Experimental Research Subject's Bill of Rights

California law, under Health & Safety Code Section 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of the signed and dated written consent form.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

_____
Signature Subject (Conservator, Guardian or Representative)

_____
Date

Participant Information and Informed Consent

Protocol Title:	A Phase 1 Randomized, Double Blinded, Placebo-Controlled Single Dose Escalation Study of OsrHSA in Adult Healthy Male and Female Volunteers
Protocol Number:	US-HY1001
Study Sponsor:	Wuhan Healthgen Biotechnology Corporation
Study Doctor:	David Nguyen, MD
Institution Address:	WCCT Global, Inc. 5630 Cerritos Ave., Cypress, CA 90630
Phone Number:	714.252.0700
After Hours Phone Number:	714.565.3365

The study doctor and/or study staff will provide you with a copy of the California Subjects Bill of Rights. You should read, review and sign the California Subjects Bill of Rights before reading this informed consent form.

INTRODUCTION:

You are being asked to participate in a research study. 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 on how to prevent, diagnose, or treat diseases and disorders.

This informed consent form gives 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 study participant.

Please take the time to read this information carefully. You should talk to the study doctor and/or the study staff about this research study and ask any questions you may have. You can also discuss this research study with other people such as your family, friends, or personal doctor. If you decide to participate in this study, you will be asked to sign and date this informed consent form. You will receive a copy of this signed and dated informed consent form to keep for your reference.

After you sign this informed consent form, the study doctor and/or the study staff will do some assessments and tests to see if you meet the requirements to participate in this research study. If you do not meet the study requirements, you will not be able to participate in this research study.

If you have a different personal doctor, the study doctor will ask if he can tell your personal doctor about your participation in this research study.

Your participation in this research study is voluntary. You are free to say yes or no. If you do not want to participate, your regular medical care and legal rights will not be affected. Even if you join this study, you may end your participation at any time.

Your study doctor is a researcher for this research study. As a researcher or Investigator, he is interested both in your health and how this study is carried out. The study doctor is being paid by Wuhan Healthgen Biotechnology Corporation (the company paying for the study or 'the study sponsor') to conduct this research study.

In this document, you will see the terms "medication", "treatment", and "treatment period"; these are terms used in research studies and are not meant to indicate that you will be receiving medical treatment for any condition. These terms apply to the study drug Recombinant Human Albumin from Oryza sativa (OsrHSA) and parts of the study where you will be receiving this investigational product.

PURPOSE OF THE STUDY

This study involves the use of an investigational drug called OsrHSA. An investigational drug is a drug that has not been approved by the Food and Drug Administration (FDA)but may be used in research studies like this one. OsrHSA has been created for the treatment of blood volume deficiency. OsrHSA is being developed as a potential alternative for use of HSA (Human Serum Albumin), the main protein of human blood plasma that plays a primary role in regulating blood volume. HSA is also used in vaccines and pharmaceuticals. OsrHSA is plant based (rice seeds) and does not have the potential risk for transmission of blood borne infectious diseases that could be present in HSA.

This study will evaluate the safety, tolerability and pharmacokinetics (PK- the way the body absorbs, distributes and gets rid of a drug) of single dose IV infusion of OsrHSA in healthy male and female participants. The immunogenicity (ability of a substance to provoke an immune system response in human body) of the study drug will also be evaluated during this research study.

STUDY DESIGN

You will be randomly assigned to one of the following treatment cohorts (groups) listed below. Randomly assigned means that the treatment you receive will be assigned by chance (like flipping a coin). Neither you nor the study doctor will know whether you are receiving the study drug or placebo. However; this information can be made available if it becomes medically necessary. You will not be allowed to choose which cohort you will be enrolled in.

This study will enroll a total of 5 cohorts. Each cohort will consist of 8 participants of which 6 will receive OsrHSA and 2 participants will receive the placebo.

- Cohort 1 will receive 20 mg/kg of OsrHSA or placebo;
- Cohort 2 will receive 40 mg/kg of OsrHSA or placebo;
- Cohort 3 will receive 80 mg/kg of OsrHSA or placebo;
- Cohort 4 will receive 140 mg/kg of OsrHSA or placebo;
- Cohort 5 will receive 200 mg/kg of OsrHSA or placebo

You will undergo a 28 day screening period from Day -28 to Day-2. Your eligibility to proceed with the study will be reviewed. Once determined you are eligible to proceed with the study, you will be asked to return to the clinical research unit on Day -1 to start your in patient (in-house) period. You will be randomized and enrolled to one of the study cohorts to receive the study drug or placebo on Day 1. You will be observed for any changes in your health and will be discharged on Day 2.

The study drug or placebo will be administered one time by intravenous (IV) infusion (the treatment is administered into a vein at a rate of lower than 2 ml/min). OsrHSA will be diluted (to make a liquid thinner or less strong by adding water or another liquid) with normal Saline (contains high concentrations of sodium chloride, which is similar to table salt). The infusion will last around 2 hours.

This is a dose escalation study, which means that the first cohort will receive the lowest dose and when it is determined safe, the second cohort/ will receive a higher dose. Dose escalation decisions will be determined based on the data (information) gathered within 7 days after dosing. The same procedure will be performed for each dosing cohort before they are dosed. The study doctor or study staff will tell you which panel you will take part in and what dose level you will receive.

You will have outpatient visits Days 3, 5, 8, 15, 22 and an End of Study visit on Day 30.

