INFORMATION SHEET AND CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

Part B: Drug-drug Interaction (Dabigatran)

TITLE: A Phase 1 Study to Evaluate Relative Bioavailability and Food Effect of an ALG-097558 Tablet Formulation and the Drug-Drug Interaction Potential of ALG-097558 and its metabolite ALG-097730 in Healthy Volunteers

PROTOCOL NO.: 24-0026
WCG IRB Protocol #20251162

SPONSOR: Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID)

INVESTIGATOR: Steven G. Hull, MD, FCCP, FAASM
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STUDY RELATED PHONE NUMBER(S): 913-333-3000 (24 hours)

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

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

RESEARCH CONSENT SUMMARY

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

Key information:

Why is this study being done?	You are being asked to take part in this study because we would like to compare the pharmacokinetics (PK) of the study drug ALG-097558 – how the study drug is taken up, moved around the body, and broken down – in healthy volunteers. ALG-097558 is being developed by Sponsor, for the potential treatment of coronavirus disease 2019 (COVID-19), which is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. You are being asked to participate in Part B of the study to see how ALG-097558 affects the PK of dabigatran (a drug used to treat and prevent blood clots, reducing the risk of stroke). The study is voluntary – it is your choice to participate in it or not.
Who is being asked to take part in this study?	You are being asked to take part in this research study because you are considered a healthy adult and have expressed an interest in participating in clinical research. About 24 adults, 18 to 65 years of age will be in Part B of this study. This study will be run at 1 research site in the United States.
How long will you have to be in this study?	If you qualify and decide to participate in the research study, your participation in the study will last for about 44 days. There will be an in-house period in the clinical research site lasting 9 days and 8 nights and then a follow-up visit.

What will happen to you during this study?	Procedures will include collection of health information, taking dabigatran (1 capsule) on Days 1 and 5, and taking ALG-097558 (6 tablets) every 12 hours on Days 4 and 5 (for a total of 18 tablets). You will take ALG-097558 and dabigatran before eating. Blood samples will be collected. You will be followed for about 10 days after administration of the last dose of study drug. Study staff will closely monitor your health and perform various safety tests while you are in the clinical research site, such as taking your vital signs, physical examinations, safety laboratory tests, and an electrocardiogram (ECG; measurement of the electrical activity of your heart). The complete list of procedures can be found later in the form.
What are the risks for being in this study?	There are risks from participating. ➢ The most common risks with the study drug ALG-097558 are headache, diarrhea, low hemoglobin, and bruising or soreness from blood collections, and pain or discomfort associated with insertion of intravenous (in a vein [IV]) catheter. ➢ The most common risks with the dabigatran are nausea, upper abdominal pain, diarrhea, and bleeding. ➢ See the "**What are the potential risks and discomforts?**" section in this consent form for more information. You should discuss these risks in detail with the study staff. ➢ There is a risk of loss of confidentiality of your health information. The complete list of risks can be found later in the form. For your safety, you should be honest about your health, lifestyle, and medication history.

Will blood be taken during this study?	During this study, blood samples will be collected from you. The total amount of blood drawn during the study will be approximately 218 mL (about 1 cup). Additional blood samples may need to be taken to monitor your health if the study staff finds it necessary. You will have blood drawn from a vein using either single needle sticks or through an IV catheter. An IV catheter is a small plastic tube that is temporarily inserted into your vein with a needle to make it easier for multiple blood samples to be taken without having a needle stick each time. This would add approximately 1 mL (about 1/5 of a teaspoon) of blood that will be discarded prior to any blood samples taken from a catheter. You may have an IV catheter in place for several hours during each day. Risks associated with having blood samples taken during the study may include the following: • Lightheadedness, dizziness, or fainting • Redness, pain, swelling, and/or infection at the site of the blood draw • Bruising • Bleeding • Low hemoglobin levels • Infection • Blood clots, which may cause inflammation, swelling, or pain
Will being in this study benefit you?	This study is for research purposes and is not intended to treat any symptoms or illness. Therefore, there will be no direct benefit to you for being in this study. By taking part in this study, you may be helping others by providing important information about the study products and by contributing to scientific knowledge.
What alternatives do you have to being in this study?	No therapeutic or other health benefits will result from participating in this study, so your only alternative is to not participate in this study.
Will you be paid for being in this study?	If you complete the screening process for this study, you may receive up to $250.00. If you qualify and decide to participate in the research study, follow all study requirements and clinical research site rules, and complete all required study visits, you may be compensated up to $5,500.00.

Future research use of blood samples	As part of this study, we would like to store your coded information and leftover samples for **future research** (that is, research that is not planned yet). If you agree for your information and leftover samples to be used for future research, you will be asked to sign an additional consent for future use of your leftover samples below. More study details are below. Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. They can explain words or information that you do not understand.

End of Key Information

INFORMATION ABOUT THIS STUDY

You are being asked to be in a research study. A person who takes part in a research study is called a research subject, volunteer, or participant. A research study is a scientific way to investigate, improve, or develop new drugs or products. Research studies are designed to answer specific questions about how certain drugs and products can be used and the effect they have on the human body. This form tells you about this study. Please read this form with care and ask the study doctor or study staff all your questions. You might find it helpful to discuss it with your family, friends, or healthcare team. When you understand what is in this form, you will be asked to sign and date it to join this study. You will receive a copy of the signed and dated form.

Taking part in this study is voluntary. This means that you can choose if you want to take part in the study. You can leave the study at any time, without giving any reason. If you choose to leave the study early, we will ask that you complete an end of study visit to collect samples for your safety. Doing so will not change your health care or your rights. If you do not want to join the study, you can talk to the study doctor about your health care.

This study is receiving funding from the National Institutes of Health (NIH).
Aligos Therapeutics, Inc. is the drug company that will supply the drug. The study doctor is paid from funding coming from NIH.

An institutional review board (IRB) has reviewed this study to help ensure that your rights and welfare are protected after you join this study. This committee will watch over this study, in accordance with regulations, while you are in it.

