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

Sponsor / Study Title:	**Arcturus Therapeutics, Inc. / "A Phase 1, First-in-human, Randomized, Observer-blind, Parallel design, Controlled, Dose Level and Schedule-finding Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of a Self-Amplifying mRNA Pandemic Influenza Vaccine (ARCT-2304) When Administered to Healthy Adults."**
Protocol Number:	**ARCT-2304-01**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

SUMMARY

You are being invited to participate in a research study. The goal of this study is to learn more about a treatment or condition. This is different than the goals of routine clinical care. In a research study, a study team, which may have study doctors other than your current doctor or health care provider, led by a Principal Investigator (Study Doctor), must follow a protocol which defines the treatment plan for all research participants. This is different from your routine clinical care, your doctor will determine the treatment plan that is best for you. Your participation in this research study is voluntary, and you should only participate if you completely understand what this study requires from you, as well as the risks and potential benefits associated. You should ask the study team any questions you have before deciding to participate in this research study. If you have any questions about your rights as a human research participant, please contact the Advarra Study Subject Advisor (adviser@advarra.com) for assistance.

You are being invited to participate in this research study because you are a healthy adult aged 18 to 80 years old who might meet the requirements for taking part in this study. This research study is designed to learn more about the safety and the immune response produced by three different dose levels of the ARCT-2304 vaccine, a pandemic influenza vaccine candidate. You may or may not receive direct medical benefit from participating in this research study. If you agree to participate in this research study, you will be asked to complete the following research procedures: physical examination, height and weight measurements, vital signs, review of medical history and demographics, pregnancy test (if you are a woman who is able to have children), blood sampling, electrocardiogram to check your heart rhythm, completion of an electronic diary (eDiary) including the training for the eDiary, vaccine administration and post-vaccine observation (for at least 60 minutes), assessment of adverse events (symptoms and side effects), review of other medications you are taking, and follow-up phone calls with the study staff. Additional procedures that are consistent with your standard of care treatment may also be performed, and the data may be used for the purposes of this research study.

Your participation will last up to approximately 9 months. You will receive 2 vaccinations, either on Days 1 and 29 (Day 1 and 29 group) or on Days 1 and 57 (Day 1 and 57 group). You will have 3 in-person visits in the first month. After that, you will have 3 in-person visits over approximately the next 7 months. Depending on which group you are assigned to, you will be contacted by phone around the first month, 4 months, and 6 months after you receive your first vaccine by a member of the study team who will ask questions about your health.

The ARCT-2304 vaccine has not been tested in humans. The following are some of the most commonly observed side effects reported by participants in research studies for similar vaccines including Arcturus mRNA COVID-19 vaccine and Arcturus mRNA seasonal influenza vaccine: pain at the injection site, tenderness at the injection site, fatigue, headache, muscle ache, joint pain, chills, fever, and dizziness. Occasionally, people may experience allergic reactions to vaccines; you will be monitored for this for at least 60 minutes after your vaccination. There have been reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the sac around the heart) with COVID-19 vaccines. There is always the possibility that unknown risks and side effects may occur.

Other vaccines options may be available to you. Your study doctor, specialist, and/or primary care doctor can discuss alternate options, and any known risks related to those options.

There is no guarantee that you will receive any benefit from this research study. You may benefit from participation in this research study if the vaccination produces a protective immune response against pandemic influenza if you are subsequently exposed to the virus. Please note that there are other factors to consider before agreeing to participate in a research study such as additional procedures, use of your personal information, costs, and other possible risks not discussed in this summary. Additional information on these aspects is provided in the remainder of this document. You are free to decline or stop participation at any time during or after deciding to participate in this research study.

INTRODUCTION

You are being invited to participate in a research study because you are a healthy adult aged 18 to 80 years old who might meet the requirements for taking part in a study. Your participation in this research study is strictly voluntary. This means that you may choose whether you want to participate. This document describes the purpose of the research study, the procedures associated with participation, the possible risks and benefits associated with study participation, and alternatives to participation available to you. The process of learning about your options and the associated risks/benefits of the available options is known as informed consent.

Please take time to read the following information carefully. You may wish to discuss it with your family, friends, and/or your primary care doctor/specialist. If you have questions, at any time, you may ask your study doctor and/or a member of the research team for more information. If you decide to participate, you will be asked to sign this form. If you decide to participate, you can change your mind at any time and withdraw from the research study without giving a reason. This form may contain words that you do not understand. Please ask the study doctor and/or a member of the study team to explain the words or information that you do not understand. You will be given a copy of the consent form to take home and to keep for your records.

WHY IS THIS RESEARCH STUDY BEING DONE? WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The main purpose of this research study is to evaluate the safety and the ability to induce (create) an immune response of three different dose levels of the study vaccine, ARCT-2304, a pandemic influenza vaccine developed by Arcturus Therapeutics, Inc. A pandemic influenza vaccine is a type of vaccine developed to protect people against a specific strain of the influenza virus that has the potential to cause a global outbreak, known as a pandemic. Unlike seasonal flu vaccines, which are updated every year to protect against the most common flu strains, a pandemic vaccine targets a new or significantly different strain of the virus that most people have little to no immunity against. The purpose of this vaccine is to help prevent widespread illness and protect public health in the event of an influenza pandemic.

The ARCT-2304 vaccine (referred to as the "study vaccine" throughout this document) is an investigational vaccine. "Investigational" means that the ARCT-2304 vaccine has not been approved by the United States (US) Food and Drug Administration (FDA) as a vaccination against influenza.