NUMBER OF PARTICIPANTS AND TIME COMMITMENT

This research study is being conducted at 1 research center in the United States and will enroll approximately 40 participants. You are being asked to take part in this research study because you are a healthy male or female between the ages 18-55 years of age. If you are selected to participate in this research study, your participation is expected to last approximately 58 days. This will include:

- A 28 day screening period
- A 3 day confinement (in-house) period in the clinical research unit from Day-1 to Day 2;
- A follow-up visit on Days 3,5, 8, 15, 22 and Day 30

PARTICIPANT RESPONSIBILITIES

As a research participant, you will be asked to complete the study procedures for this research study, come to the clinical research unit for all of your scheduled visits, follow the instructions listed in this informed consent form, and notify the study doctor and/or study staff if any information regarding your health or availability to participate in this study changes.

Some drugs, foods, drinks, or activities can increase or decrease the effect of the study drug. This can be a risk to your health or lead to false study results. Some of the restrictions that you are

expected to follow and requirements for this research study are listed below. Please go through the list carefully and discuss any questions you have with the study staff or study doctor**.**

During this study you must:

- be able to read, understand and sign this Informed Consent form.
- be willing to comply with all study requirements and procedures.
- be a healthy male or female participant between the ages of 18-55.
- be a non-smoker. You will be required to abstain from using nicotine products from screening and throughout the study.
- not have a history of difficulty in accessing your veins during blood draws.
- not have significant medical history like heart, lung, stomach disease, etc.
- not have history of or active disease of the bile ducts, liver, kidney or spleen.
- be able to follow the contraception requirements as discussed on the "REPRODUCTIVE RISKS" of this ICF.
- not have a history of severe infection within 4 weeks to dosing.
- not have any known allergies, hypersensitivities or inability to consume rice or rice products.
- not use any prescription drugs, herbal supplements, or nonprescription drugs including oral medication for seasonal allergies within 1 month or 5 half-lives (whichever is longer) prior to study drug administration, or dietary supplements within 1 week prior to study drug administration, unless, the study doctor or the sponsor decides that the medication will not interfere with the study. Half-life is defined as the amount of time for a drug in your body to be reduced by 50%. Over-the-counter multivitamins will be permitted.
- not have participated in any clinical research study involving investigational or marketed drug or device within 30 days prior to the first dosing, administration of biological product (substance made from living organisms or its products and is used for diagnosis or treatment of diseases) for clinical research purposes within 90 days prior to the first dosing, or participation in any other investigational studies involving no drug or device administration.
- not have donated blood 12 weeks prior to dosing and will not donate blood for at least 3 months after the last dose administration
- not be pregnant or nursing if you are a female participant.
- not have history of substance abuse within one year prior to screening or use of soft drugs (such as Marijuana) within 3 months prior to screening visit, or hard drugs (such as cocaine, heroin, etc.) within 1 year prior to screening and throughout the study.
- have not received any immunization with live or disease-causing vaccine within 4 weeks prior to study drug administration.
- not have a significant alcohol abuse within one year prior to screening or regular use of alcohol within six months prior to screening. Refrain from intake of alcoholic beverages from 72 hours prior to study drug administration until Day 8 (after dosing). It is encouraged to refrain from drinking alcohol beverages after Day 8 until the completion of the study.
- not consume food containing poppy seeds within 24 hours prior to admission
- not consume food or beverages containing xanthine derivatives or xanthine-related compounds (coffee, black/green tea, chocolate) or energy drinks from 48 hours prior dosing until End of Study visit.

- be able to comply with fasting requirements throughout the study.
- refrain from strenuous exercise for 48 hours before admission to the research center and throughout the study You may participate in light recreation activities during the study such as watching television, reading, etc.)
- be able to comply to position restrictions of specific study procedures for safety reasons.

You should immediately contact the study doctor or study staff if you need to take any prescription or other medication not given to you by the study doctor.

For your safety, we ask that you follow all of the rules and regulations of the research unit. If you do not follow the rules and regulations or the restrictions described above, there may be a risk to your health and/or false study results. Violations of these rules, regulations and restrictions may make it necessary to discontinue you from the study.

STUDY PROCEDURES

The study doctor will examine you to determine whether or not you are eligible to participate in this research study. Before performing the specific assessments and procedures of this research study, you need to provide consent by signing and dating a hard copy of this informed consent form.

The following procedures will be performed during your participation in this study as outlined in the Schedule of Events table:

- Informed Consent: You will be asked to voluntarily confirm your willingness to participate in this research study, after having been informed of all aspects of the study that are relevant to your decision to participate. You will be asked to sign this Informed Consent form.
- Your eligibility to participate in the study will be confirmed. This will include demographics information (including your age, gender, ethnicity and race), review of your complete medical/surgical history including any significant/relevant diseases, surgeries or other medical events during the past 5 years and any new conditions reported while enrolled in the study (including prescription drugs, over the counter medications, supplements and herbal products, alcohol, tobacco/nicotine, and drug use etc.).
- Your height and weight will be collected. Your Body Mass Index (BMI) will be calculated. BMI is the measurement of a person's body fat based on their height and weight. You should be wearing lightweight clothing and no shoes during these measurements.
- You will undergo a complete physical examination during screening and at the End of Study. This will include assessment of the Cardiovascular (heart), Pulmonary (lungs), Gastrointestinal (stomach and intestines), Nerve System (assessment of sensory and motor responses, especially reflexes, to determine whether the nervous system is impaired) and skin. Partial Physical exam can be done at other visits if there are any changes from the previous examinations.
- Your vital signs will be collected. This will include your oral body temperature, blood pressure, heart rate and respiratory (breathing) rate. Your vital signs will be collected after you have been resting in a sitting position after at least 5 minutes in a quiet setting.

