paiConsent to Participate in a Research Study

Full Title:	**A Randomized, Double-Blind, Placebo-controlled, Single-ascending Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of JK07 in Subjects with Heart Failure with Reduced Ejection Fraction (HFrEF)**
Study Number:	**JK07.1.01**
Version:	**Amendment 3**
Sponsor:	**Salubris Biotherapeutics, Inc.**
Study Doctor Name:	**<INSERT SITE PI NAME>**
Research Site Address(es):	**<INSERT SITE ADDRESS>**
Daytime Telephone Number(s):	**<INSERT SITE PHONE NUMBERS>**

24-Hour Contact Number(s) In Case of Emergency: <INSERT EMERGENCY PHONE #>

Invitation:

You are being asked to take part in this research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. The physician conducting the study or one of our team members will go through the consent form with you and answer any questions you have.

- Part 1 of this document tells you the purpose of this study and what will happen to you if you take part. Part 1 allows you to gain a quick understanding of the study and decide if you want to read further details about participation.
- Part 2 gives you more detailed information about the conduct of the study, providing further details for you to consider.

Please read this consent form carefully and take as much time as you need to decide whether to take part in this study. You may want to discuss your participation with family, friends or your General Practitioner / Family Doctor (GP) / own Cardiologist. You have the right to have all your questions or concerns addressed prior to signing this Informed Consent Form.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Standard care (or “routine care”) is the treatment normally given for a certain condition or illness. In this study, you will continue to receive the same standard care that you receive currently.
- In addition to your standard care, in this study you may receive JK07, an experimental (investigational) study drug that is being tested for safety and potential beneficial effects on heart function in patients with heart failure due to decreased heart function. An investigational study drug is one that has not been approved by the U.S. Food & Drug Administration (FDA), an agency responsible for protecting and promoting public health in the USA. This drug has been tested in animals but not yet in people. This study tests different single doses of the drug to see what the effects are, if any, along with the usual approved standard therapy that you are already taking.
- Your medical records may become part of the research record, but only after any information which would identify you is removed (de-identified). If that happens, your de-identified medical records may be looked at and/or copied by the sponsor of this study and

government agencies or other groups associated with the study. However, your personal information will be kept private.
- Your medical insurance may be billed for any standard medical care you receive during the research study.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PART 1

1. What is the purpose of the study?

The main purpose of the study is to evaluate the safety and activity of the investigational product in subjects with heart failure who have a lower than normal amount of blood pumped by the heart (weaker hearts). This study is a "first-in-human" study of the protein JK07 and will determine if, and at what dose, this product is safe and tolerable, how long it stays in your body, and whether it has any effect on your heart function. This study could lead to further and future studies of this product in larger patient populations. JK07 is a protein which was designed to stimulate your heart in a way that promotes regeneration and better functioning, including increasing the amount of blood that your heart pumps (stronger hearts).

Different doses of the study drug will be given to groups of 5 to 9 study participants. Each participant will receive only one single dose. The first study participants will receive the lowest dose. If the drug does not cause significant side effects at these lower doses, it will be given to other study participants at progressively higher doses. The dose will continue to increase for every group of study participant until either side effects occur that require the dose to be lowered or stopped, or if significant improvement in heart function is observed.

For each group receiving a dose of the study drug that hasn't been tested previously, the first subject will receive the actual study drug. For the remaining participants in each group, 75% will receive the actual study drug and 25% will receive the placebo (inactive "look-alike"). The investigational product will be administered by intravenous injection or infusion, using the IV line. The investigational product will only be given once, on Day 1 after you are admitted to the hospital and a few tests are performed to compare with the same tests which will be performed after the infusion. You will not know at the time you start the screening process whether you will be the first person in the group who receives the study drug, or one of the other people in the group who could receive either JK07 or placebo.

Sometimes we do not know what dose will be best for an investigational study drug. To find out, we need to compare different dose levels. We put people into groups and give each group a different dose. The results are then compared to see if one is better than the rest. To try to make sure the groups are the same to start with, patients are put into a group by chance (randomly).