The ARCT-2304 vaccine is a type of self-amplifying messenger ribonucleic acid ("sa-mRNA") vaccine to be used as a shot for prevention of an influenza infection. An mRNA vaccine helps protect you from getting sick by teaching your body how to fight a specific virus. The study vaccine contains a small piece of material called mRNA, which gives your cells instructions to make a protein that looks like part of the virus. Once your cells make this protein, your immune system recognizes it as something foreign and starts to produce antibodies. These antibodies are your body's way of learning how to defend against the virus. If you ever come into contact with the actual virus, your immune system will remember and use these antibodies to help protect you from getting sick. ARCT-2304 is a self-amplifying mRNA vaccine; "self-amplifying" means the mRNA can make copies of itself to help your body make more of the protective antibodies it needs, providing stronger and longer-lasting protection against the flu.

The ARCT-2304 vaccine includes sa-mRNA for the H5N1 influenza virus strain. The H5N1 virus is a type of flu virus that mainly affects birds but can sometimes infect people. The H5N1 virus can cause severe illness and spread quickly, so getting vaccinated could help protect you from getting sick. It could also help prevent the virus from spreading to others. We are looking to learn about the study vaccine's ability to cause an immune response (immunogenicity) by checking whether the body develops antibodies against the influenza virus.

Approximately 200 participants will be in this research study; 120 adults (18 to 59 years of age) and 80 older adults (60 to 80 years of age). Research participants in each age cohort will be divided into 4 groups (this is sometimes referred to as randomization). In groups 1, 2, and 3, the research participants will receive 2 doses of the ARCT-2304 vaccine (each group will have a different dose of the ARCT-2304 vaccine) and, in group 4, research participants will receive 2 doses of the control vaccine. Each group will be further split in two subgroups. Half of the participants in each group will receive the second dose 28 days after the first vaccination and the other half of the research participants in each group will receive the second vaccination 56 days after the first vaccination.

The control vaccine is a seasonal flu vaccine licensed in the United States. A seasonal flu vaccine is designed to protect against the flu viruses that are expected to be the most common during the flu season. For participants 18 to 59 years of age, the control vaccine administered for the first dose is Flucelvax Trivalent® and the second dose is "placebo" or inactive vaccine. Trivalent means that there are 3 strains of the influenza virus in the vaccine. In this case, the

strains are the A/H1N1, A/H3N2, and one influenza type B strain. For participants 60 to 80 years of age, the control vaccine administered for the first dose is Fluad Trivalent® and the second dose is "placebo" or inactive vaccine. The strains in this vaccine are the A/H1N1, A/H3N2, and one influenza type B strain. In the United States, the Fluad Trivalent® is approved only for individuals over 65 years of age; therefore its use in this study for participants ages 60-64 years of age is investigational.

Randomization means research participants are assigned by chance (like the flip of a coin) to one group or another. Randomization will be performed separately for each age group, 18 to 59 and 60 to 80 years of age. Within each of these age groups, there will be a "lead-in" group of 8 participants; these will be the first 8 participants to receive the ARCT-2304 vaccine or control vaccine. After the first 8 participants in each age group receive their first study vaccination, an independent Data Safety Monitoring Committee will review all of the data collected up to 7 days after the study vaccination and, if there are no safety concerns, then enrollment will be opened for the rest of the participants in each age group.

WHO IS SPONSORING THIS RESEARCH STUDY?
This research study is being sponsored and conducted by Arcturus Therapeutics, Inc. ("Arcturus"), who is also the manufacturer of the ARCT-2304 vaccine. Your study doctor has agreed to participate in this research study as a Study Doctor and will receive payments to cover some research costs such as the cost of performing tests and collecting and reporting study information.

HOW LONG WILL I BE INVOLVED IN THIS RESEARCH STUDY?
Your participation in this research study will last approximately 9 months. You will receive 2 study vaccinations, either on Days 1 and 29 (Day 1 and 29 group) or on Days 1 and 57 (Day 1 and 57 group). You will have 7 in-person study visits including a screening visit over the 9-month time period. You will also be contacted by phone on Days 120 and 180 after your first study vaccination if you are in the Day 1 and 29 group or on Days 29, 120, and 180 after your first study vaccination if you are in the Day 1 and 57 group. A member of the study team will contact you and will ask you questions about your health. If you are in one of the "lead-in" groups, you will have additional phone calls to check about your health on the second and fourth days after each of your study vaccinations (on Days 2, 4, 30, 32, 120, and 180 for the Day 1 and 29 group or Days 2, 4, 29, 58, 60, 120, and 180 for the Day 1 and 57 group).

WHAT WILL HAPPEN IN THE RESEARCH STUDY? WHAT AM I BEING ASKED TO DO?
<u>Screening/Day -28-Day 1</u>:
Before any study-related tests/procedures are performed, you will be asked to read and sign this consent document. If you agree to be in the research study and sign the consent form, the following screening tests and procedures will then be performed to evaluate your overall health and determine if you qualify to take part in this research study. Screening tests may be performed up to 28 days before the Day 1 study vaccination. The following assessments and tests will be performed:

- Height and weight
- Collection of medical history and demographics
- Physical examination
- Vital signs (blood pressure, heart rate, respiratory [breathing] rate, and body temperature)
- Pregnancy test, if applicable. If you are postmenopausal, a follicle stimulating hormone (FSH) may be checked to confirm your postmenopausal status

- Blood sample to test for viruses in your blood (Hepatitis B, Hepatitis C, and HIV). The study doctor may be required by law to report the result of these tests to the local health authority
- Blood sample for safety testing
- Electrocardiogram
- Review of medications and vaccinations

It is possible that after the results of the above tests are reviewed, you will not be able to take part in this research study. There may be other reasons why you cannot participate and, if so, your study doctor will discuss these reasons with you.

Study Treatment Period/Day 1 through Day 29 or Day 1 though Day 57
After it is determined that you are eligible (you qualify) to participate in this research study, you will receive one of the three different doses of the ARCT-2304 vaccine or the control vaccine.