- You will have an Electrocardiogram (ECG) test be performed. An ECG records the electrical activity of the heart using electrodes placed on the skin. ECG procedure will be performed after you have been resting in a supine (lying face upward) position after at least 5 minutes in a quiet setting.
- Blood samples will be collected for:
    - routine laboratory test (including HIV, Hepatitis B, C and Syphilis);
    - if you are a woman of childbearing potential, this will include a blood pregnancy test. If applicable, a follicle stimulating hormone test (FSH) to confirm postmenopausal status will be performed.
    - PK analysis
    - ADA (refer to the "Anti-Drug Antibody (ADA)" section of this ICF for more information about this blood sample collection) analysis
    - Ig E (antibodies produced by the immune system) and Ig G (the most abundant type of antibody, is found in all body fluids and protects against bacterial and viral infections) analysis
    - Blood samples for Colloid Osmotic pressure measurement (pressure induced by proteins in your blood vessels)
- Urine Samples will be collected for:
    - routine laboratory tests;
    - urine test to check for drugs of abuse and nicotine use
    - Pregnancy test if WOCBP (Woman of Childbearing Potential)
- Alcohol breath test will be performed.
- Abdominal Ultrasound will be performed. This is a type of imaging test that is used to look at organs in the abdomen, including the liver, gallbladder, spleen, pancreas, and kidneys.
- You will be asked if you have any injection site reactions before and after the dosing and in different scheduled time points.
- You will be randomized to receive a single dose of placebo or the study drug OsrHSA. On Day 1, OsrHSA or placebo will be administered as single IV infusion. You will be observed overnight in the research unit. On day 2, safety procedures and assessments will be performed and once completed, you will be discharged from the unit. There will be an observational period of 7 days upon completing the IV infusion dosing. You will have outpatient visits on Day 3, Day 5, Day 8, Day 15, and Day 22. Your End of Study visit will occur on Day 30 after the infusion.
- You will be asked if there have been any recent changes in your health and medications.

Schedule of Activities

Protocol Activity		Clinical Research Unit (CRU) Confinement									Outpatient Visits					
	Screen -D28 to – D2	Pre-dose -D1 to dose	Dose initiation	0.5 h ± 5m after Dose initiation	1.0h ± 10m after Dose initiation	EOI	0.5h Post EOI	4h ± 10m	12h ± 10m	D2 24h ± 30m	D3 ± 6h	D5 ± 6h	D8 ± 1d	D15 ± 2d	D22 ± 2d	D30 ± 2d
Signed Informed Consent (ICF)	×															
Inclusion/Exclusion Criteria	×	×														
Demographics	×															
Weight	×	×								×	×		x			x
Medical History	×	×									×	×	×	×	×	×
Physical Examination	×	×				×	×	×	×	×	×	×	×	×	×	×
Current Medications/OTC/supplements	×	×												×		×
Vital Signs	×	×		×	×	×	×	×	×	×	×	×	×	×	×	×
12 Lead Electrocardiogram (ECG)	×	×			×	×	×	×	×	×	×	×	×	×	×	×
Abdominal Ultrasound)	×															
Adverse Events (AE)	**Ongoing**															
Laboratory Tests																
Urine Drug Screen	×	×														
Alcohol Breath Test	×	×									×	×	×	×	×	×
Urine Cotinine Test	×	×									×	×	×	×	×	×
Pregnancy Test for Female[2]	×	×												×		×
Ig E and Ig G Against Rice	×								×		×	×		×		×
Hematology & Serum Chemistry	×	×					×			×			×			×
Coagulation Tests	×												×			
Screening for HIV, HBV, HCV, Syphilis [3]	×															
Urine Analysis (U/A)	×						×	×	×	×	×	×	×	×	×	×
Study Drug Administration			×	×		×										
Injection Site Reaction		×		×		×	×		×	×						

Protocol Activity		**Clinical Research Unit (CRU) Confinement**									**Outpatient Visits**					
	Screen **-D28 to** **– D2**	**Pre-dose** **-D1 to dose**	**Dose initiation**	**0.5 h ± 5m after** **Dose** **initiation**	**1.0h ± 10m after Dose initiation**	**EOI**	**0.5h** **Post EOI**	**4h** **± 10m**	**12h** **± 10m**	**D2** **24h** **± 30m**	**D3** **± 6h**	**D5** **± 6h**	**D8** **± 1d**	**D15** **± 2d**	**D22** **± 2d**	**D30** **± 2d**
Pharmacokinetics (PK)		×		×		×	×	×	×	×	×	×	×	×	×	×
Colloid Osmotic Pressure		×		×		×	×	×	×	×	×	×	×	×	×	×
Anti-Drug Antibodies (ADA); Anti-HCP antibody		×											×	×	×	×

D= Day, H=hour, M=minutes, EOS= End of Study

[1]Medical History: includes any significant or relevant diseases, surgeries, or other medical events during the past 5 years and any new conditions arising while enrolled in the study.

