clinical research site for an unscheduled visit. Any unscheduled visit may be compensated up to $100.00 per visit as determined by the study staff.

When you check in, if you spend the required night(s) as per the protocol and continue to meet eligibility criteria but cannot enroll due to the cohort being full, you may receive up to an additional $500.00 as determined by the study staff.

At any time, you may leave the study early or the study staff may withdraw you from the study early. If you leave the study early for any reason, you will only be paid for the visits you complete. If you leave the study early during any in-house portion of the study, you will only be paid for the overnight stays you completed.

If you test positive for any excluded substances for a urine drug screen performed at any time during the study, including the Screening Visit, you will not receive payment for the visit.

If you do not follow the study requirements, the clinical research site rules, or any other instructions given to you by the study staff, you may be fined and/or removed from the study. For example, if you are found to have brought illegal substances such as drugs and alcohol or found to be using an illegal substance in the clinical research site, you will be removed from the study and/or fined. If you are fined, money will be deducted from your earned study compensation. If you are removed from the study, you will only receive compensation for any study visit(s) you have completed up to that point.

If you choose to leave the study early or are removed from the study due to not following the study requirements, the clinical research site rules, or any other instructions given to you by the study staff, you will only be paid for up to one overnight visit prior to or at the time you leave the clinical research site. Any remaining compensation for the visits you have completed will be paid on the original discharge date of the in-house stay.

If the study staff believes it is in your best interest to remove you from the study for your safety, health, or well-being, you will only receive compensation for the overnight stays you completed. You will be paid at the time you leave the clinical research site or the next business day.

If you receive compensation totaling $600.00 or more in any one calendar year, Dr. Vince Clinical Research is required to report this information to the Internal Revenue Service (IRS). This compensation will be considered earned income and you may be required to report this compensation to the IRS as well. You will be responsible for paying any taxes on any compensation you receive from this or any study you participate in during any calendar year. Dr. Vince Clinical Research will send you an IRS Form 1099 to report your compensation to the IRS. Please ensure your current address is on file with the clinical research site to ensure the form is mailed to the correct address. If you have any questions about the form, please ask the study staff.

What if I am injured because of taking part in this study?
If you are physically injured or get sick because of being in this study, please call the study staff immediately. For any serious or life-threatening injuries or illness, please call 911.

Dr. Vince Clinical Research will provide immediate medical treatment and follow-up care without cost to you for any study-related injury. A study-related injury is a physical injury or illness that is directly caused by the study drug administered during the study or is caused by your direct participation in the study. A study-related injury does not include the following:

- Injuries or illness directly caused by the natural course of an existing underlying illness or medical condition
- Not following the instructions provided by the study staff.

Dr. Vince Clinical Research or the study sponsor will not be responsible for any dental care or dental-related expenses that occur during the study including but not limited to fillings, crowns, bridges, implants, replacements, or broken teeth unless the expense is a study-related injury as described above.

The study sponsor, Clear Scientific, Inc., will cover the reasonable medical expenses necessary for the treatment of any study-related injury that are not covered by your medical insurance policy or the government. The costs for any other medical issues not directly caused by your participation in the study will be your responsibility. You will not receive any financial compensation for lost wages, disability, pain and suffering, or expenses other than medical care required for a study-related injury. If you are injured because of this study, you do not give up your right to pursue a claim through the legal system.

If you have Medicare, Medicaid or TRICARE, the reasonable medical expenses necessary for the treatment of the study-related injury may not be billed to Medicare, Medicaid, or TRICARE. Any medical expenses should be submitted to the study staff first so that they may review them with the study sponsor. Payment will be issued if it is determined that the medical expenses were a direct result of your participation in the study. Please contact the study staff for any questions.

Will my information or samples be used for future research?
There is no future research planned for your provided biological samples such as blood or urine. The results of this study, including your individual study results, will not be provided to you.

Who will have access to my personal and/or medical information?