You will be randomly assigned to receive one of the three different doses of ARCT-2304 or the control vaccine. Among the four different groups, you will have a 75% chance of receiving one of the three different doses of ARCT-2304 vaccine and a 25% chance of receiving control vaccine.

This is an observer-blind study, which means neither you nor the study doctor nor the study staff who are monitoring you for side effects will know to which of these study vaccine groups you have been assigned. The provider who dispenses your study vaccine (the pharmacist) and the provider who injects your study vaccine will know which study vaccine group you have been assigned.

You will have 3 in-person visits during the study treatment period on Days 1, 8, and 29 (Day 1 and 29 group) or on Days 1, 8, and 57 (Day 1 and 57 group). Depending on which group you are randomized to, you may also have a phone call on the second and fourth days after your first study vaccination (the study staff will call you to review any symptoms/side effects, medications, and vaccinations).

The following assessments and tests will be performed:

- Height and weight
- Physical examination
- Vital signs (blood pressure, heart rate, respiratory rate, and body temperature)
- Pregnancy test, if applicable
- Blood sample for immune response testing (Days 1, 8, and 29 or Days 1, 8, and 57)
- Blood sample for safety testing
- Vaccination administration (Days 1 and 29 or Days 1 and 57)
- Post-Study Vaccination safety assessment (you will stay at the study site for at least 60 minutes after each vaccination) (Days 1 and 29 or Days 1 and 57)
- Distribution of electronic diary (eDiary) and training (Day 1)
- eDiary review (only on Day 8)
- Review of symptoms and side effects
- Review of medications and vaccinations

You will receive the ARCT-2304 vaccine or the control vaccine as an intramuscular (into the muscle) injection in the deltoid muscle (shoulder) of, preferably, your non-dominant arm, using a

sterile needle. After your injection, you will be observed by study staff for at least 60 minutes for any reactions.

You will be given an eDiary to record any symptoms or side effects that you might experience after vaccination. The study staff will instruct you on how to complete the eDiary, which you will complete daily for 7 days after each study vaccination. You will be instructed on generalized symptoms and temperature monitoring. You will also be asked to check for specific types of reactions at the injection site approximately 6 hours after your study vaccination. The eDiary should then be completed at the same time each day for a total of 7 days after each study vaccine administration.

Follow-Up Period/Day 30 through Day 240 or Day 58 through Day 240
Following the study treatment period, you will enter the follow-up period, during which you will have 3 more in-person visits. You will have follow-up phone calls on days 120 and 180. Depending on which group you are assigned to, you may also have a phone call on the second and fourth days after your second study vaccination.

In-Person Visits (Days 36, 57, and 240 [Day 1 and 29 group] or Days 64, 85, and 240 [Day 1 and 57 group])

- Physical examination
- Vital signs (blood pressure, heart rate, respiratory rate, and body temperature)
- Blood sample for immune response testing (Days 36, 57, and 240 or Days 64, 85, and 240)
- Blood sample for safety testing (only on Day 36 or Day 64)
- eDiary review (only on Day 36 or Day 64)
- Review of symptoms and side effects
- Review of medications and vaccinations

Your study participation will be considered complete on Day 240 (Month 9).

Occasionally, additional visits could occur as described below.

Unscheduled Visit
"Unscheduled" (or "as needed" visits) may occur for any possible cardiac events, or to follow up on any symptoms/side effects that you may have experienced after receiving the study vaccine. Unscheduled visits could be conducted as in-person visits at the clinic or hospital, as in-home visits, or as telemedicine/telephone visits. Assessments at unscheduled visits could include:

- Physical examination
- Vital signs (blood pressure, heart rate, respiratory rate, and body temperature)
- Pregnancy test, if applicable
- Blood sample for safety testing
- Electrocardiogram, if applicable
- Review of symptoms and side effects
- Review of medications and vaccinations

Early Termination Visit
If you stop participating in this research study earlier than Day 240 (Month 9), you will be asked to complete an Early Termination Visit. Assessments at this visit could include:

- Physical examination
- Vital signs (blood pressure, heart rate, respiratory rate, and body temperature)

- Review of symptoms/side effects
- Review of medications and vaccinations

Study Tests/Procedures:
These exams, tests, and procedures are being done to evaluate your health and response to the study vaccine(s). At each of the study visits, you will be asked how you are feeling, if you have had any side effects, if you may be pregnant, if you have had any medical procedures, and about any medications you are taking and vaccinations you have received. It is important you check with your study doctor before starting any new medications. If you experience side effects, changes in your health, and/or changes in medications, please contact your study doctor or a study team member.

You will have the following tests, procedures, and assessments:

Test/Procedure	**Description**
Informed Consent	Before any study procedures, your study doctor will obtain your written informed consent to participate.
Review your medical/health history or any changes in your health since your last visit/phone call and any medications you are taking	A study doctor or designee will ask you questions regarding your health history or any changes in your health and any medications/vaccinations you are taking and/or start to take during the research study at each visit. Since females who are pregnant or breastfeeding are not allowed to participate, the study doctor will review your menstrual history and recent sexual activity to assess whether you may be pregnant, if you are a female of childbearing potential.
Physical Exam	At the Screening visit, a study doctor or designee will do a complete physical exam including your general appearance, weight and height, abdomen, head and neck, eyes, ears, nose, throat, chest, heart, liver, extremities, skin, thyroid, lymph nodes, and neurologic (brain) function. After the Screening visit, physical exams will be symptom -directed (the study doctor will examine you based on any symptoms you might be having).
Vital Signs	A study doctor will measure your blood pressure, heart rate, respiratory rate, and body temperature.
Electrocardiogram (ECG)	Several small, sticky pads will be placed on your chest, arms, and legs. In some areas, it may be necessary to shave a small spot of body hair so the adhesive patches can be properly placed on your body. A wire from each pad goes to a machine that makes an electrical recording of your heart rhythm. This test takes about 5 minutes. • This would not typically be done as a part of your standard of care treatment.
Blood Samples	Blood samples will be taken by a needle stick into a vein in your arm. The maximum amount of blood that will be taken at any single visit is approximately 70 mL (or a little less than 5 tablespoons), and the maximum amount of blood