[2]Only in women of childbearing potential. Urine pregnancy test will be done at screening and EOS, serum pregnancy test will be done pre-dose and on D15, or as clinically indicated.

[3]HIV screening (Antigen/antibody test), HCV antibodies, hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs), total hepatitis B core antibody (anti-HBc), IgM antibody to hepatitis B core antigen (IgM anti-HBc), Syphilis

HIV, Hepatitis B and C, Syphilis Authorization
Part of the blood test that will be done includes a test for HIV, Hepatitis B, C and Syphilis test.

HIV is the virus that causes AIDS. A positive 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. There are treatment options available for people who have HIV.

If you take the test for HIV, Hepatitis B, C and Syphilis test, your test results are Confidential. Your results can only be given to the people you allow to have it by signing a separate release form; however, the study doctor may be required by law to report positive HIV, Hepatitis B, C and Syphilis test results to the local health authorities. Taking the HIV, Hepatitis B, C and Syphilis tests is voluntary. You do not have to take the tests; however, the tests are needed to participate in this research study. If you decide not to take the tests, you cannot participate in this study. Your study doctor will discuss with you if the test results are positive and what the local laws require with regard to reporting the test results. The results of these tests must be negative in order for you to be in this study.

Do we have your permission to perform an HIV, Hepatitis B, C and Syphilis? Please initial one of the following options after you have made your decision on whether you consent to these tests.

_____ You **have** my permission to perform an HIV, Hepatitis B, C and Syphilis test.

_____ You **do not have** my permission to perform an HIV, Hepatitis B, C and Syphilis test. I understand that by declining the tests I will not be able to participate in this study.

If it is determined that you continue to qualify for this research study based on the results of the screening visit assessments and procedures, and the study doctor agrees that you may continue to participate in the study, you will be asked to report to the clinical research unit on Day-1 to begin your confinement (in-stay) period.

However, if you do not qualify for this research study based on the results of the Check-in assessments, and/or the study doctor does not agree that you can participate, your study participation will end, and you will be allowed to go home.

UNSCHEDULED VISITS
You may be asked to report to the clinical research unit for an unscheduled visit if the study doctor feels it is necessary for your safety. This may occur if you have experienced any side effects. In the event that you are asked to return to the clinical research unit for an unscheduled visit, some or all of the assessments and procedures outlined above may be performed. The study

doctor may also request to have procedures performed that are not listed above to ensure your safety throughout the study.

EARLY TERMINATION VISIT
If for any reason it is determined that it is no longer safe for you to continue in this research study or you no longer wish to continue your participation in this research study, all or some of the visit procedures above may be performed to ensure that there are no safety issues before discontinuing your participation.

Additional assessments or procedures may be performed if the study doctor feels they are necessary to ensure your safety.

FASTING AND MEALS
You will be on a standard house diet while you are at WCCT Global, Inc. This means that you will be allowed only the food and drinks that are approved by WCCT Global, Inc. during the study. Meal substitutions (food or drink) will not be allowed. There will be no seafood or high-fat food provided during confinement.

BLOOD SAMPLES
Blood samples will be collected approximately 30 times during your participation in this research study. A total of approximately 238 mL (about 1 and 1 /2 cups) of blood will be drawn for this study. In some cases, additional blood samples may be taken when the study doctor considers this necessary to follow your results for safety.

For comparison, a standard blood donation at a blood collection center, once in any 56-day period, is about two cups of blood (500 mL).

The study doctor may decide that placing an IV catheter (a small plastic tube) into one of your veins for drawing blood may be helpful to decrease the number of needle sticks and minimize discomfort. A catheter is a flexible tube inserted into the vein that allows taking several blood samples without repeated needle insertion into the skin. At each blood collection time point; the first 1 mL of blood will be drawn and discarded as waste; then the blood sample will be collected. After each blood collection, a very small amount of saline (salt water) will be injected into this needle for flushing to prevent clogging. The blood draw procedure may cause pain, infection, swelling and redness at the needle site. Rarely, some people experience dizziness, upset stomach, or fainting when their blood is drawn.

Anti-Drug Antibody (ADA)
Blood samples will be taken during the study to check if your body is responding to the study drug by making antibodies (proteins that are found in bodily fluids that are used by the immune system to detect and respond to threats). Additional blood samples may also be taken if you experience any symptoms that are believed to be caused by those antibodies. The blood sample will be tested to check if drug antibodies are present.

RISKS AND DISCOMFORTS

Risks of OsrHSA:

Participation in a clinical research study involves some unforeseeable risks of side effects that could occur. This study is the second human experience with OsrHSA. Since OsrHSA has not yet been administered to a large group of humans, it is not known which side effects might occur. Thus, safety findings from animal studies and from one human study in 5 subjects to date are summarized below. Animal studies have been performed using various doses of OsrHSA to try to predict what type of side effects might occur in people who receive single doses of OsrHSA. However, animal studies do not always predict human response to drugs.

Animal studies (monkeys and rats):

- Lesions in the kidney in monkeys
- Enlargement of bone cells in monkeys
- Decrease of food consumption in rats
- Irregular heart beat and inability of the heart to pump blood correctly in monkeys
- Inflammation in the lung in monkeys

Human Study:

OsrHSA has been administered at a dose of 2.5 g in 5 subjects in one clinical study. There have been no deaths reported. There was only 1 adverse (unfavorable) event reported and was the following:

Liver, gallbladder or pancreas disorders

- Increase in the level of substances (called enzymes) in blood that may indicate liver problems

There was also 1 serious event reported which was the following:

Liver, gallbladder or pancreas disorders

- Gallstone

Overdosage
To date, there have been no reported cases of overdose for HUMAN ALBUMIN. No data are available in regard to over dosage in humans; however, hyperoncotic symptom could happenwith overdoses in healthy people because OsrHSA is hyperoncotic. You will be monitored for the possibility of circulatory overload.