This study involves the use of a "placebo" and an investigational study drug. A "placebo" is an inactive product that has no therapeutic effect. The effects of JK07 will be compared to the effects of the placebo. Neither you nor your study physician will know if you've received JK07 or the placebo, unless you are the first subject in a new dose group. If you agree to participate in this study and are determined to be fully eligible based on other screening tests, you will be randomly assigned to receive either JK07 or the placebo. You will then be enrolled into the dose group which is actively enrolling at the time. If you are the first subject in a dose group, you will definitely receive JK07; you will not be randomly assigned, and you will not receive the placebo. If you are not the first subject in a dose group, you will have approximately a 75% chance of receiving JK07. If you do not receive JK07, you will receive a placebo. Note that you will only receive one dose of JK07 or placebo throughout your participation in the study.

2. Why have I been invited?

You are being invited to participate in this study because you have heart failure with reduced ejection fraction, in which your heart pumps a lower than normal amount of blood. This means that your heart does not pump blood out of the heart as well as it should. If you agree to participate in this study, your physician will conduct additional tests to ensure you are fully eligible for participation in this study. Up

to 63 subjects will take part in this study at approximately 8 different medical facilities/hospitals in the United States.

3. Do I have to take part?

Your participation in this study is completely voluntary. You can leave the study at any time; you do not need to provide a reason. If you decide not to join the study or leave the study after you start the study, your access to medical care or the future benefits to which you are otherwise entitled will not be affected.

4. How long will I be in this research?

Your total involvement in this study would be approximately 7.5 months, with approximately 15 visits with the study team. The details of each visit are below.

5. What will happen to me if I take part?

If you agree to take part in the study, you will be asked to sign and date this consent form. If you do not sign this consent form, you will not be able to join the study. You will only receive a single dose of the of the investigational product in this study, during your first visit to the hospital, and all subsequent visits are only to monitor the effects of the product which was administered.

- Smoking, e-cigarettes or the use of any nicotine-containing products (including patches) is not permitted from 2 weeks prior to receiving the study product until the final follow-up visit 6 months later.
- Use of CBD (cannabidiol) products or use of any CBD-containing products (including foods and supplements) is not permitted from 2 weeks prior to receiving the study product until the final follow-up visit 6 months later.
- Alcohol consumption will not be permitted from 3 days prior to receiving the study product (Day -3) through completion of study procedures on Day 3, and then within 24 hours prior to any subsequent visit.
- Consumption of caffeine or xanthine-containing products (e.g., coffee, tea, cola drinks, chocolate) will not be permitted from 1 days prior to receiving the study product (Day -1) through completion of study procedures on Day 3, and then within 24 hours prior to any subsequent visit.

Screening Visits

Before you begin treatment in this study, you will need to have certain tests performed, called screening tests, to see if you meet the rules and requirements for taking part in the study. Your study doctor will ask you to sign this consent form before these tests or any other tests are performed, unless they would normally be performed as part of your standard care.

The tests and procedures listed below will be done within 45 days prior to the day you receive the study product (either JK07 or placebo). These screening tests might not be done all in the same visit.

A. Review of medical history (the study team will review your records for important medical history and a review of all medications you are taking; this may involve you answering some questions, so the study team fully understands your medical history);
B. Physical exam (may include your height, weight and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature));
C. Urinalysis
D. Blood draw: Approximately 5 teaspoons of blood will be drawn for a variety of tests (including ~~a~~ test for the function of your liver, kidneys, thyroid, heart, blood lipids like cholesterol and triglycerides, blood-clotting capability, and assessment of certain viral infections), to establish a “baseline” with which to compare your blood tests after receiving the study product; additionally, if you are a female of childbearing potential, you will also have a blood pregnancy test to ensure you are not pregnant;

E. Heart rhythm monitoring/recording for 14 days using a wearable patch; a small adhesive, water-resistant sensor will be placed on your chest to record the electrical activity of the heart for 14 days during the screening period;
F. A standard electrocardiogram ("ECG") where 12 electrodes will be affixed to your skin (chest, arms, legs) to record the electrical activity of your heart.
G. Echocardiography, which uses high frequency soundwaves (ultrasound) to create a picture of your heart.

Day of Receiving the Product ("Day 1")

You will be admitted to the hospital by 7:00 a.m. for at least a 2-day hospital stay. You must have abstained from food (called "fasting") for 10 hours prior to arriving to the hospital. You will follow a prescribed meal plan during your hospital stay.