Test/Procedure	**Description**
	taken during the research study is approximately 290 mL (a little less than 20 tablespoons). Blood will be taken for the tests described below. • This would not typically be done as part of your standard of care treatment.
Pregnancy Test	If you are a female who can get pregnant, a sample of your blood or urine will be taken to test for pregnancy. To take part in this research study, the pregnancy test must be negative. If necessary, your study doctor may also perform an additional blood test to confirm menopause. • This would not typically be done as part of your standard of care treatment.
Safety Laboratory Tests (blood)	Blood samples will be taken to check your blood counts, coagulation ("clotting" time), and the health of your organs, including your kidneys, liver, and/or heart or to follow up on any symptoms/side effects that you may have experienced after receiving the study vaccine.
Immunogenicity (immune response)	Blood will be collected on Days 1, 8, 29, 36, 57, and 240 or Days 1, 8, 57, 64, 85, and 240 to check whether you develop any antibodies or other type of immune response against the strains of the influenza virus in the study vaccine. • This would not typically be done as part of your standard of care treatment.

Study Schedule For Vaccine Administration on Days 1 and 29

Study Period	**Screening Period**	**Study Treatment Period**			**Follow-Up Period**					
Visit Type	**In-Person**	**In-Person**	**In-Person**	**In-Person**	**In-Person**	**In-Person**	**Phone Call**	**Phone Call**	**In-Person**	**Unschedul-ed**
Visit Name or Number	**Screening**	**1**	**2**	**3**	**4**	**5**	**-**	**-**	**6**	**-**
Study Day(s)	**-28 to 1**	**1**	**8**	**29**	**36**	**57**	**120**	**180**	**240***	**-**
Visit Window (Days)	**-28**	**-**	**+2**	**-1/+2**	**-1/+3**	**-3/+3**	**-7/+14**	**-7/+14**	**-7/+28**	**-**
Informed consent	X									
Height/weight	X									
Medical history (including prior medications/vaccinations) and demographics	X									
Physical examination	X	X	X	X	X	X			X	X
Vital signs	X	X	X	X	X	X			X	X
Pregnancy test, if applicable	X	X		X						X**
Electrocardiogram	X									X**
Randomization		X								
Blood sample for viruses*****	X									
Blood sample for safety labs	X	X	X	X	X					X**
Blood sample for immune response***		X	X	X	X	X			X*	
Study vaccine administration and post-vaccination observation (at least 60 minutes)		X		X						
Phone Call****			Days 2 & 4	Days 30 & 32						
eDiary training		X								
eDiary check			Day 2 (±1), Day 5 (±1)	Day 30(±1), Day 33(±1)						

Study Period	**Screening Period**	**Study Treatment Period**			**Follow-Up Period**					
Visit Type	**In-Person**	**In-Person**	**In-Person**	**In-Person**	**In-Person**	**In-Person**	**Phone Call**	**Phone Call**	**In-Person**	**Unschedul-ed**
Visit Name or Number	**Screening**	**1**	**2**	**3**	**4**	**5**	**-**	**-**	**6**	**-**
Study Day(s)	**-28 to 1**	**1**	**8**	**29**	**36**	**57**	**120**	**180**	**240***	**-**
Visit Window (Days)	**-28**	**-**	**+2**	**-1/+2**	**-1/+3**	**-3/+3**	**-7/+14**	**-7/+14**	**-7/+28**	**-**
Side effect and medication/vaccination review/data collection		X	X	X	X	X	X	X	X	X
Study completion									X	

*If you stop participating in the study at any time before Day 240, you will have all of the procedures scheduled for Day 240, with the exception of blood sample collection for immune response, and this will be considered an Early Termination visit.
**These procedures will be done if applicable. Your study doctor will decide if these are needed.
***For all participants, blood samples will be collected for the analysis of antibody-mediated immunogenicity. For a subset of participants, blood samples will be collected for analysis of cell-mediated immunogenicity.
****Additional phone calls that will be performed for the “lead-in “groups.
*****Hepatitis B, Hepatitis C, and HIV.

Study Schedule For Vaccine Administration on Days 1 and 57

Study Period	**Screening Period**	**Study Treatment Period**				**Follow-Up Period**					
Visit Type	**In-Person**	**In-Person**	**In-Person**	**Phone Call**	**In-Person**	**In-Person**	**In-Person**	**Phone Call**	**Phone Call**	**In-Person**	**Unscheduled**
Visit Name or Number	**Screening**	**1**	**2**	**-**	**3**	**4**	**5**	**-**	**-**	**6**	**-**
Study Day(s)	**-28 to 1**	**1**	**8**	**29**	**57**	**64**	**85**	**120**	**180**	**240***	**-**
Visit Window (Days)	**-28**	**-**	**+2**	**-1/+2**	**-1/+2**	**-1/±3**	**-3/+3**	**-7/+14**	**-7/+14**	**-7/+28**	**-**
Informed consent	X										
Height/weight	X										
Medical history (including prior medications/vaccination) and demographics	X										
Physical examination	X	X	X		X	X	X			X	X
Vital signs	X	X	X		X	X	X			X	X
Pregnancy test, if applicable	X	X			X						X**
Electrocardiogram	X										X**
Randomization		X									
Blood sample for viruses*****	X										
Blood sample for safety labs	X	X	X		X	X					X**
Blood sample for immune response***		X	X		X	X	X			X*	
Study vaccine administration and post-vaccination observation (at least 60 minutes)		X			X						
Phone Call****		Days 2 & 4			Days 58 & 60						