Hypervolemia may occur if the dosage and rate of infusion are too high. If hypervolemia is suspected, the infusion will be stopped immediately. In this case, your hemodynamic parameters will be carefully monitored.

Adverse Drug Reaction Overview
Adverse reactions to albumin are rare. Such reactions may be allergic in nature or due to high plasma protein levels from excessive albumin administration. Allergic manifestations include urticarial (hives), chills, fever, and changes in respiration, pulse and blood pressure. The possibility of an anaphylactic reaction (whole body allergic reaction) occurring in association with albumin is considered extremely rare. In the case of an anaphylactic reaction, the infusion will be discontinued, and you will be administered treatment appropriately.

In addition, with any medication, there is a small but real risk of allergic reactions that can be fatal. These reactions usually start shortly after taking the study drug. They manifest as skin itching and redness, swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing and breathing.

If you experience any of the reactions mentioned above, you must immediately tell the study doctor/his study staff right away or proceed to the nearest hospital emergency department or call 911.

ALLERGIC REACTION
In addition to the risks listed above, there may be unknown, infrequent, and unforeseeable risks associated with the use of this study drug, including severe or life-threatening allergic reactions or unexpected interactions with another medication. Symptoms of an allergic reaction may include rash, flushing, itching, sneezing or a runny nose, abdominal pain, diarrhea, swelling of the face, tongue or throat, dizziness, lightheadedness or fainting, trouble breathing, irregular or racing heart rate, and seizures.

If you experience an injury, bad effect, or any other unusual health experience during this study, you must immediately contact the study doctor or the study staff listed on page 1 of this consent form. In the event of a medical emergency, please visit your nearest hospital's emergency room or call 911.

ADDITIONAL RISKS AND DISCOMFORTS ASSOCIATED WITH STUDY PROCEDURES:
The possible risks and/or discomforts associated with the procedures described in this study include:

- Blood draw and IV catheter placement: Removal of blood by a needle may produce pain, bruising, bleeding, swelling, dizziness, or rarely, fainting or infection. For the IV catheter, there is also a risk of infiltration (leakage under the skin around the puncture site). The IV catheter will be flushed with a fluid called normal saline. Normal saline is sterile water (free from any contaminants) with 0.9% salt to make it able to mix with

blood. About 1-2 ml of blood will be drawn and discarded to flush saline from the catheter each time blood samples are collected via the catheter.

- Electrocardiogram (ECG): The ECG procedure may cause discomfort and/or bruising during the attachment and removal of the leads (sticky pads) to and from the skin as well as irritation at the site of the lead application. Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used. The sticky pads may be cold upon contact to the skin. In some cases, we may have to shave the area of the body where the sticky pads are attached to ensure that the pads stick to your body.

- Psychological discomforts: Some of the procedures may cause embarrassment or anxiety, or the questions the study doctor and/or research staff ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question. If you do not wish to participate you can stop at any time.

- Physical Exam: There are no risks with a physical exam. It will be similar to examinations you have had in your doctor's office in the past.

- Fasting (nothing to eat or drink except water): You may experience a drop in your blood sugar levels which can result in dizziness, headaches, or even fainting. Also, you may experience stomach ache and gastric reflux.

- Placebo: A placebo is not designed to have any chemical effects on your body; however, you may feel some discomfort. Placebo will be identical in appearance to the study drug. No risks are expected from taking a placebo.

- Intravenous infusion of the study drug or placebo: Insertion of a catheter into your vein can cause pain at the site of insertion, redness, swelling and infection. Infusion reactions, including severe or life-threatening allergic reactions may occur. Symptoms of an allergic reaction may include rash, flushing, itching, sneezing or runny nose, abdominal pain, diarrhea, swelling of face, tongue or throat, dizziness, lightheaded or fainting, trouble breathing, irregular or racing heart rate, and seizures. The study doctor can treat these reactions. Please tell the study staff or study doctor immediately if you are experiencing any of these symptoms.

- Although we try to make sure that all subjects are healthy upon participation in the study, the risk of contagious infection is increased because you will be in contact with a number of people during your stay at the site.

- Abdominal Ultrasound: An ultrasound is a safe procedure that uses low-power sound waves. There are no known risks.

- Other procedures: blood pressure measurement, weight, and height, are generally of no risk to you. Some of the questions may embarrass you at some point, consider all information is necessary and will be used in your best interests.

NEW FINDINGS UNKNOWN RISKS

There may be risks to being in this study that we don't know about now. You will be informed in a timely manner (both verbally and in writing), if during the course of this research study, significant new information becomes available that may relate to your willingness to continue to participate in this research study or to changes that are related to the way in which this research study will be done.