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Urinalysis (additionally, if you are a female of child-bearing potential, you will have a urine pregnancy test to ensure you are not pregnant)
C. Medical events and medications: Review of your medical records and a discussion with you to determine if you have had any medical events since your last office visit. The study team will also review all medications you are taking; this may involve you answering some questions for the study team to allow full understanding of your medical history;
D. Blood collection from your IV tube 9 times over the course of the first day (approximately 6 tablespoons of blood in total), and finger-pricks 8 times to also test levels of blood glucose (sugar)
E. Echocardiography;
F. ECG;
G. Receive either JK07 or the placebo, administered intravenously (through a tube inserted in your vein); This will be the only dose of the investigational product that you will receive in this study.
H. Checking for any adverse events and any new medications (an adverse event is a change in your health/condition, or injury, and should be reported to your investigator throughout the study);
I. Checking your injection site for a reaction (if any).

Day after Receiving the Product ("Day 2")

This will be the second day of your hospital stay. You will follow the prescribed meal plan, which includes fasting for 10 hours prior to your 24-hour procedures, which includes the following;

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Checking for any adverse events and reviewing medications;
C. Checking your injection site for any reaction;
D. Blood collection from your IV tube (approximately 2 teaspoons of blood); including a finger-prick to test levels of glucose (sugar)
E. Echocardiography
F. Urinalysis;
G. ECG.

Day 3

You will likely be discharged on the third day of your hospital stay. Before discharge, the following procedures will be performed;

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Checking for any adverse events and reviewing medications;
C. Checking your injection site for any reaction;
D. Blood collection from your IV tube (approximately 6 teaspoons of blood); including a finger-prick to test levels of glucose (sugar)
E. Urinalysis;
F. ECG.

Note for all visits – you must fast (abstain from food) for 10 hours prior to each visit, and you must also abstain from ingesting caffeine- or xanthine-containing products (such as coffee, tea, cola drinks and chocolate) or alcohol for 24 hours prior to <u>each visit</u>.

Day 4

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 2 teaspoons of blood); including a finger-prick to test levels of glucose (sugar)
D. Urinalysis;
E. ECG.

Day 7

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 6 teaspoons of blood);
D. Urinalysis;
E. ECG;
F. Echocardiography.

Day 11

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 1 teaspoon of blood);
D. ECG.

Note: Your physician may elect to have this Day 11 visit conducted remotely (by telehealth with the physician or the physician's staff), due to coronavirus concerns and your safety versus the data to be collected. Should this visit be conducted remotely, the physical exam, blood draw and ECG may not be performed.

Day 15

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 6 teaspoons of blood);
D. Urinalysis;
E. ECG;
F. Echocardiography.

Day 22

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 1 teaspoon of blood);

Note: Your physician may elect to have this Day 22 visit conducted remotely (by telehealth with the physician or the physician's staff), due to coronavirus concerns and your safety versus the data to be collected. Should this visit be conducted remotely, the physical exam and blood draw may not be performed.

Day 30

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 7 teaspoons of blood);
D. If you are a female of child-bearing potential, you will have a urine pregnancy test to ensure you are not pregnant;
E. ECG;

F. Echocardiography.

Day 60

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 6 teaspoons of blood);
D. If you are a female of child-bearing potential, you will have a urine pregnancy test to ensure you are not pregnant;
E. ECG;
F. Echocardiography.

Day 90

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 6 teaspoons of blood);
D. If you are a female of child-bearing potential, you will have a urine pregnancy test to ensure you are not pregnant;
E. ECG;
F. Echocardiography.

Day 135

A. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
B. Adverse events and medications;
C. Blood draw (approximately 5 teaspoons of blood);
D. If you are a female of child-bearing potential, you have a urine pregnancy test to ensure you are not pregnant;
E. ECG;
F. Echocardiography.

Day 180 (final visit)

A. An End of Study or Day 180 Follow-up visit will be completed once you complete the study or in the event you need to leave the study early;
B. Physical exam and vital signs (for example, your heart rate, blood pressure, respiratory rate and temperature);
C. Adverse events and medications;
D. Blood draw (approximately 6 teaspoons of blood);
E. If you are a female of child-bearing potential, you will have a urine pregnancy test to ensure you are not pregnant;
F. ECG;
G. Echocardiography.