Why is this study being done?
This study is being done to compare the PK of the study drug ALG-097558 – how the study drug is taken up, moved around the body, and broken down – in healthy volunteers. You are being asked to participate in Part B of the study to see how ALG-097558 affects the PK of dabigatran

(a drug that is typically used to treat and prevent blood clots, reducing the risk of stroke). The combination of dabigatran with ALG-097558 is considered investigational.

About 24 adults, 18 to 65 years of age will be in Part B of this study. This study will be run at 1 clinical research site in the United States.

ALG-097558 is an investigational medicine. An investigational medicine means the medicine has not been approved by the health authorities for use by the general public. ALG-097558 is being developed by Aligos Therapeutics and funded by the Sponsor, for the potential treatment of COVID-19, which is caused by the SARS-CoV-2 virus. ALG-097558 works by blocking a specific enzyme (type of protein) called 3CLpro that the virus needs to make copies of itself (replicate) and spread in the body.

The information from this study will help Sponsor decide if there are certain drugs that cannot be taken with ALG-097558.

From this point onwards, any references to the word "study drug" will mean ALG-097558.

What should you know about this study?

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

What will happen during the study?

You will be in the study for up to 44 days. You will be asked to visit the clinical research site approximately 3 times, with 1 of those visits requiring you to stay overnight for 8 nights.

The study is divided into the following parts or periods: Screening, Dosing, and Follow-up. A general overview of each study period is provided here.

Screening Period (up to 28 days prior to the first dose of the study drug): If you want to volunteer for this study, your study doctor will first check if you can take part in this study. This is called screening. Screening tests can be done anytime within 28 days before you get the first dose of the study drug. During this visit, the study doctor will perform several tests and exams to check your overall health. These will include taking blood and urine samples to check overall health, drug and alcohol screening, blood pregnancy test, follicle-stimulating hormone test (a hormonal test to confirm postmenopausal status), reviewing your medical and surgical history, conducting a complete physical examination, performing an ECG (a test that checks the electrical activity of your heart), and monitoring your vital signs (such as breathing rate, blood pressure, heart rate, and oral [by mouth] temperature).

During Check-In (Day -1) for your overnight stay, your study doctor will do some tests and health checks to confirm that you are fit for this study and can get study drug on Day 1. These will include taking blood and urine samples to check overall health, drug and alcohol screening, urine pregnancy test, reviewing your medical and surgical history, conducting a physical examination based on symptoms, performing an ECG, and monitoring your vital signs. If you have positive urine pregnancy test result, a blood pregnancy test will be performed to confirm it. You will be asked to stay at the clinical research site for at least 8 nights.

Dosing Period (Day 1 to Day 5): On Day 1, you will take dabigatran as 1 capsule. On Days 4 and 5, you will take the study drug as 6 tablets per dose (every 12 hours) for a total of 3 doses or 18 tablets. On Day 5, in addition to the study drug, you will take dabigatran as 1 capsule. All medicine will be taken with about 240 mL of water (about 1 cup).

Each study drug tablet will have 100 mg of the study drug. You must not eat or drink anything except water for at least 10 hours before taking the study drug and at least 4 hours after receiving the study drug. Except as part of dosing, you may drink as much water as you like, except during 1 hour before and 1 hour after you take the study drug.

On Days -1 through 7, you will be asked to stay at the clinical research site so the study doctor can collect blood samples for PK, review your medications, and check if you have any changes in your health. Pharmacokinetics shows how drugs move through and are removed by your body after you take the drug (study drug and/or dabigatran).

In Part B, three participants will be dosed first for an early safety assessment. The safety review team will evaluate the safety and tolerability data of these three participants. If there are no safety concerns, the remaining participants will only be dosed if the safety review team determines that it is appropriate to proceed.

On Check-out (Day 8), your study doctor will do various tests and health checks which are described below. Once these tests and health checks are complete, you will be discharged and can leave the clinical research site. If you have any side effects, you may be asked to stay at the clinical research site until the study doctor determines it is safe for you to leave. When you are discharged, you'll be given the date and time for your Follow-up Visit.

Follow-up Period (Day 15, about 10 days after your last dose): About 10 days after your last dose of study drug, you will be asked to return to the clinical research site for a Follow-up Visit. At this visit, you will be asked to have a final health exam, ECG, vital signs, and lab tests performed.

Below are the descriptions of study tests detailing what happens at each visit.

Procedures and Assessments
During the study, you will receive the tests and procedures specified in the following sections. The study staff might also ask you to repeat tests and procedures or receive additional tests and procedures if they consider that this is necessary for your health and safety or for study-related purposes.

You will be asked to read, sign, and date this form before you have any study tests or exams. The following tests and exams will be done during the study:

- **Demographics:** The study staff will ask questions about you, including your age, date of birth, sex, race, and ethnicity.
- **Medical History:** The study staff will review your family, medical, and surgical history, including any existing illness, planned surgeries, and previous and current medications including any vaccinations.
- **Physical Examination:** The study staff will do a complete physical examination to check your overall health both at Screening and at the Follow-up Visit. In addition, a physical examination that focuses on any symptoms you may have will be done as needed throughout the study.
- **Height and Weight:** Your height (at Screening only) and weight will be measured at Screening and Follow-up Visit.
- **Vital Signs:** Your vital signs including your oral temperature, breathing rate, blood pressure, and heart rate will be measured after you have rested lying down or in a semi-reclined position (a posture where the body is partially reclined or tilted back, but not fully lying down flat) for 5 minutes. Your vital signs will be measured before and after you take the study drug. Vital signs will be collected at Screening and Check-In, on Days 1 through 8, and at your Follow-up Visit. On Study Days 1 and 5, you will be asked to have your vital signs measured just before you get the study drug and 1, 2, and 4 hours afterwards.
- **Electrocardiogram:** The study staff will do this test to measure your heart's rhythm. Before having an ECG, you will be asked to rest for at least 5 minutes. You will be asked to have sticky patches put on your skin that are connected by thin wires to a machine that records your heart rate and rhythm. You will be asked to have ECGs at Screening and Check-In, on Days 1, 3, 5, 8, and at your Follow-up Visit. On Study Days 1 and 5, you will be asked to have ECGs just before you get the study drug and 1, 2, and 4 hours afterwards. Electrocardiograms may be repeated in certain situations as your study doctor determines.
- **Stay at Clinical Research Site Overnight:** You will be asked to stay at the clinical research site for 8 nights. During this time, you will be asked to have tests and exams, take the study drug, and be closely watched by the study staff.