REPRODUCTIVE RISKS

Females

If neither you nor your male partner is surgically sterile (male partner vasectomized since at least 6 months) and if you are not postmenopausal (absence of menses for 2 years without an alternative medical issue.), you are required to avoid becoming pregnant while you are participating in this study since there may be risks to you or the fetus (unborn baby) associated with the use of OsrHSA during pregnancy. For this reason, if you believe that you are pregnant or have a chance of being pregnant you should not participate in this study. A pregnancy test will be performed prior to the start of study procedures. If you are pregnant, you will not be allowed to participate in the study

You are therefore required to use one of the following methods of contraception until 30 days after the administration of the investigational product:

Double methods of Contraception

- Simultaneous use of Intra-uterine contraceptive device (IUD - often T-shaped birth control device that is inserted into a woman's uterus to prevent pregnancy) placed at least 4 weeks prior to study drug administration, and condom for the male partner.

- Simultaneous use of hormonal contraceptives (example: birth control pills, implants, patch, depot injections starting at least 4 weeks prior to study drug administration and must agree to use the same hormonal contraceptive throughout the study, and condom for the male partner.

- Simultaneous use of diaphragm (reusable dome-shaped cup that prevents pregnancy by creating a barrier between a woman's uterus and a man's sperm) with intravaginally applied spermicide and male condom for the male partner, starting at least 21 days prior to study drug administration.

You are not considered a WOCBP (Woman of Childbearing Potential) if you are:

- Postmenopausal (2 years post-menopausal with confirmation by FSH test – blood sample test at screening); or
- Surgically sterile [defined as having either of the following procedures:]

- Bilateral oophorectomy (had both your ovaries removed);
- Hysterectomy (had your uterus removed);or
- Tubal ligation (had your tubes tied)

Except abstinence, no method of contraception is 100% effective.

The Study doctor can help answer questions on the most effective methods for avoiding pregnancy during this study.

If you become pregnant during this study, you will discontinue OsrHSA immediately. The study doctor will help you understand how OsrHSA might affect your pregnancy. This will be based on all the information available at that time. You will be instructed to consult with an OB/GYN doctor for pre-natal (pregnancy) medical care. Your study doctor will be available to counsel other doctors about how OsrHSA might affect your pregnancy.

If you think you may have become pregnant even though you used required contraception while in the study, you should contact the clinical site manager immediately (see the phone number on page 1 of this ICF).

With your permission, follow-up information about the pregnancy and the outcome will be collected and documented.

Males

Since OsrHSA may have an effect on sperm, your female partner has to avoid becoming pregnant while you are participating in this study. Therefore, if you are not vasectomized for at least 6 months and if your female partner is not surgically sterile and not postmenopausal, you must use one of the following methods of contraception throughout the study and for 90 days after the study drug administration:

Double methods of Contraception

- Simultaneous use of a male condom and, for the female partner, hormonal contraceptives (used since at least 4 weeks) or intra-uterine contraceptive device – IUD- (placed since at least 4 weeks);

- Simultaneous use of a male condom and, for the female partner, a diaphragm with intravaginally applied spermicide.

If you have a pregnant or breastfeeding female partner, you must agree to remain abstinent from heterosexual intercourse or use a male condom during each sexual encounter throughout your participation in this study.

Except abstinence, no method of contraception is 100% effective.

If you are a male participant and your female partner becomes pregnant during this study, please tell the study doctor or his study staff right away. The study doctor will notify Wuhan Healthgen Biotechnology Corporation of the pregnancy. If she consents, follow-up information about the pregnancy and the outcome will be collected and documented.

BENEFITS

There is no medical benefit to you for your participation in this study. This research study is not intended to provide any therapeutic or other health-related benefits. Your participation in this research study may help patients in the future.

ALTERNATIVES TO PARTICIPATION

This study is not designed to diagnose, treat, or prevent any disease. The only alternative is to not participate in this study.

COMPENSATION, COSTS AND REIMBURSEMENT

Compensation for this study is as follows:

If you follow all study requirements, and complete all required study visits, you may receive up to $2,900.00. If you do not complete the study, you will be compensated for the visits you do complete based on the following breakdown:

Clinic Visit	Compensation
Screening	$150.00
Day -1	$300.00
Day 1	$350.00
Day 2	$300.00
Day 3	$300.00
Day 5	$300.00
Day 8	$300.00
Day 15	$300.00
Day 22	$300.00
Day 30	$300.00
Total	**$2,900.00**

You will receive payment within 4-6 weeks of your final visit.

- If the results of the drug, alcohol, and/or cotinine (nicotine) tests are ***positive*** during your screening visit, you will **NOT** be able to continue in the study, and you will **NOT** receive any compensation. If the drug or alcohol, and/or cotinine tests are **positive** at any point after that, you will only receive compensation for any study visit(s) you have completed up to that point (except the visit where you test positive), but you will **NOT** be able to continue in the study.

If you complete all of the screening visit procedures, you will receive $150.00. If for any reason, you do not complete the entire screening visit procedures (only complete partial), you will receive 50% of the total amount as outlined below:

- Partial payment of $75.00 of the total screening payment for completing any procedures prior to having your blood drawn.
- Remaining balance of $75.00 of the total screening payment for completing your blood draw after all other screening procedures have been performed.
- You will receive payment in the form of a check. You will receive payment within 4-6 weeks of your final study visit.
- If for any reason you choose to discontinue or are withdrawn from the study, you will be compensated for each completed visit. If you have not passed the screening visit and are considered a screen fail, you will receive payment within 4-6 weeks from the time you are informed of your screening status.