Study Period	**Screening Period**	**Study Treatment Period**				**Follow-Up Period**					
Visit Type	**In-Person**	**In-Person**	**In-Person**	**Phone Call**	**In-Person**	**In-Person**	**In-Person**	**Phone Call**	**Phone Call**	**In-Person**	**Unscheduled**
Visit Name or Number	**Screening**	**1**	**2**	**-**	**3**	**4**	**5**	**-**	**-**	**6**	**-**
Study Day(s)	**-28 to 1**	**1**	**8**	**29**	**57**	**64**	**85**	**120**	**180**	**240***	**-**
Visit Window (Days)	**-28**	**-**	**+2**	**-1/+2**	**-1/+2**	**-1/±3**	**-3/+3**	**-7/+14**	**-7/+14**	**-7/+28**	**-**
eDiary training		X									
eDiary check		Day 2 (±1), Day 5 (±1)			Day 58 (±1), Day 61 (±1)						
Side effect and medication/vaccination review/data collection	X	X	X	X	X	X	X	X	X	X	X
Study completion										X	

*If you stop participating in the study at any time before Day 240, you will have all of the procedures scheduled for Day 240, with the exception of blood sample collection for immune response, and this will be considered an Early Termination visit.
**These procedures will be done if applicable. Your study doctor will decide if these are needed.
***For all participants, blood samples will be collected for the analysis of antibody-mediated immunogenicity. For a subset of participants, blood samples will be collected for analysis of cell-mediated immunogenicity.
****Additional phone calls that will be performed for the “lead-in “groups.
*****Hepatitis B, Hepatitis C, and HIV.

WHAT ARE THE POSSIBLE RISKS? WHAT ARE THE POTENTIAL DISCOMFORTS/BAD THINGS THAT CAN HAPPEN FROM PARTICIPATING IN THIS RESEARCH STUDY?
There are possible risks or side effects that you might experience from participating in the research study. You will be monitored for the risks and side effects throughout your participation in the research study. You should contact the study doctor if you think you are having side effects or experiencing a change in your health. Possible risks and discomforts are detailed below; however, there may be other risks and side effects that are not yet known.

Study Vaccine ARCT-2304-Related Risks
The study vaccine has not been tested in humans.

However, Arcturus sa-mRNA COVID-19 vaccine and Arcturus sa-mRNA seasonal influenza vaccine, developed using a similar technology, have been administered to more than 20,000 and more than 100 research participants, respectively. Arcturus sa-mRNA vaccines have been found to be well tolerated and generally safe. You might experience side effects like those reported for the Arcturus sa-mRNA vaccines, but there may also be other risks and side effects with the ARCT-2304 vaccine that are not yet known.

The side effects listed below have been reported by research participants receiving 1 of the Arcturus sa-mRNA vaccines. These side effects are usually mild and do not last long.

Very common (occurring in more than 1 in 10 [10%] people)
- Headache
- Dizziness
- Muscle ache
- Joint pain
- Pain at the injection site
- Tenderness at the injection site
- Fatigue (tiredness)
- Chills
- Fever

Common (occurring in between 1 in 100 [1%] and 1 in 10 [10%] people)
- Diarrhea
- Nausea
- Vomiting
- Swelling at the injection site
- Redness at the injection site
- Hardness at the injection site

Uncommon (occurring in between 1 in 1000 [0.1%] and 1 in 100 [1%] people)
- Hypersensitivity (allergic reactions) including rash, urticaria (pink or red, itchy rashes), pruritus (itching), and allergic dermatitis (skin inflammation)

Please tell your study doctor if you notice any side effects, including those mentioned above or any other unusual symptoms.

<u>Potential Serious Side Effects of Currently Licensed COVID-19 Vaccines</u>
Other COVID-19 vaccines (e.g., COVID-19 mRNA vaccines) have been associated with reports of myocarditis and pericarditis. Myocarditis is an inflammation of the heart muscle

(myocardium). This inflammation can reduce the heart's ability to pump and cause rapid or irregular heart rhythms (arrhythmias). Pericarditis is swelling and irritation of the thin, sac-like tissue surrounding the heart (pericardium). Pericarditis often causes sharp chest pain. Myocarditis and pericarditis have been reported in males and females, most commonly within 7 days after a second dose of COVID-19 vaccine. These were reported mostly in adult males under the age of 40 years and in boys 12 to 17 years of age. Cases have been reported in older males and in females as well, and also following other doses.

Symptoms of myocarditis or pericarditis include chest pain; shortness of breath or feelings of a fast heartbeat; fluttering or pounding heart; swelling of the legs, ankles, and feet; light-headedness; collapse; and fatigue. Although some reported cases required hospitalization with intensive care support, available data from short-term follow-up suggest that most individuals had resolution of their symptoms with conservative management. Information is not yet available about potential long-term sequelae (consequences/effects). Also, it is not known whether the risk of myocarditis or pericarditis is increased following additional doses of currently available COVID-19 vaccines.

Participants should seek medical attention and notify study staff immediately should symptoms occur post-study vaccination. Your study doctor may refer you to a cardiologist for further evaluation and management and will also follow up with you until your symptoms and any abnormal test findings resolve. Due to this risk, blood samples will be collected to monitor the health of your heart and you will have electrocardiogram testing during the research study.

One participant (84 years old male) in an ongoing study with an Arcturus sa-mRNA COVID-19 vaccine was diagnosed with myopericarditis 30 days after receiving the last dose of study vaccine, and the event was resolving.