If you participate in this study, your personal and medical information will be collected including the following:

- Your name
- Address
- Date of birth
- Medical records and medication history
- Information gathered for this study
- Records about the study (such as drugs or treatments)

Your personal and medical information will be shared with individuals and organizations that conduct or watch over this study, including:

- Study staff
- Study sponsor, sponsor's associated companies, and their representatives such as monitors, auditors, or Contract Research Organizations (CROs)
- Government agencies, such as the Food and Drug Administration (FDA)
- WCG IRB, the institutional Review Board (IRB) that reviewed the research

Your personal and medical information will be protected from disclosure to others to the extent required by law. However, the IRB and government agencies may inspect, copy, and disclose your records without your consent, which may have your name on them. Therefore, your total privacy cannot be guaranteed. If the results of this study are presented at meetings or printed in publications, your name will not be used.

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.

Will your personal and medical information be kept confidential?

As part of this research study, the study staff will collect personal information about you and your health. The study staff will take the following steps to protect your personal and medical information:

- Using a study participant number to keep your study records from identifying you
- Limiting the number of people who have access to the study records
- Avoiding the use of any specific information such as your name, initials, date of birth, or any other information that could identify you in publications or reports resulting from the study

Your personal and medical information will be protected as required by laws and/or regulations and it will not be made publicly available. Your name will not appear on any forms or documents used by the study staff and you will always be identified by a study participant number and/or your initials. Additionally, any biological samples such as blood, urine or other samples collected as a part of this study will not be labeled with your name or initials.

Should you require any outside medical care or hospitalization during the study, the study staff may contact your personal or treating doctor with your consent. In an emergency, your personal information may be required to communicate with your primary doctor and your consent may not be able to be requested.

The study staff will make every effort to protect your personal and medical information. However, total privacy cannot be guaranteed and there is always a chance that despite the best efforts of the study staff, your personal and medical information may be inadvertently released or improperly accessed by unauthorized individuals. It is possible for someone to use that information to discriminate against you when you apply for insurance or employment.

As part of your participation in this study, you will be monitored and/or recorded on video monitoring devices and cameras throughout the clinical research site. These monitoring devices and cameras will not have any audio. Restrooms will not have any video monitoring or recording. This is to ensure all study procedures are being conducted correctly and safely and to monitor your health and safety while you are in the clinical research site. Additionally, representatives from the study sponsor, IRB, FDA, or other government agencies, such as monitors and auditors, may view areas of the clinical research site, and you may appear in images or recordings taken with video and audio monitoring devices. By signing and dating this consent form, you agree to be monitored and/or recorded while you are in the clinical research site.

Can you be removed from this study without your approval?

At any time during the study, the study staff can remove you from the study for any of the following reasons:

- You don’t show up for your scheduled study visits
- You don’t follow the study procedures or instructions from the study staff
- You don’t follow the rules of the clinical research site
- You get a serious illness or injury that requires ongoing medical care
- You participate in another research study at the same time you are in this study
- You become pregnant
- The study staff believes it is in your best interest to remove you from the study for your safety, welfare, or the integrity of the study
- The study is stopped or cancelled by the study sponsor, IRB, FDA, or any other government or regulatory agencies. If this happens, we will tell you why.

Can you change your mind about being in this study?

Being in this study is voluntary. This means you can decide if you want to be in the study or not. If you decide to be in the study, you can choose to leave the study at any time without any penalty or loss of benefits to which you would otherwise be entitled.

If you decide you no longer want to be in the study, you should inform the study staff immediately. If you decide to no longer be in the study, you will be asked to complete the Early Termination Procedures.

Who can answer your questions about this study?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What about my legal rights?

You will not lose any of your legal rights to which you are otherwise entitled by signing this consent form.

Authorization to use and disclose health information

A federal regulation known as the Privacy Rule gives you certain rights to protect the privacy of your protected health information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality (security and privacy) of your protected health information. Researchers covered by this rule are required to get your authorization (permission) to use and disclose (share with others) any protected health information that could identify you. Under this federal law, your records cannot be used or disclosed by Dr. Vince Clinical Research for research purposes unless you sign this form. You may not take part in this study unless you sign this form.