Additional Information

Please be advised that compensation for participation in a study is taxable income. Personal information about you, including your name, address, and social security number, may be released for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS). WCCTG (study site) will issue you an IRS Form 1099-MISC, Miscellaneous Income, listing your compensation as reportable income. Non-resident aliens without a social security number or tax identification number (TIN) may be subject to withholding of 30% and U.S. residents without a social security number will be subject to a withholding of 24% at the time of payment under Internal Revenue Code Section 1441.

If for safety reasons you are required to stay at WCCTG for a longer period of time than expected, you will be compensated at a rate proportional to the entire compensation for the study (i.e. a similar amount to the compensation for a clinic visit or an overnight stay as in the table above). If you are withdrawn from (asked to leave) the study for medical reasons, because you no longer qualify for the study based on the evaluation of the safety assessments, and/or the study doctor does not think it is in your best interest to continue to participate in the study for safety reasons, you will be compensated the full amount for all the visits you complete, including the visit in which you are withdrawn from the study.

If you are withdrawn from the study because you no longer qualify for the study based on the evaluation of the check-in assessments, and/or the study doctor does not agree you can participate in the study, you will receive compensation for the check-in and baseline assessments performed on Day 1. However, if you are withdrawn from the study because you have not complied with (followed) the study rules at any time, you may receive compensation up to the day that you are considered non-compliant (failed to follow the study rules). Non-compliance with the study rules includes, but is not limited to, improper conduct, taking alcohol and/or any drugs (including recreational drugs), or consuming any foods/beverages that are not allowed in the study.

If you decide to withdraw from the study for a non-medical reason, you will receive compensation for the visits you have completed for your time and inconvenience.

ANY ANTICIPATED EXPENSES
You are not expected to incur any additional unanticipated costs while you participate in the study. All study related visits, procedures and study medication will be provided to you at no cost.

COMPENSATION FOR INJURY
WCCT Global, Inc. will provide immediate medical treatment and follow-up care, without cost to you, for side effects or injuries caused as a direct result of your participation in this research study. The costs for any other medical problems not directly caused by your participation in this research study are your responsibility. There are no plans to provide you with financial compensation for such things as lost wages, disability, or discomfort due to injury. You do not lose any legal rights by signing this form.

- A **study-related injury** is a physical injury that is directly caused by the study drug administered as described in the study protocol.
- A **study-related injury** does not include injuries directly caused by any of the following:
    - The natural course of an existing underlying disease or medical condition.
    - Not following the instructions provided in this informed consent form or by study doctor and/or staff.

Medicare, Medicaid and TRICARE Beneficiaries

If you are a Medicare, Medicaid or TRICARE beneficiary, the costs of necessary medical treatment of the study-related injuries described above may not be billed to Medicare, Medicaid and TRICARE. These medical bills should be submitted first to study doctor so that they may review them with the study sponsor. The study doctor and the study sponsor will issue payment if is determined that the fees were incurred as a direct result of your participation in the study. Contact your study doctor if you have any questions about this restriction.

If you believe that you have experienced a study-related injury, please contact the study doctor and/or study staff at the numbers listed on page 1 of this informed consent form immediately. In the event of a medical emergency, please visit your nearest hospital's emergency room or call 911.

EMPLOYEES OF WCCT GLOBAL, INC.

If you are an employee of WCCT Global, Inc., and you decide to participate in this research study, your participation is strictly voluntary. Your employment status and benefits will not be affected by your enrollment or withdrawal from this research study. Your confidentiality will be maintained and protected by the study doctor and/or study staff. Your payment will be at the same level and processed in the same manner as other participants. You will be required to sign a separate Non-Coercion Statement form.

FAMILY MEMBERS OF WCCT GLOBAL, INC. EMPLOYEES

If you are a family member of a of WCCT Global, Inc. employee, you will be treated in the same manner as other participants and will not be entitled to any special benefits. Your family member's employment status will not play a determining factor in your study enrollment. Your payment will be at the same level and processed in the same manner as other participants. You will be required to sign a separate Non-Coercion Statement form.

WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the study doctor and/or research staff immediately**. The study doctor and/or research staff may also end your participation in this study without your consent if you do not follow instructions, miss scheduled visits, your safety and welfare are at risk, or the study sponsor decides to stop the study.

If you experience any of the side effects listed in the Risks and Discomforts section or if you become ill during your participation in this research study, you may need to be withdrawn from the study, even if you would like to continue. The study doctor and/or research staff will make the decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to complete an end of study visit for your safety. You are free to accept or decline these additional procedures.

CONFIDENTIALITY
The study doctor and staff will handle your personal health information (information that can identify you) in a confidential manner to the extent required by law.

Wuhan Healthgen Biotechnology Corporation will use your personal health information for purposes of conducting this research study as well as future scientific research.

Wuhan Healthgen Biotechnology Corporation may also use this information to obtain permits to sell drugs from some countries. The sponsor will ensure that those who analyze the data on behalf of the sponsor in other countries have appropriate measures to provide an adequate level

of protection. The study records will be stored both as hard copies as well as computer records. In order to protect privacy, the information will be classified and displayed in a way that cannot personally identify you. The study doctor will replace your name with a unique code. If the results of this research study are published, you will not be identified. By signing this consent form and the Authorization, you are granting the usage of your information.

The study doctor will retain the list that links your personal medical records, each participant's name and code number for at least 2 years after the last approval of a marketing application and until there are no pending or contemplated marketing applications or at least 2 years after the formal discontinuation of clinical development of the study drug.