6. Expenses and payments

Study products and all study-related testing, including the 3-day in-hospital stay, will be provided to you by the sponsor at no charge. You will not need to pay for any tests and procedures which are performed just for this study. These study-related tests and study-related procedures include ECGs, echocardiograms, blood tests, urinalyses, pregnancy tests, blood draws to monitor the investigational product, or exams done by the physician. However, you and/or your health plan will need to pay for all other standard tests and procedures that you would normally have as part of your regular medical care. These standard tests and procedures are blood tests performed prior to receiving the investigational product, your prior and current medications, exams done by your regular physician, and various related costs.

You will be paid for participating in this study, to cover reasonable expenses incurred for travel and accommodation for completing study visits. You will be paid $225 per day for your two full days in the hospital (“Day 1” and “Day 2”) and $75 for the day of discharge (“Day 3”) and each return visit (Days

4, 7, 11, 15, 22, 30, 60, 90, 135, 180). If you complete all study visits, you can expect to have received $1275 in total. Additionally, if you live more than 30 miles away from the study facility, you will be compensated $250 to cover a hotel stay the night prior to your hospital admission, since you must be admitted into the hospital study unit by 7:00 a.m. Ensure you inform your coordinator if you live more than 30 miles away and will stay at a hotel the night prior to your hospital admission for this study.

If a commercial product is developed from this research, rights to the product will belong to the sponsor and their collaborators (persons or companies partnering with the sponsors). You and your family will not receive any financial benefits or compensation from or have any rights in any developments, inventions or other discoveries that might come out of this research.

7. What do I have to do?

If you take part in this research, you will be responsible to:

- Follow the instructions you are given by the study doctor or other study staff;
- Report to the study doctor or other study staff immediately any changes in your health;
- Return to the study doctor's office as scheduled for your visits;
- Fast for 10 hours prior to every study visit;
- If sexually active, employ adequate birth control/contraceptive measures for the duration of the study;
- Abstain from smoking (or use of nicotine products) from 2 weeks prior to receiving the study product through the end of study participation (approximately 6 months after receiving the study product or the time of withdrawal from the study if earlier);
- Abstain from use of CBD (cannabidiol) products or use of any CBD-containing products (including foods and supplements) is not permitted from 2 weeks prior to receiving the study product until the final follow-up visit 6 months later.
- Abstain from ingesting caffeine- or xanthine-containing products (e.g., coffee, tea, cola drinks, chocolate) from 1 day prior to receiving the study product (Day -1) through completion of study procedures on Day 3, and then within 24 hours prior to any subsequent visit;
- Abstain from ingesting alcohol from 3 days prior to receiving the study product (Day -3) through completion of study procedures on Day 3, and then within 24 hours prior to any subsequent visit.
- Tell the study doctor or study staff if you want to stop being in the research study.

8. What are the alternatives for diagnosis or treatment?

You may choose not to participate in this study. You do not have to be in this study to receive treatment for your heart failure. Other choices for treatment of your disease could be different drugs or drug combinations, or surgical procedures. There may be standard approaches or other investigational regimens available to you; you should discuss this with your doctor. Your study doctor will discuss the risks and benefits of these other options with you.

9. What are the possible disadvantages and risks of taking part?

There are risks associated with any treatment, whether investigational or standard care. The tests/procedures listed below are standard medical procedures but do come with their own risks or discomforts.

<u>Echocardiogram:</u>
An echocardiogram uses sound waves to produce images of your heart. This commonly used test allows your doctor to see how your heart is beating and pumping blood. A clear, easily wipe-able gel is placed on your chest and a blunt probe (transducer) is moved about on the skin to beam ultrasound waves to create a moving image of your heart structure and function. It is a safe, painless procedure and usually takes 30 minutes. There are no known complications associated with having it.

<u>Electrocardiogram (also called an ECG or EKG):</u>
An electrocardiogram records the electrical activity of the heart through small electrode patches attached to the skin on your chest, legs and arms. You will lie flat on a table for about 10 minutes

while the machine records the heart's electrical activity. You may experience redness or itching where the pads were placed. There are no known complications associated with having it.

ECG Patch:
During the study screening period, an ECG patch with an attached sensor will also record the electrical activity of the heart, but only one device will be placed on the skin on your chest. You will wear this for 14 days, after which the device will be returned for reading. You may experience redness or itching where the patch was placed. There are no known complications associated with having it.

Blood Sampling:
Blood tests may cause pain, bruising, bleeding or swelling at the site where blood is taken or a needle is inserted. You may also experience dizziness or fainting while blood is being taken. There is also a very small risk that an infection may occur.