This section, called an “Authorization,” explains how your protected health information will be used and disclosed during this research study and describes your rights, including the right to see your protected health information.

By signing this consent form, you allow the study staff to use your Protected Health Information and biological samples in order to conduct this study and for the Sponsor to use information related to you for research conducted with your samples. Your “Protected Health Information” is information about you that could be used to identify you. This information could include, but is not limited to, your name, address, telephone number, photograph, date of birth, social security number, new and existing medical records, or the types, dates, and results of various tests and procedures. This may include information in your medical record and information created or collected during the research study.

By signing this consent form, you also allow the study staff to disclose your Protected Health Information to other parties for clinical research and safety reporting purposes, including the following:

- Sponsor, its affiliates and licensing partners
- Business partners assisting Sponsor, its affiliates and licensing partners
- Regulatory agencies such as the Food and Drug Administration (FDA)
- The Institutional Review Board (IRB) that reviewed this research

Your Protected Health Information may no longer be protected by the Privacy Rule once it's disclosed by the study staff, although other confidentiality safeguards may apply. If you have questions about how your Protected Health Information will be protected, you can ask the study staff.

In no event will you be identified by name in any published reports about this research study or in any other scientific publications or presentations.

You have the right to see and copy your Protected Health Information related to the research study for as long as this information is held by the study staff. However, to ensure the scientific integrity (accuracy and reliability) of the research study, you may not be able to review some of your records related to the research study until after the research study has been completed.

This authorization does not expire. However, you have the right to cancel this authorization at any time by giving written notice to the investigator at the address listed on the first page. If you cancel this authorization, you will not be allowed to continue in this study. If you cancel this authorization, neither Dr. Vince Clinical Research or the Sponsor will continue to use or disclose your Protected Health Information under this authorization for this study, unless the study staff needs to use or disclose some of your Protected Health Information to preserve the scientific integrity of the study. Information given to the Sponsor before you cancel this authorization may still be used by the Sponsor. No new information will be added.

Under federal law, your Protected Health Information cannot be used or disclosed for research purposes unless you sign this authorization. You may refuse to sign this authorization. If you do not sign this authorization, you cannot participate in this study. If you leave the research study early, you do not have to cancel this authorization. If you do leave the research study early and decide to cancel your authorization, the Protected Health Information that has already been collected may continue to be used and disclosed as described above.

You will need to read, in a language that you understand well, the above information. The content and meaning of this information will be explained to you. You will be asked to voluntarily consent and offer to take part in this research study and authorize the use and disclosure of your Protected Health Information.

You have not forfeited any of your legal rights by signing this authorization. You will receive a copy of this signed and dated consent form.

Your signature on this form will authorize (give permission for) Dr. Vince Clinical Research to collect and use information that can identify you.

<u>Statement of consent to be in the research study</u>

- This Informed Consent Document was given to you in a language you understand well, and you have read the above information or had it read to you.
- The information in this document describes the purpose and nature of this study.
- You have had sufficient time to review all the information in this document.
- You have been given an opportunity to ask questions about the information in this document.

- You have received satisfactory answers to all your questions.
- Your participation in this study is completely voluntary.
- You can leave the study at any time without giving a reason and without affecting your healthcare or benefits.
- You have not forfeited any of your legal rights by signing this document.
- Your signature on this document will authorize (give permission for) Dr. Vince Clinical Research to collect and use information that can identify you.

You will receive a signed and dated copy of this form for your records.

You agree to participate in this study, and you are not giving up your legal rights by signing this document.

_____	Date: __ __/__ __ __/__ __ __ __
Printed Name of Participant	D D M M M Y Y Y Y
_____	___ ___:___ ___
Signature of Participant	Time
_____	Date: __ __/__ __ __/__ __ __ __
Printed Name of Person Obtaining Consent	D D M M M Y Y Y Y
_____	___ ___:___ ___
Signature of Person Obtaining Consent	Time