The Food and Drug Administration (FDA) and other regulatory authorities, Alpha IRB, clinical study facility employees and Wuhan Healthgen Biotechnology Corporation representatives can view this list, compare and confirm your clinical study information and medical records. As long as authorized (permitted) by law, medical records will not be disclosed (shared). By signing this consent form, you agree that any person who has justifiable reasons can view your medical records directly.

The collected information may be sent to Wuhan Healthgen Biotechnology Corporation company's other members, contractors and regulatory authorities.

After the clinical study staff and the study doctor disclose your health information protected by law to others, this information may be re-disclosed and may not be protected by the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Identifiers may be removed from your identifiable private information and after the identifiers are removed, the information may be used for future research studies without your additional consent.

You can request to view your information and request to correct errors. Wuhan Healthgen Biotechnology Corporation may postpone information viewing if it would hinder the clinical study itself. At any point in time, if you decide to leave the clinical study, there is a possibility that Wuhan Healthgen Biotechnology Corporation will continue to use your information that was collected up to the point you left the study as long as it is permitted by law.

IF YOU HAVE QUESTIONS

If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.

A 24 hour number is also listed on page 1 of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you have questions, concerns or complaints about your rights as a research volunteer or about taking part in this study, or to obtain information or offer input, you may contact Alpha IRB, Attn: Marianne Thornton, toll free at (888) 265-5766 between the hours of 8:00am-5:00pm Pacific Time.

Alpha Independent Review Board
1001 Avenida Pico, Suite C #497
San Clemente, CA 92673
(888) 265-5766 (toll free)

Alpha IRB is a group of people who perform independent review of research studies to protect the rights and welfare of study participants. Although Alpha IRB has approved the information provided in this informed consent form and has approved for the study doctor to do the study, this does not mean Alpha IRB has approved you being in the study, or that the study is without risks. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PRIMARY CARE PROVIDER

WCCT Global, Inc. can inform your primary care provider of your participation in this study. Please initial one of the following options after you have made your decision:

_____ N/A, I do not have a Primary Care Provider.

_____ No, I would not like WCCT Global, Inc. to inform my primary care provider of my participation in this study.

_____ Yes, I would like WCCT Global, Inc. to inform my primary care provider of my participation in this study. Please provide the following information:

Name of Healthcare Provider: _____

Address of Healthcare Provider: _____

VOLUNTARY PARTICIPATION STATEMENT

You should not sign this informed consent form unless you have read and signed the attached "Experimental Subject's Bill of Rights." **Participation in this study is voluntary.** You may refuse to participate or stop your participation at any time and there will be no penalty or loss of benefits. You will be given a copy of this signed and dated informed consent form, and the attached "Experimental Subject's Bill of Rights" to keep for your reference.

Your signature below indicates you have read the information in this informed consent form and have had a chance to ask any questions you have about this study.

I confirm that I have read and understand the information presented to me in this informed consent form, which is presented to me in a language that I read and understand, and I agree to participate in the study.

_____ _____

Participant Signature **Date**

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent **Date**

_____

Printed Name of Person Obtaining Consent

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

A new privacy rule has been issued to protect the privacy rights of patients. This rule (the "Privacy Rule") was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your health information and requires your written permission for your health information to be used in this study. This section, called an "Authorization," explains how your health information will be used and disclosed (shared) during this study and describes your rights, including the right to see your health information.

By signing this consent form, you allow the study doctor to use your Personal Health Information and samples to carry out this study and the Sponsor to use information related to you for research conducted with your samples. Your "Personal Health Information" is information about you that could be used to identify you, such as 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 study.

By signing this consent form, you also allow the study doctor to disclose your Personal Health Information to other parties in other countries for clinical research and safety reporting purposes, including to the following: (1) Sponsor, its affiliates and licensing partners; (2) business partners assisting Sponsor, its affiliates and licensing partners; (3) regulatory agencies such as the Food and Drug Administration and other health authorities; and (4) Alpha IRB.

Your Personal Health Information may no longer be protected by the Privacy Rule once it is disclosed by the study doctor, although other confidentiality safeguards apply. Please refer to the CONFIDENTIALITY section above to see how Sponsor will treat your Personal Health Information confidentially. If you have questions about how your Personal Health Information will be protected, you can ask the study doctor. You have the right to see and copy your Personal Health Information related to the study for as long as this information is held by the study doctor. However, to ensure the scientific integrity of the study, you agree that you may not be able to review some of your records related to the study until after the study has been completed.

You will not know the results of any future study-related research performed with your samples and such information will not be placed in your medical records. You may cancel this Authorization at any time by sending a written notice to the study doctor at his address listed on the first page. If you cancel this Authorization, the study doctor will no longer use or disclose your Personal Health Information under this Authorization for this study, unless the study doctor needs to use or disclose some of your Personal Health Information to preserve the scientific integrity of the study. Information given to Sponsor before you cancel this Authorization may still be used by Sponsor.

If you do not sign this consent form, you cannot participate in the study. If you cancel this Authorization in the future, you will no longer be able to participate in the study. For further information regarding cancellation, see the Voluntary Participation/Right to Withdraw section above.

This Authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner. By signing below, you allow the study doctor to use or disclose your Personal Health Information as described above.

_____

Participant's Name (Print)

_____ _____

Participant's Signature Date