Potential Extremely Rare, Serious Side Effects

Severe allergic reaction: In some people, a vaccine might cause an allergic reaction. In rare cases, this allergic reaction can be very severe and lead to anaphylaxis, a condition that can cause itchy rash, throat swelling, a drop in blood pressure, and possible death. If you had an allergic reaction after being vaccinated in the past, or if you have allergies to any product in the study vaccines, you need to inform the study doctor. The study doctor will decide if you can participate in the research study.

Symptoms of an allergic reaction may include:

- A rash
- Shortness of breath or wheezing
- Sudden drop in blood pressure
- Swelling around mouth, throat, or eyes
- Fast heartbeat
- Sweating or fever
- Diarrhea or abdominal pain

You will be monitored for at least 60 minutes after your study vaccine to check for symptoms of an allergic reaction, and appropriate medical treatment will be readily available in case of an allergic reaction.

RISKS OF STUDY PROCEDURES

Test/Procedure	Risk
Electrocardiogram (ECG)	You may feel a slight discomfort when the electrodes (sticky tabs) used with the ECG machine (heart rhythm tracing device) are placed on your skin and removed. You may also have a rash or skin irritation at the place where the electrodes/sticky tabs are placed.
Blood Samples	Blood testing requires a needle stick into a vein to remove blood samples. This may cause some brief discomfort. There is a slight risk of harm to nearby nerves or later development of a local skin infection at the site of needle stick. Some known risks, although rare, related to blood drawing are pain, burning, local infection, or the development of a bruise at the place where the needle is used to draw the blood. Syncope (fainting) can occur following, or even before, any blood draws as a psychogenic (from mental stress) or vasovagal (reduced blood flow to brain) response to the needle injection. You will remain under observation after blood draw and through completion of the study visit.

REPRODUCTIVE RISKS AND CONTRACEPTIVE REQUIREMENTS

The effects of the ARCT-2304 vaccine on your fertility, including future fertility, the unborn child, and on the newborn baby are not known. Because of this, females who can become pregnant must use a highly effective method of birth control from the start of participation in this research study until at least 60 days after receiving the study vaccine. In addition, you should not breastfeed while in this research study, as the study vaccine may also affect a breastfeeding child. Participants who are pregnant and breastfeeding are not allowed to participate in this research study. A pregnancy test will be done before the study vaccine is given to anyone who can become pregnant. The study vaccine will only be given if the pregnancy test is negative.

The study doctor might do a test to measure serum follicle stimulating hormone (FSH) level to confirm menopause, if considered necessary.

If you have the potential to become pregnant, you must agree to use a highly effective form of birth control including the following during participation in this research study and for at least 60 days after you receive the last dose of the study vaccine:

- Combined (estrogen and progestogen containing) hormonal contraception associated with inhibition (prevention) of ovulation
    - Oral
    - Intravaginal
    - Transdermal (through the skin, for example, a “patch”)
- Progestogen-only hormonal contraception associated with inhibition (prevention) of ovulation
    - Oral
    - Injectable
    - Implantable
- Intrauterine device (IUD)

- Intrauterine hormone-releasing system (IUS)
- Bilateral tubal occlusion (both fallopian tubes blocked)
- Vasectomized partner
- Sexual abstinence

Your study doctor must approve your form of birth control. Ask your study doctor about the contraceptive methods that are available, and which might be best for you.

If you do become pregnant during the course of this research study, tell the study doctor immediately, and consult an obstetrician or maternal–fetal specialist. If you become pregnant while in this research study, we will ask permission to collect information about your pregnancy and the health of your child up to 12 months of age in a separate consent form. Details of pregnancies in female partners of male participants will be collected according to local regulations.

WHAT MAY HAPPEN TO MY INFORMATION AND SAMPLES COLLECTED AS PART OF THIS RESEARCH STUDY?

Collection of Identifiable Specimens

Your samples and any information and data collected in this study may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. You will not be paid for any commercial use or other use of the samples and this information, nor will you have any financial or property interest in any products or processes that result from this study.

Blood samples will be taken from you in this research study. For females able to have children, urine samples may also be collected. The samples will be collected and used for the tests as outlined in this consent form.

The maximum amount of blood collected will be approximately 290 mL (a little less than 20 tablespoons). All samples will be identified by a participant code and will not identify you. Blood samples collected for safety tests will remain at the study site and be sent for testing at a local or central when required. These samples will be destroyed after being tested or when analysis is completed.

Your samples for immune response to influenza virus testing will be sent to CTI Laboratory and may later be sent to another laboratory, Nexelis, for further processing.

Samples are required to be retained for clinical regulatory reasons to ensure scientific study results are accurate and verifiable.

If you agree, a separate sample may also be taken for future scientific research not related to this research study (limited to, research related to influenza or pandemic disease, or research to improve scientific understanding). Also, your leftover samples may be used for future scientific research not related to this study. You can state on the signature page if you agree to this or not. There is no problem if you do not agree. You can still be part of the research study.

None of your blood samples in this study will be used for genetic testing that would result in information about your future health risk.

You have the right to ask for your samples to be destroyed after study-related testing is complete. Contact your study doctor to request that your samples be destroyed. All data collected up to the point of sample destruction will be used as described in this consent form.

We may share your identifiable information with contracted laboratories, contractors and business collaborators, research institutions, and research-based commercial organizations, which may be international.

We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total confidentiality. We will protect your confidentiality during storage and sharing by de-identifying your information. "De-identifying" means that all identifiers will be removed so that identifiable information about you will not be shared with future researchers.

You will likely not directly benefit from future research with your information and samples. Research with your information and samples may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information and samples, or have changed your mind, you can contact the study doctor using the information listed on the first page of this form. If you change your mind, your samples will not be used for further research, but they may still be used in any ongoing research (or research that has already been started).