- **Blood Sample Collections:** You will have blood drawn from a vein using either single needle -sticks or through an IV catheter. An IV catheter is a small plastic tube that is temporarily inserted into your vein with a needle to make it easier for multiple blood samples to be taken without having a needle stick each time. The total amount of blood collected from you during the study will be approximately 15 tablespoons (218 mL).
- **Health Checks:** The following blood tests will be performed on the blood collected (above) to check your overall health including:
    - To count the number of white and red blood cells and platelets (cells that help your blood clot); to check how long it takes for your blood to clot; measure the levels of certain proteins, vitamins, iron, and minerals (electrolytes). These tests will be done at Screening and Check-In, on Days 3, 8, and your Follow-up Visit.
    - Test for hepatitis A, B, C, E, and HIV: These tests will be done at the Screening Visit. If the results show that you have HIV, or hepatitis, you will be told this privately and be given information about medical follow-up. Positive results for certain infectious diseases like HIV and hepatitis will be reported to the local health authorities, as required by law. You can still take part in this study if you have had hepatitis C, been treated, and maintained a response below detection for ≥ 6 months; your study doctor will tell you more about this.
- **Blood Samples for PK Analysis**. Blood samples will also be collected for PK analysis. You can find more details about the days when the blood will be collected and the timing of each collection in the next section of this form.
- **Pregnancy Tests:** People who can get pregnant will have a blood pregnancy test at Screening and a urine pregnancy test at the Check-In Visit and Follow-up Visit. Additional urine pregnancy tests may be done as needed, at the discretion of the study doctor. Positive urine pregnancy results will be confirmed by a blood pregnancy test.
- **Follicle-Stimulating Hormone:** This will be checked only at the Screening Visit if you are female and haven't had a period in over 1 year to confirm that you are postmenopausal.
- **Health and Medications:** You will be asked about your health and any medications you are taking at the Screening Visit. At other visits, you will be asked if you have changed any of your medications, started taking new medications (including supplements) or had a vaccination since you started the study.
- **Changes in Your Health:** At each study visit, you will be asked about how you are feeling or whether you have had any changes in your health. Tell the study doctor immediately if you have any reaction or side effect.
- **Alcohol, Smoking, and Drug Tests:** You will be asked to collect urine during the Screening Visit and Day -1 Visit (Check-In Visit). Your urine will be tested for alcohol, cotinine, methadone, amphetamine, barbiturates, cocaine, opiates, benzodiazepines, and cannabinoids.

PROCEDURES BY STUDY DAY

Screening Visit (Day -28 to Day -2):
You will be asked to fast (no food or drink other than water) for at least 10 hours before these tests and procedures will be performed to ensure accurate test results. You will be given an identification wristband to wear during your visit to the clinical research site.

The Screening Visit will include the following tests and procedures:

- You will be asked about your demographic information.
- You will be asked about your medical history including any surgical procedures you have had, and your history of recreational drug use, as well as alcohol, caffeine, and tobacco use.
- You will be asked about any prior (up to 30 days prior to Screening) and/or current medications you are taking, including prescription medication, over-the-counter medication, vitamins, and supplements. If female, birth control history will also be checked.
- Your study doctor will talk with you about the birth control methods that you are required to follow during the study to avoid pregnancy
- A complete physical examination
- Vital signs will be collected.
- Height and weight
- Body mass index (BMI) will be calculated – this is a measure of your weight in relation to your height.
- ECG will be performed.
- Blood and urine samples for laboratory tests
- Urine drug screen*
- Urine cotinine test (amount of nicotine in your body)*
- Urine alcohol test*
- Blood test for human immunodeficiency virus (HIV) and Hepatitis A, B, C, and E*
- Blood pregnancy test for females who can get pregnant*
- Blood test for post-menopausal females to confirm post-menopausal status

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

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

Clinical Research Site Check-In/Admission Day -1

You will be required to fast (no food or drink other than water) for at least 10 hours before the Check-In Visit.

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

You will be required to stay at the clinical research site for 9 days and 8 nights. All meals, snacks, and drinks will be provided to you during your stay at the clinical research site, but you will only be allowed to eat the food and drinks during the scheduled mealtimes. You will be allowed to drink water as needed unless specific restrictions are required. You will be informed of any specific water restrictions during the study.

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

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

- You will be asked about any changes to your health, medical history, and medication use since your Screening Visit.
- A symptom-directed physical examination
- Vital signs will be collected.
- ECG will be performed.
- Blood and urine samples for laboratory tests
- Urine drug screen*
- Urine cotinine test (amount of nicotine in your body)*
- Urine alcohol test*
- Urine pregnancy test for females who can get pregnant*

*These tests must be negative for you to participate in this study. Positive urine pregnancy results will be confirmed by a blood pregnancy test.

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

Check-In Controlled Search:

To ensure that the clinical research site remains pleasant for all involved, we may ask that study volunteers change into a gown. This helps to ensure that no prohibited items are brought into the clinical research site. You will be provided with a list of all prohibited items, which you can refer to avoid bringing items that are not allowed at the clinical research site.

You will be asked to step into the dressing room, remove all clothing (including undergarments), and change into a gown. Once you have done so, study staff will verify the absence of prohibited

items. Your bags and possessions will also be checked for prohibited items. Upon completion, you will change into your undergarments and scrubs. Any prohibited items will be placed in your locker to be retrieved upon discharge. We appreciate your understanding and cooperation in this process.