10. What are the side effects of any treatment received when taking part?

This is a "first-in-human" study, and, as such, JK07 has not been previously evaluated in human subjects.

Since at this time, JK07 has not been administered to people, it is not known what side effects may be seen. The possible side effects that may be expected based on studies conducted with JK07 in animals given either similar or much higher doses, and in some cases multiple doses, were generally limited to occasional infusion reactions with flushing, increased salivation, transient weight loss, short-term heart rate or rhythm changes, and transient elevations of liver function tests.

The product consists of two different proteins which have been biologically fused together. One of them is a specific growth factor which is designed to help your heart to recover some of the function it has lost by generating more and stronger heart muscle cells.

This is a highly specific protein for stimulating heart muscle development, and while there is no evidence that this particular growth factor is associated with stimulating abnormal tissue growth, or any indication it could stimulate early cancer growth anywhere in the body, the second protein has been included as part of the investigational study drug to block the interaction of the growth factor with proteins outside of the heart. This second protein is intended to protect you from any negative effects outside of the heart, but it will not block the effects in the heart.

In many years of animal studies, as well as with prior experience over the past decade in humans using similar versions of the same growth factor, no apparent increased risk of cancer has been seen, even without this additional blocking protein designed to improve the safety of the treatment.

Nevertheless, there is at least a theoretical possibility that this molecule could worsen an undetected pre-existing cancer. For additional safety monitoring, enrollment into this study will include a thorough cancer screening evaluation.

Prior human studies using similar but different versions of the same growth factor, without the blocking protein, noted the occasional side effects of transient nausea, headache, fatigue, dizziness, minor skin rash, diarrhea, cough, abdominal cramping, temporary liver function test abnormalities, transient low blood sugar and low blood pressure, short-term chest pain, and transient ECG abnormalities of mild heart rhythm disturbances, including a temporary speeding up of the heart rate. The additional blocking protein may help to avoid some of these side effects.

11. Harm to the unborn child

Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick) during screening. On the day of study product administration (Day 1), you will have a urine pregnancy dipstick test to confirm absence of pregnancy. These must be negative before you can continue in this study.

Women cannot be pregnant or breast-feeding, nor should they attempt to become pregnant while participating in this study. If you are sexually active and able to have children, you must agree to use a highly effective method of contraception (e.g., condom, intrauterine device [IUD], oral contraceptive, or double-barrier method), for the duration of study participation.

Men who are in this research study should not get a sexual partner pregnant while participating in the study. Men must be surgically sterile, abstinent, or if engaged in sexual relations with a woman who could become pregnant, must use an acceptable method of contraception (double-barrier methods such as condoms with spermicidal gel or foam) while taking part in this study. Male subjects with a pregnant or breastfeeding partner must remain abstinent or agree to use a double-barrier method of contraception (including the use of a male condom).

If you or your partner become pregnant or think you or your partner may be pregnant while in the study, you must notify your study doctor immediately.

12. What are the possible benefits of taking part?

There is no guarantee or assurance that you will benefit from taking part in this research study. JK07 is designed to promote cardiac function through repairing damaged heart muscle cells, and to protect your heart cells from dying. You may feel better if JK07 has its intended effect. Future patients with the same disease may also benefit from the results of this study. Risks and benefits of participating in this study should be discussed with the study physician.

13. What happens when the research study stops?

When the research study stops, your data, along with the data from other research subjects, will be analyzed and ultimately submitted to the FDA and other regulatory authorities. The results of this study may form the basis for further study of this product.

Your study doctor may end your participation in the study early without your consent if he/she determines it is in your best interest.

14. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed in Part 2.

15. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the Information Sheet

1. What if relevant new information becomes available?

New information about JK07 may become available while this study is ongoing. If this happens, your research doctor will provide you with this information and discuss whether you should continue in the study. If you decide not to remain in the study, your research doctor will arrange for your care to continue. If you decide to continue in the study, he/she may ask you to sign an agreement outlining the discussion.

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

2. What will happen if I don't want to continue in the study?

You can change your mind and refuse to participate in the study at any time before or after the study begins. You will not be penalized in any way if you decide to withdraw from this research study. You should inform your study doctor of your decision to withdraw in writing. You should consult your doctor who will advise you as to what treatment regimen you should follow after you end your participation in this study. Data collected up to the time of your withdrawal will be used and analyzed.