WHAT ARE THE POTENTIAL BENEFITS? WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM PARTICIPATION IN THIS RESEARCH STUDY?
Taking part in this research study may or may not make your health better. However, your participation may add to the medical knowledge about the use of the ARCT-2304 vaccine in the event of an influenza pandemic.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE? WHAT OTHER ALTERNATIVE CHOICES ARE THERE?
You do not have to be in this study to receive an influenza vaccine. Your medical care will not be affected if you decide not to participate in this research study.

Other possible options include:

- Receiving an approved influenza vaccine outside of a study
- Taking part in another research study if one is available

Talk to your study doctor about your choices before you decide if you will take part in this research study.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH STUDY?
During this research study, we may find more information that could be important to you (such as new information about how the drug works or newly discovered side effects). If we discover new information about the study that could affect your decision to stay in the study, you will be notified in a timely manner. You will be able to ask questions about this new information and can discuss it with your family, friends, or primary care doctor.

WILL I BE PAID TO BE IN THE RESEARCH STUDY?
«Compensation»

If you complete all study visits and phone calls you will receive up to [$XXX]. If you withdraw from the research study before it is completed, you will receive [$XXX] for each of the visits you completed and [$XXX] for each of the phone calls you completed. A completed visit or phone call means all scheduled study procedures have been carried out.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***[“following each completed visit”, “monthly”, “quarterly”, “at the end of your participation in the research study”, “following each completed visit or at the end of your participation in the research study, whichever you prefer”]***.

If you have any questions regarding your compensation for participation, please contact the study staff.

Reimbursement compensates for your time, travel expenses, parking and inconvenience. This reimbursement is not made for undergoing risk nor is it to compensate you for any loss of earnings as a result of your participation.

You will be reimbursed for your time and travel via [XXX]. You will be reimbursed approximately [e.g., 2 weeks, one month, etc.] after you submit your travel receipts to the study staff.

Please note: In order to be compensated for your participation in this research study, you must provide your Social Security Number. Your Social Security Number will not be provided to study Sponsor and only kept at the site. Additionally, please note that the study center is required to report to the Internal Revenue Service (IRS) any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

If you have any questions regarding your compensation for participation, please contact the study staff.

WILL I HAVE TO PAY FOR ANYTHING? WILL IT COST ME ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?
All medication, tests and medical care required as part of the study will be provided to you at no of charge. Arcturus will supply the study vaccine, ARCT-2304, and the control vaccine at no charge while you take part in this research study.

There will be no charge to you for those laboratory tests and other procedures that are being done specifically for the purposes of this research study. If you are injured as a result of participating in this research study, Arcturus will reimburse the study center for the costs of providing necessary medical treatment. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for any injury that is not included in what Arcturus has agreed to cover. This is discussed further below in the “What Happens if I Am Injured From Being in the Research Study?” section below.

WHEN IS THE RESEARCH STUDY OVER? CAN I LEAVE THE RESEARCH STUDY BEFORE IT ENDS? WHAT IF I WANT TO STOP PARTICIPATING?

Your decision to participate is entirely voluntary. You may refuse to participate or withdraw from the research study, at any time, without penalty or loss of benefits to which you are otherwise entitled. Your ongoing medical care will not be affected by your decision to be in this research study or to withdraw from the research study. If you decide to withdraw from the research study, please talk to your study doctor to make sure this is done safely. Any data or information collected prior to your withdrawal will be retained by the study Sponsor. The study doctor may ask you to have some end-of-study tests for your safety, if needed.

Your participation may be stopped without your consent by the study Sponsor, study doctor, or the FDA for any reason. For example, your participation may be stopped:

- If it is deemed to be in the best interest of your health and welfare
- If you have not followed the research study instructions and/or directions communicated by the study doctor/study team
- If you become pregnant
- If the study Sponsor, the study doctor, or the FDA has decided to stop the research study due to new information or regarding study vaccine side effects
- For any other reason that is not known at this time

If you are removed from the research study, your study doctor will explain to you the reason(s) why you were removed. The study doctor and study team will help arrange for your continued care outside of the research study.

WHAT HAPPENS IF I AM INJURED FROM BEING IN THE RESEARCH STUDY?

If you have a medical emergency during your participation in this research study, you should go to the nearest emergency room. If you think you have been injured because of taking part in this research study, you should contact the Study Doctor or Emergency contact listed on page 1 of this form as soon as possible. You may also contact your own primary care doctor or seek treatment outside of the study center. Be sure to tell the treating doctor or his/her staff that you are in a research study being conducted at this study center. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

The study center may also offer you the care needed to treat side effects and/or injuries that occur while you are taking part in this research. If you experience a research-related injury, you will be compensated according to local law. A “research-related injury” means physical illness or injury caused by the study vaccine or procedures required by the study and does not include the following side effects or injuries that:

(i) Are a result of an underlying disease or a pre-existing medical condition;
(ii) Are a result of any treatment for an underlying disease or medical condition that is standard of care for such disease or condition; or
(iii) Are caused by the study center’s negligence or willful misconduct.

We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for any injury that is not included in what Arcturus has agreed to cover. You may also be responsible for some of these costs. There are no plans for the study center or Arcturus to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

You may receive bills for side effects/injuries that occur during your participation in this research study, even if they may be covered by Arcturus. If you have questions about these bills and whether or not they are covered by the research study, please bring copies of these bills to a member of the study team and they will be able to answer your questions.

To pay medical expenses, the study Sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the study Sponsor has to check to see if you receive Medicare and, if you do, report the payment it makes to Medicare.

HOW WILL MY INFORMATION BE KEPT PRIVATE?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive healthcare information from being disclosed without the consent or knowledge of the participant. Because your participation in research requires the study team to collect, use, and disclose your healthcare information, this additional information is provided to you to describe the potential uses and the protections in place to secure your information.