Dosing Period Day 1

Before you receive the first dose of dabigatran, the following tests and procedures will be performed:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken.
- Vital signs will be collected.
- ECG will be performed.
- A blood sample will be collected for dabigatran PK testing.

Dabigatran will then be administered with approximately 240 mL (1 cup) of room temperature water. Your mouth and hands will be inspected to verify the dosing is completed.

After receiving the dabigatran, the following procedures will be performed:

- A symptom-directed physical examination will be performed 1 time.
- Vital signs will be collected at different times as per protocol requirement.
- ECG will be performed at different times as per protocol requirement.
- Blood samples will be collected for dabigatran PK testing at different times as per protocol requirement.

Dosing Period Days 2 and 3

You will be required to fast (no food or drink other than water) for at least 10 hours before the procedures on Day 3 only.

The following tests and procedures will be performed:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken.
- A symptom-directed physical examination
- Vital signs will be collected.
- ECG will be performed (Day 3 only).
- Blood and urine samples for laboratory tests (Day 3 only)
- Blood samples will be collected for dabigatran PK testing 2 times on Day 2 and 1 time on Day 3.

Dosing Period Day 4

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

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken.

- Vital signs will be collected.
- A symptom-directed physical examination
- A blood sample will be collected for dabigatran PK testing.

Study drug will then be administered with approximately 240 mL (1 cup) of room temperature water. Your mouth and hands will be inspected to verify the dosing is completed.

You will not be allowed to have water at least 1 hour before until at least 1 hour after you receive the study drug.

Dosing Period Day 5

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

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken.
- Vital signs will be collected.
- ECG will be performed.
- A blood sample will be collected for study drug PK testing.
- A blood sample will be collected for dabigatran PK testing.

Study drug and dabigatran will then be administered with approximately 240 mL (1 cup) of room temperature water. Your mouth and hands will be inspected to verify the dosing is completed.

You will not be allowed to have water at least 1 hour before until at least 1 hour after you receive the study drug and dabigatran.

After receiving the study drug and dabigatran, the following procedures will be performed:

- A symptom-directed physical examination will be performed 1 time.
- Vital signs will be collected at different times as per protocol requirement.
- ECG will be performed at different times as per protocol requirement.
- Blood samples will be collected for study drug PK testing at different times as per protocol requirement.
- Blood samples will be collected for dabigatran PK testing at different times as per protocol requirement.

Dosing Period Days 6 and 7

The following tests and procedures will be performed:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken.
- A symptom-directed physical examination
- Vital signs will be collected.

- A blood sample will be collected for study drug PK testing (Day 6 only).
- Blood samples will be collected for dabigatran PK testing 2 times on Day 6 and 1 time on Day 7.

Discharge Day 8

You will be required to fast (no food or drink other than water) for at least 10 hours before the discharge procedures.

The following tests and procedures will be performed:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken.
- A symptom-directed physical examination
- Vital signs will be collected.
- ECG will be performed.
- Blood and urine samples for laboratory tests
- A blood sample will be collected for dabigatran PK testing.

Following the Day 8 test and procedures, you will be discharged from the clinical research site if the study doctor determines it is medically acceptable for you to leave. You will be informed by the study staff when you will be required to return to the clinical research site for your Follow-up Visit.

Follow-up Visit Day 15

You will be required to fast (no food or drink other than water) for at least 10 hours before the Follow-up Visit.

You will report to the clinical research site for your Follow-up Visit on Day 15. You will be given an identification wristband to wear during each visit to the research site.

The following tests and procedures will be performed:

- You will be asked by study staff about how you are feeling, any changes in your health, and any medications you may have taken.
- A complete physical examination
- Vital signs will be collected.
- ECG will be performed.
- Blood and urine samples for laboratory tests
- Urine pregnancy test for females who can get pregnant. Positive urine pregnancy results will be confirmed by a blood pregnancy test.

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

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

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

WHAT HAPPENS TO THE SAMPLES COLLECTED FROM YOU?
Blood and urine samples will be collected from you in this study. Your samples will be sent to a local laboratory (Dr. Vince Clinical Research, 7401 W. 91st Street, Overland Park, KS 66212) and PK samples will be sent to a PK analysis laboratory (Syneos Health, 301A College Road East, Princeton, New Jersey 08540) for testing. Your samples will only be identified by a code and will not show who you are. After the study tests are completed, some of your samples may be stored, for up to 15 years, in case any samples need to be re-tested. After this time, your samples will be stored unless you do not agree to this future use. If you do not agree the samples will be destroyed unless you allow the use of your leftover samples for future research by signing where indicated. Anyone who works with your samples will keep your coded samples and the results private.

During and after the study, you will keep the right to have your samples destroyed if you contact your study doctor, as long as your samples are still coded and can be found. If you leave the study, your samples may not be destroyed. If you want your samples to be destroyed, you will have to ask your study doctor. All the samples and test data collected before you left the study will still be used for study purposes. After you leave this study, no new samples or test data will be collected from you for the study.

Sponsor would like to know if you allow the use of any of your leftover samples for future research. This means that your samples may be tested to:

- Learn more about the effects of the study drug on COVID-19
- Understand more about the study drug and how your body responds to the study drug
- Understand more about COVID-19
- Develop new tests or assays related to the study drug and COVID-19.

Sponsor would like you to allow them to use your leftover blood samples for future research that may help understand more about the study drug or COVID-19:

☐ Yes, I agree to have my leftover blood sample(s) used for future research related to the study drug or COVID-19.

☐ No, I do not agree to have my leftover blood sample(s) used for future research related to the study drug or COVID-19.

Printed Name of Volunteer, in full

Signature of Volunteer **Date (dd-Mmm-yyyy)**

WHAT IS EXPECTED FROM YOU?