If you decide not to continue, you will be asked to return for a final end-of-study visit to obtain final data. Please note that all visits after you receive the study product are intended to monitor your safety. See the section in Part 1 under Day 180 for the details of this end-of-study visit.

3. Whom do I call if I have questions or problems?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact the study doctor listed on page 1 of this consent form.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the [IRB name] Institutional Review Board (IRB) at (xxx)-xxx-xxxx.

4. Injury

You should notify the study doctor listed on page 1 as soon as you believe you have experienced any study-related illness or injury. However, there is no commitment by the study hospital or your study physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

In the event of an injury or illness that is determined to be directly related to the proper use of the study medication or properly performed study procedures, the sponsor, Salubris Biotherapeutics, Inc., will pay all reasonable and necessary medical expenses to treat such illness or injury (excluding the underlying disease or condition or any natural progression thereof) provided you have followed the directions of the study doctor and his/her staff [and are not otherwise eligible for reimbursement by your personal insurance, a government program or other third party coverage for such medical expenses]. No other compensation will be offered by the sponsor. Financial compensation for such items as lost wages, disability or discomfort due to research-related injury will not be made available.

5. Will my taking part in this study be kept confidential?

This section gives more specific information about the privacy and confidentiality of your health information. It explains what health information about you will be collected during this research study and who may use, give out and receive your health information. It also describes your right to inspect your medical records and how you can revoke this authorization after you sign it.

Your health information includes your personal medical history, information from laboratory tests, blood tests, physical exams and other tests or procedures described in this consent form. Information learned during telephone calls and study visits done as part of this research study are also part of your health information. In addition, personal medical information located at other medical facilities where you received treatment will be used and given out to conduct the study and to evaluate the results. By signing this form, you agree that your health information may be used and disclosed during this research study. Again, neither your name, nor any personally identifiable information will be disclosed. Only information that is needed for the research study will be collected. Your health information will only be used and given out as explained in this consent form or as permitted by law.

The data collected during this study will be the sole property of Salubris Biotherapeutics, Inc. The results may be presented in publication or presentation, but your identity will be kept confidential.

Your study doctor, study staff, the institutional review board and their staff, legal counsel, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the study or make sure it is being done properly will see your health information, and may give out your health information during the research study without identifying this health information as yours.

Other persons and organizations including the sponsor of this study (Salubris Biotherapeutics, Inc.), or their representative will see and use your privacy-protected health information during this study. Government regulatory agencies such as the Office of Human Research Protections, the U.S. Food and Drug Administration, and Regulatory authorities in other countries may also review your health information. The study doctor may also notify your primary care physician and/or cardiologist of your participation in this research study.

Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to redisclosure by the recipient.

You do not have to give your authorization to use or give out your health information. However, if you do not give authorization, you cannot participate in this research study.

You may cancel your authorization to use your personal health information at any time by giving a written notice to your study doctor. Once you cancel your authorization, no new health information about you will be gathered and you will no longer be able to participate in this study. However, information gathered before that date may be used or given out if it is needed for the research study or any follow-up.

Your authorization to use and give out your health information will continue until you cancel your authorization. You have the right to look at your medical records at any time during this research study.

6. Involvement of the General Practitioner/Family doctor (GP)

Your personal doctor, in addition to your cardiologist, should be informed of your participation in this research study. By consenting to participate in this study, you also agree that the study doctor can inform your family doctor/general practitioner of your participation in this study.

7. What will happen to any samples I give?

You will have blood samples taken at nearly every study visit. These samples will be used in a variety of tests performed locally at the study hospital and also at a centralized laboratory. Some of your samples will be shipped to central laboratories for analysis.

8. What will happen to the results of the research study?

The results of this study will be provided to the FDA and other regulatory authorities, which could lead to future studies and ultimately approval of JK07 for use in patients with heart failure. The results may also be included in publications, presentations and marketing/advertising. No personal information will be disclosed.

A description of this clinical trial is available on http://www.ClinicalTrials.gov (NCT04210375), 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.

9. Who is organizing and funding the research?

This research is being organized and funded by Salubris Biotherapeutics, Inc. Salubris Biotherapeutics, Inc. is compensating the hospital for their staff's time and effort to conduct this study. They are also paying for the costs of study-related procedures.

10. Statement of Consent

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. By signing this consent form, I authorize for my personally identifiable data to be shared as described in this consent form. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time