As a part of this research, records that contain information or data about you and your health may be collected and used. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available; however, absolute confidentiality cannot be guaranteed. Your personal information may be given out if required by law.

You will be assigned a unique research participant registration number upon enrollment. This number will be used to identify you throughout the course of the research study so that your identity is protected. The key to this code (which links your name back to the personal health information collected during this study) will be stored in a secure area and only the study team will have access to this code. If you have questions about the specific information that will be released, you should ask your study doctor.

WHY IS MY HEALTH INFORMATION BEING USED?

Your personal contact information is important for the study team to contact you during the research study. For this research study, we may need to contact you via email to provide you information about scheduling and appointment notes, or to send you information about your participation in the research study. Email communications are often not secure and may be seen by others as a result. By signing this informed consent form, you

accept the risk. Please inform a member of the study team if you do not wish to be contacted by email. Other health information and results of tests and procedures, as noted above, are used to:

- Do the research
- Oversee the research
- To see if the research was done right

WHO CAN SEE OR USE MY INFORMATION?

The following individuals may use or share your information for this research study:

- The study doctor and the study team
- Authorized members of the workforce of the study center support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide care as part of this research study or as part of your routine care, to manage accounting or billing matters, etc.). This includes members of the Institutional Review Board (IRB), an ethics committee responsible for reviewing and overseeing research studies to ensure that they are safe and being well managed
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB
- The FDA
- The Data Safety Monitoring Board
- The Cardiac Safety Committee
- Sponsor and its representatives and contractors

WHO, OUTSIDE OF THE STUDY CENTER, MIGHT RECEIVE MY INFORMATION?

As part of the research study, the study doctor, the study team, and others listed above may disclose your study-related records, including the results of the research study tests and procedures. This study data may be processed and transmitted using secure computer systems. In all disclosures outside of the study center, you will not be identified by name, medical record number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. In records and information disclosed outside of the study center, you will be assigned a unique code number.

Your original medical records also may be reviewed by the study Sponsor or its designated representatives, the IRB overseeing this research study, and any regulatory or safety oversight organizations, like the FDA, or other agencies. They may review these records to check data collected for the research study, to ensure it is being done properly, and to analyze the results.

Once your personal health information is disclosed to others outside of the study center, it may no longer be covered by federal privacy protection regulations.

The study doctor or study staff will inform you if there are any additions to those who can see or use your information during your active participation in the research study. Any additions will be subject to procedures developed to protect your privacy.

If you sign this document, you give authorization to the research study's Sponsor, Arcturus, or their designee that has been contracted to help in the conduct of the research study and the review of your data, to view your data and medical records remotely. This review may occur outside of the study center in a manner that protects the confidentiality of your data. In preparing copies captured in an electronic database or paper copies of your medical records for remote review by the monitor, the study center staff will de-identify the records, removing any directly identifiable information, such as your name and full date of birth. The records will only be identifiable using the participant number assigned to you by the study center.

WHAT INFORMATION ABOUT ME MAY BE COLLECTED, USED OR SHARED WITH OTHERS?

The following personal health information may be collected and used for the purposes of this study.

- Name, address, email address, telephone number, gender, date of birth
- Information about other medical conditions that may affect your care
- Medical data
- Information on side effects (adverse events) you may have experienced, and how these were treated

- Long-term information about your general health status; this may include information from other healthcare providers
- Numbers or codes that will identify you, such as your medical record number
- Information related to study visits and other tests/procedures performed while you are participating in this research study

The results of the research study, including your de-identified information, may also be presented at meetings or in articles written about the research study (publications). If the results of the research study (including your research or health information) are published or used/transferred overseas, your identity will remain confidential. If your information is used/transferred overseas, it will no longer be covered by federal privacy protection regulations.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

HOW LONG MAY THE STUDY CENTER USE OR DISCLOSE MY PERSONAL HEALTH INFORMATION?

Your authorization for use of your personal health information for this specific study does not expire. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign this authorization document.

Your information may be held in a research database. However, the study center may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The IRB grants permission
- As permitted by law

CAN I CHANGE MY MIND ABOUT GIVING PERMISSION FOR USE OF MY INFORMATION?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor for the research study at the address listed on the first

page of this form. If you withdraw your permission, you will not be able to stay in this research study. If you withdraw your permission, the Sponsor may keep and continue to use any data collected before your consent is/was withdrawn.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY HEALTH INFORMATION?

Then you will not be able to be in this research study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Printed Name of Research Participant

_____

Signature of Research Participant Indicating Authorization Date

WILL I RECEIVE THE RESULTS OF RESEARCH TESTING?

Clinically relevant results from clinical testing will be disclosed to you; this will be done in the context of discussion with your study doctor and/or clinical treatment team. Results from clinical testing done as part of this research will be placed in your medical record. Results placed in the medical record will be available to you per HIPAA regulations, as noted above.

You have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor’s or study site’s decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00082006.

OPTIONAL CONSENT FOR USE OF SAMPLES

Please indicate whether you agree (Yes) or do not agree (No) to your samples being used in future scientific research not related to this research study. This is optional and you do not have to agree to this to take part in the rest of the research study.

_____ Yes, I agree to the use of my samples for research related to vaccine or pandemic disease purposes as described in the relevant section of the Research Participant Informed Consent Form.

_____ No, I do not agree to the use of my samples for research purposes as described in the relevant section of the Research Participant Informed Consent Form.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

RESEARCH PARTICIPANT STATEMENT

I have read the information in this combined informed consent document. I have had an opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily agree to participate as outlined in this research study until I decide otherwise. I agree that if I decide to withdraw and leave the study, the information and data collected about me up to the point when I withdraw may continue to be used.

I do not give up any of my legal rights by signing this document. I will receive a copy of this signed and dated document.

By signing this document, I agree to take part in this research study.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date