While you are in the study you must:

- Follow the instructions of the study doctor and the study team because it is important for your own safety.
- Commit to the time required to attend all study visits described above.
- Not take any other drugs or remedies unless the study doctor has allowed them first. This includes prescription and over-the-counter drugs (including vitamins and herbs).
- Not participate in any other research study that involves taking another study drug during this study or within 4 weeks of starting this study.
- Tell the study doctor about any new treatments or drugs you take during the study.
- Give correct and honest information about your health history and current health.
- Tell the study doctor about any health problems you have during the study.
- Complete all scheduled visits required for the study.
- Complete all unscheduled visits if needed for follow-up on your health and to monitor your safety.
- Follow all rules of the clinical research site.
- If you become pregnant, or you get your partner pregnant, tell your study doctor as soon as you know (for additional information, please see section on “Are there any reproductive risks?” below).
- Agree to not post or discuss the study on social media.
- Be in touch with your study doctor or study staff and tell them if you have a change in your contact details or if you no longer wish to be in the study.
- Discuss with the study doctor before getting any vaccine, including a COVID-19 vaccine.
- During the study and for at least 90 days after your last dose of the study drug, you should not donate eggs or sperm.
- Starting at least 56 days before the Screening, you should not donate blood or plasma.

- From at least 7 days before the Screening Visit and until your Follow-up Visit, you should not smoke or use any tobacco or nicotine containing products (chewed or smoked).
- From at least 30 days before the Screening Visit and until your Follow-up Visit, you should not participate in another research study or use any other investigational drugs or products.
- From at least 1 week before taking the first dose on Day 1 and throughout the study until the last dose, you should not take any medications (prescription and over-the-counter), vitamins, and/or herbal supplements.
- Starting at least 72 hours before the Screening and Check-In Visits, you should avoid consuming any food or drink that contains poppy seeds to prevent false-positive drug screening results.
- From at least 1 week before you check-in to the clinical research site until your Follow-up Visit, you should not consume any food or drink containing alcohol.
- Starting at least 48 hours before taking the first dose and until your Follow-up Visit, you should avoid taking excessive caffeine (not more than approximately 355 mL coffee [1.5 cup] per day or approximately 710 mL [or 2 cans] of regular caffeinated soda per day).
- You should avoid eating or drinking grapefruit, grapefruit juice, and Seville oranges from at least 7 days before taking the first dose on Day 1, and throughout the study until your last dose of the study drug.
- For at least 7 days before taking the first dose on Day 1 and throughout the study until the last dose, you should avoid eating or drinking apple or orange juice, citrus fruits, vegetables from the mustard green family (such as kale, broccoli, watercress, collard greens, kohlrabi, Brussels sprouts, and mustard), and charbroiled meats.
- For at least 24 hours before taking the first dose on Day 1, you should avoid eating or drinking any food or drink containing quinine, such as tonic water, bitter lemon, or bitter alcoholic beverages.
- You must not eat or drink anything hot or cold within 10 minutes before checking temperature by mouth.
- For at least 24 hours before your Check-In Visit, you should avoid exercising intensively (exercise that increases your heart rate and breathing, making it difficult for you to speak in full sentences, like running, cycling, and singles tennis) or lifting heavy objects before visits where blood is collected. Light ambulatory activities (gentle physical activities that can be performed while walking or moving around, like slow walking, light stretching, or casual movements) are allowed.
- Take study drug as instructed by your study doctor.

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

WHAT WILL HAPPEN AT THE END OF THE STUDY OR IF YOU STOP YOUR PARTICIPATION EARLY?

At the end of the Dosing Period, after you check-out from the clinical research site, you will be asked to return to the clinical research site for a Follow-up Visit. At this visit, a final complete physical exam, ECG, vital signs, and some lab tests will be done for the study or for your health.

Your study doctor and/or Sponsor may learn new facts during the study that might make you want to stop taking the study drug or leave the study. You will be told about the new facts. You can then decide if you want to still be in the study. If you leave the study, there will be no penalty, and you will not lose any benefits you are entitled to. Leaving the study will not affect the quality of the health care you are given.

The study doctor may stop you from taking the study drug or end your participation in this study for any of the following reasons:

- You are not a good fit for the study.
- You have severe or unacceptable side effects.
- Staying on study drug or in the study would be harmful for you.
- You withdraw your consent.
- You need treatment that is not allowed in this study.
- You did not follow instructions about what to do in the study.
- You did not show up for your scheduled study visits.
- You did not follow the rules of the clinical research site.
- You participated in another research study at the same time you are in this study.
- The study is canceled.
- You become pregnant.

The study doctor will tell you the reason(s) why you should stop being in the study.

If you leave the study early, the study doctor will ask you to complete the Follow-up Visit (such as a final physical exam, ECG, vital signs, and lab tests) for your own health. If you cannot see the study doctor in person, someone from the study staff will call you by phone. This is done to have complete data about your health at the end of the study.

BENEFITS AND RISKS

Are there any possible benefits of being in the study?

The information we get from you during this study may help doctors learn more about the study drug and this may help future patients. There are no expected benefits to you from your participation in the study.

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

What are the potential risks and discomforts?
All drugs can cause effects that are not wanted. These are called side effects.

Side Effects of Dabigatran
This medication is used for the treatment and prevention of blood clots to reduce the risk of stroke. Common side effects of dabigatran can include indigestion, nausea, upper abdominal pain, stomach and intestinal hemorrhage, diarrhea, and bleeding.

Side Effects Seen in a Clinical Study of ALG-097558
To date, single ALG-097558 doses up to 2000 mg or 7 twice-daily ALG-097558 doses up to 800 mg have been administered to 74 healthy volunteers. These dosing regimens were well tolerated with no serious or severe side effects. The most common side effects of ALG-097558 reported in 2 or more volunteers include headache (in 2 volunteers) and diarrhea (in 3 volunteers). The 3 volunteers who experienced diarrhea were administered a different formulation (solution preparation) that included a component called polyethylene glycol, often used as a laxative. The tablet formulations that will be used in this study do not contain polyethylene glycol and are not expected to cause diarrhea.

No concerning laboratory, ECG, vital sign, or physical examination findings have been identified in anyone dosed with ALG-097558. Nevertheless, your study doctor will monitor you with similar safety assessments in this study and will regularly ask about your symptoms to closely monitor these and any other side effects.

Side Effects Seen in Studies of Animals at High ALG-097558 Doses
In addition to the human safety data, ALG-097558 has also been given to animals for up to 2 weeks at various doses, including doses much higher than those planned in the study. In general, ALG-097558 was well tolerated in these studies, with the following observed in animals dosed with ALG-097558 at high doses:

- Increased heart rate, blood pressure, and body temperature: When animals were given ALG-097558 doses at blood levels that were at least 23- fold higher than blood levels expected with doses planned in this study, they experienced increases in heart rate, blood pressure, and body temperature. Because these increases occurred in animals at much higher doses than those planned in this study, and no such effects were observed in animals at lower doses or in the clinical study of ALG-097558 conducted in humans at higher doses and longer durations than planned in this study, it is believed that there is a low risk for these side effects to occur in this study.
- Increased liver enzyme levels: Mild increases in liver enzymes, which are a way to measure liver function and sometimes indicates liver injury when they are elevated, were observed at high doses in some animals. These increases occurred at blood levels of

ALG-097558 that were at least 23-fold higher than the blood levels expected with the dose planned in the study. They were also reversible – levels went back to normal after stopping ALG-097558. Further, these side effects were not observed in the clinical study of ALG-097558 conducted in humans.

Importantly, all these side effects observed in animals occurred at much higher ALG-097558 blood concentration than planned in this study, they went away after stopping dosing and were detectable with routine tests. Although these side effects were not observed in the prior clinical study and are not expected in this study, given the much lower study drug concentrations expected, they will nevertheless be closely monitored by your study doctor throughout the study.

If any of these happen to you, tell your study doctor. If you notice any side effects that are not mentioned here, please tell your study doctor.

You may have dizziness, headache, stomach discomfort, and/or fainting due to fasting.

You may also have side effects from the tests you have during the study such as the following:

Electrocardiogram Risks

An electrocardiogram (ECG) is a test that records the electrical activity of your heart. Small sticky pads called electrodes will be placed on your body. There is no pain related to an ECG, but the electrodes may be cold when applied and may cause skin irritation such as redness, itching, or soreness when removed. In some areas, it may be necessary to shave a small amount of your body hair so the electrodes can be placed on your body. Irritation from shaving could also occur. Female participants may need to remove their bra for the ECG.

Blood Draw/Sample Risks

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

The total amount of blood drawn during the study will be approximately 218 mL (about 1 cup). A catheter may also be used for a minimal number of blood sample collections. This would add approximately 1 mL of blood that will be discarded prior to any blood samples taken from a catheter. In comparison, a standard blood donation at a blood collection center is about 500 mL (about 2 cups) taken once every 56 days (2 months). Additional blood samples may need to be taken to monitor your health if the study staff finds it necessary.

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

- Lightheadedness or fainting
- Redness
- Pain
- Bruising

- Bleeding
- Low hemoglobin levels
- Infection
- Blood clots, which may cause inflammation, swelling, or pain

Oral Administration Risks

Oral administration involves substances being taken through the mouth. In this study, all volunteers will receive study drug in tablet form and dabigatran in capsule form. Water will be given to help with taking the study drug. Risks associated with oral administration may include the following:

- Unpleasant taste
- Irritation of the mouth and/or throat
- Discomfort from swallowing
- Cough
- Vomiting

Risks with Fasting

- Dizziness
- Headache
- Stomach discomfort
- Fainting

Blood Pressure Measurement Risks

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

HIV and Hepatitis Testing Risks

In order to participate in this study, and if you are exposed to another person's blood, you must have your blood tested for the human immunodeficiency virus (HIV) and hepatitis viruses.

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

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

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

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

Risks of Loss of Confidentiality

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

Unknown/Unforeseeable Risks

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

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

Are there any reproductive risks?

The effect of ALG-097558 on an unborn baby, a breast-fed child, the female egg, or on the male sperm is unknown. There may be risks to an unborn baby that are currently unforeseeable. Therefore, volunteers who are pregnant, breast-feeding, or planning to breastfeed or become pregnant during the study will not be allowed to take part. Volunteers who could become pregnant must have a pregnancy test to rule out pregnancy before getting study drug. After joining the study:

- If you think you are pregnant during the study, tell the study doctor or study staff at once.
- If you think you got your partner pregnant during the study, tell the study doctor or study staff at once.

Female volunteers who are able to get pregnant and who are having sex with a person who can get them pregnant must use a highly effective birth control method for at least 30 days prior to the Screening Visit, during the study, and for 90 days after your last dose of the study drug. Birth control methods that can be used while in this study include the following:

- Intrauterine devices (IUD) or intrauterine hormone-releasing system (IUHS): These are small devices that a doctor puts inside a woman’s uterus to prevent pregnancy. Some IUDs release hormones that stop the woman from releasing eggs and make it harder for sperm to reach the egg.

- Implantable progestogen-only hormone contraception associated with inhibition of ovulation: This is a small rod that a doctor puts under the skin of a woman's arm. It releases hormones that prevent the woman from releasing eggs, which makes it difficult for her to get pregnant.
- Bilateral tubal occlusion or tubal ligation: These are procedures where a woman's fallopian tubes are either blocked or tied. This prevents the egg from meeting the sperm, so pregnancy cannot occur.
- Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation — pills (oral), intravaginal, skin patch (transdermal) injectable, and implant: These are different types of birth control methods that contain both estrogen and progestogen hormones. They work by stopping the woman from releasing eggs and making it harder for sperm to reach the egg.
- Progestogen-only hormone contraception associated with inhibition of ovulation — pills (oral) and injectable: These are birth control methods that only contain progestogen hormones. They also prevent the woman from releasing eggs and make it harder for sperm to reach the egg.
- Your only partner had a vasectomy (at least 26 weeks before the Screening Visit), and a lack of sperm was confirmed after the surgery: Vasectomy is a procedure that some men have to prevent them from making a woman pregnant. It involves blocking the tubes that carry sperm. If your partner had a vasectomy and it was confirmed that there is no sperm, then it means he cannot make you pregnant.
- Combination of male condom with cap, diaphragm, or sponge: This is a double-barrier method where both a male condom and another barrier method (cap, diaphragm, or sponge) are used together for added protection against pregnancy.

The following are not allowed as a sole method of contraception during the study:

- Progestogen-only oral hormonal contraception where preventing ovulation is not the main way the contraception works: These are birth control pills that contain only a hormone called progestogen. They work by thickening the cervical mucus and changing the lining of the uterus to prevent pregnancy. These do not necessarily prevent the release of an egg from your ovaries.
- Male or female condom: Condoms are barrier methods of contraception that can be used by both males and females. They create a barrier between the penis and vagina to prevent sperm from reaching the egg. Condoms should be used in combination with spermicide, which further helps to kill sperm.
- Cap, diaphragm, or sponge with spermicide: These are devices that can be inserted into the vagina to cover the cervix and prevent sperm from entering. They are used in combination with spermicide, which helps to kill sperm.
- Periodic abstinence: This method involves tracking the menstrual cycle and avoiding sexual intercourse during the fertile period when there is a higher chance of pregnancy. It can be done using different methods like calendar tracking, monitoring symptoms, or using temperature changes to determine fertility.

- Withdrawal (coitus-interruptus): This method involves the man pulling out his penis from the vagina before ejaculation to prevent sperm from entering.
- Spermicides alone: Spermicides are substances that contain chemicals to kill or immobilize sperm. They can be used alone as a contraceptive method.
- Lactational amenorrhea method: This method utilizes breast-feeding as a form of contraception in women who have recently given birth and have not yet started having their periods again. Breast-feeding can suppress ovulation and reduce the chances of pregnancy, but it is important to follow specific guidelines for this method to be effective.

You must discuss with the study doctor the type of birth control that you use before you begin the study. The study doctor must approve the method you use before you can enter the study.

If you become pregnant during the study or within 3 months of the last dose of study drug, you must tell the study doctor immediately. The study doctor will advise you about your health care and will ask about your pregnancy and its outcome.

If you can get someone pregnant, you must use a condom with spermicide every time you have intercourse, during the study and for 90 days after your last dose of study drug, and your partner must use a highly effective contraception method of birth control. This is because it is not known if the study drug may affect your sperm or an unborn child. You must also not donate sperm until 90 days after your last dose of the study drug.

If you become pregnant, or you get your partner pregnant, within 3 months of the last dose of study drug, the study doctor may ask you and your partner if they may collect details about the health of your baby for scientific and health reasons. You and/or your partner will be asked to sign a new form to allow collection of data about the health of your baby for 1 year after birth. A separate ICF may be provided to explain these follow-up activities.

The study Sponsor will use this information about your partner's pregnancy and its outcome to learn more about the effects of the study drug on pregnancy.

What happens if there is new information?
Sometimes during a research study, new information that may affect your decision to continue to take part in the study becomes available. If this happens, the study doctor will inform you in a timely manner and discuss with you if you want to continue in the study. If you decide to continue in the study after knowing about new information, you may be asked to sign an updated ICF.

COSTS AND COMPENSATION FOR STUDY PARTICIPATION

Are there any costs if you decide to take part in the study?
There is no cost to participate in this study. However, you will receive study participation stipends as described below.

Will you receive any payment if you take part in the study?
You will receive payment for your time and travel associated with being in this study.

If you qualify and decide to participate in the research study, follow all study requirements and clinical research site rules, and complete all required study visits, you may be compensated up to $5,500.00. If you do not complete the study, you will be paid for the visits you do complete based on the following breakdown:

Visit	**Per Day**
Screening	$250
Day -1 Check-In	$500
Day 1 In-House Stay	$500
Day 2 In-House Stay	$500
Day 3 In-House Stay	$500
Day 4 In-House Stay	$500
Day 5 In-House Stay	$500
Day 6 In-House Stay	$500
Day 7 In-House Stay	$500
Day 8 Discharge	$0
Day 15 Follow-Up Visit	$250
Completion Payment	$1,000
Total	**$5,500**

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

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

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

The Day 1 through Day 7 in-house stay will be compensated in the amount of $3,500.00 ($500.00 per overnight stay) paid on Day 8.

The Day 15 Follow-up Visit will be compensated in the amount of $250.00 paid at the end of the visit.

If you complete all visits listed above within the scheduled timeframe, you will receive the Completion Payment amount of $1,000.00. Your participation in the study is not completed until

you have met all end of study requirements, the study staff has reviewed and cleared you of all study procedures, and no further follow-up is required. The Completion Payment amount will be issued within 14 days (2 weeks) of the last study visit on Day 15 when you have met all requirements for study completion and no further follow-up is required.

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

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

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

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

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

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

Incident	**Penalty**
#1 - Warning	0
#2	$100
#3	$350
#4	$850*

*** Penalty may increase by $250 and/or removal from the study.**

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

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

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

Will you receive compensation for injury resulting from the study?
If you are physically injured or get sick because of being in this study, please call the study staff immediately at the phone number listed on the first page of this document. For any serious or life-threatening injuries or illness, please call 911.

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

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

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

You should tell the study doctor as soon as you feel that you have had an illness or injury related to the study, so that you can get proper health care. No long-term medical care or financial compensation for research related injury will be provided by the NIH or the Federal Government.

You do not give up any of your legal rights by signing and dating this form. A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 17, 2020, with the twelfth amendment extended to December 31, 2029. This Declaration limits the legal rights of a subject participating in clinical studies utilizing medical countermeasures against COVID-19, such as ALG-097558 used in this study. Because this study is covered by the PREP Act Declaration, covered persons, such as the manufacturers, study Sponsor, researchers, healthcare providers, and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

If you believe that you may have been harmed as a result of this research study, certain claims for serious injury or death caused by the countermeasure may be eligible for compensation through the Countermeasures Injury Compensation Program (CICP). This is a program set up by the United States Government.

Information about this program can be found at https://www.hrsa.gov/cicp/about/index.html or by calling 1-855-266-2427. If you are eligible for this program, you must file a claim within one year of the administration or use of the covered countermeasure.

The study Sponsor and other researchers will not provide any other form of financial compensation for illness or injury, such as compensation for pain and suffering, disability, or lost wages for missed work. Your study doctor can explain more about this to you if you have questions.

It is important that you follow all the instructions given by the study doctor and study staff about this study and that you answer all questions accurately about existing conditions and other medications.

By signing this form, you are not giving up your legal rights and are not releasing the study doctor or Sponsor from their legal and professional responsibilities.

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE, SHARE, AND DISCLOSE PERSONAL HEALTH DATA

What happens to the data collected about you?
The information below explains how your health records and the research data we get from you and from the samples collected from you during the study may be used and shared with others.

A federal regulation known as the Privacy Rule gives you certain rights to protect the privacy of your Protected Health Information. The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality (security and privacy) of your Protected Health Information. Researchers covered by this rule are required to get your authorization (permission) to use and disclose (share

with others) any Protected Health Information that could identify you. Under this federal law, your records cannot be used or disclosed by Dr. Vince Clinical Research for research purposes unless you sign this form.

This section, called an "Authorization," explains how your Protected Health Information will be used and disclosed during this research study and describes your rights, including the right to see your Protected Health Information.

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

The study staff will record basic personal details about you, including your name, contact details, sex, age, race, and ethnicity to be used only for study purposes, as well as data on your health history and any study data collected about you during the study.

In addition to the study doctor, study staff, and other site personnel, the following people may review your health records on-site that contain your identifying information:

- Government health agencies, such as the Food and Drug Administration (FDA), and their staff involved in keeping research safe for volunteers
- TRI/ICON staff observing the study (monitors and auditors) who check to make sure that the study is being run as planned, and that the data collected about you are correct
- Members of the IRB that approved this study and ensures that your rights and well-being are safeguarded
- Contractors and consultants working for Sponsor and for health authorities
- Other representatives of Sponsor
- Employees of Sponsor, or its authorized agents, who may be with the study monitors and auditors for quality and training purposes.

All staff who can see (with access to) your records are required to keep your data private. Your name and other data that can identify you will not be attached to records or samples released to Sponsor, and its service providers, such as laboratories and companies responsible for processing your data (outside of their viewing the on-site records as noted above). When shared/released, your information and samples will only be identified by a code. Only the study doctor and authorized staff will be able to connect this code to your name with a list that will be kept safe by the study staff for an indefinite period of time.

After your coded data are sent to Sponsor, the results of the study will be analyzed and reported. Sponsor may use your coded information (when aggregated with other volunteer data) to get the study drug approved for use in different countries.

The results may also be analyzed again at a later date or may be combined with the data of other studies. Sponsor and people who work with them may use the results of this study to understand the disease better or to review the safety or effectiveness of the study drug, or for other research purposes. There is risk that your data may be re-disclosed for the purpose of these analyses and no longer protected by the Privacy Rule.

You have the right to see (access), correct, and limit the access to your personal data, but in order to preserve research integrity, these rights will be suspended until the study is complete. Additionally, you have the right to withdraw your authorization for the processing of your data. You can exercise those rights after the study is over by telling the study doctor.

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

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

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

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

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

To help us protect your privacy, we have a Certificate of Confidentiality from the NIH. The researchers can use this Certificate to legally refuse to give information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except for reporting of communicable diseases to state and local health departments, or in the following circumstances where such disclosure is permitted:

- If required by other federal, state, or local laws, such as for reporting of communicable diseases.
- If you consent; or
- For the purposes of scientific research that is compliant with regulations protecting human subjects.

A Certificate of Confidentiality does not prevent disclosure of your information to the NIH, FDA, or federal funding agency.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you give your consent to release information to a medical care provider, an insurer, or other person to receive research information, then the researchers will not withhold that information.

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

What if you change your mind and do not want your data to be used or disclosed?
If you leave the study early or withdraw your authorization for the processing of your data, data collected up to that point will still be kept with other data from the study and used as described in this form. No new data will be collected from you for the study unless you clearly agree to that. If you withdraw your authorization for the processing of your data, you will not be able to continue participating in this study. However, this will not affect your standard treatment (treatment that you would receive even if not participating in the study).

Will information about this study be publicly available?
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. This website only shows data in English, but you can ask the study staff at any time and be given the information that is available to the public.

After this study is over, a brief report of the overall results may be prepared for the general public. The study results may also be shared with scientific journals and the scientific community. Whenever the results of the study are shared or published, your identity will remain private.

CONTACTS

Who can you contact with further questions?
If you have any questions about the study or if you feel that this study has caused you harm or injury, please contact the study doctor whose details are given on the first page of this form.

If you have any questions about your rights as a person taking part in this study, please contact the IRB that has reviewed and approved this study, also given on the first page of this form.

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

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

WHAT ABOUT MY LEGAL RIGHTS?
You will not lose any of your legal rights to which you are otherwise entitled by signing this consent form.

STATEMENT OF CONSENT

- I have read and understood the statements in this ICF.
- I have had the chance to ask questions, and I am satisfied with the answers given to me.
- I understand that this study may only be performed by collecting and using my health data. Therefore, by signing this form, I specifically give permission for my data to be checked, transferred, and processed as described in this ICF.
- I agree to take part in this study of my own free will and give my consent to the study procedures.
- I understand I can leave the study at any time without giving a reason and without affecting your healthcare or benefits.
- I agree to use an acceptable method of birth control if I am capable of having children.
- I understand that I will receive a copy of this signed and dated written ICF.

Printed Name of Volunteer, in full

Signature of Volunteer **Date (dd-Mmm-yyyy) and Time**

- I have presented the study and answered the volunteer's questions
- I will give the volunteer a copy of this signed and dated ICF.

Printed Name of Person Obtaining Consent (Investigator/Delegate), in full

Signature of Person Obtaining Consent **Date (dd-Mmm-yyyy) and Time**