INFORMED CONSENT FORM

Sponsor: **Trellis Bioscience, Inc.**

Study Title: **A Phase 1, Double-Blind, Single Ascending Dose Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of TRL345 in Healthy Volunteers**

Study Doctor: **Samer Haddad, M.D.**
Telephone: **(602) 437-0097 (Normal Business Hours)**
(602) 757-6087 (24-hour Nurse's Line)

Address: **Celerion**
2420 W. Baseline Rd
Tempe, AZ 85283

You have been offered this consent form in English and Spanish, and have chosen this format as your preferred language. (please check one box)

Please confirm that this is correct: ☐ Yes ☐ No

It is important that you give a true and complete medical history. You must be honest about your past and present usage of medications. Giving information that is not true could be very harmful to your health. If you give false information, you may be dismissed from the study.

You are being asked to take part in a research study sponsored by Trellis Bioscience, Inc. Celerion is being paid by Trellis to conduct this study. You should read this form before you decide if you want to take part in the study. This form will tell you about the study. The Study Doctor or study staff can explain words or information that you do not understand. Ask the study staff as many questions as needed for you to decide if you want to take part in the study. Research studies are voluntary and include only those who wish to take part. If you decide to take part in this study, you must sign your name at the end of the form and date it. You cannot take part in this study until you sign and date this form.

1. PURPOSE OF THE STUDY

The study drug, TRL345, is experimental. That means the United States Food and Drug Administration (FDA) has not approved it for sale or use. TRL345 is a human monoclonal antibody that specifically recognizes and neutralizes a virus called Human Cytomegalovirus (HCMV). The monoclonal antibody TRL345 is being studied to treat infections with HCMV. This study will provide an important basis for determining the best dose to use in follow-up studies in subjects with HCMV infections.

This is the first study in which TRL345 will be given to humans.

The purposes of this study are to:

- Learn about the safety and tolerability of TRL345 when given as an intravenously (IV) as a single dose in healthy subjects.
- Find out how much TRL345 is in the blood after a single IV infusion.
- Assess the immunogenicity of TRL345 as measured by anti-drug antibodies (ADAs)
- Select a safe and tolerable dose for further evaluation in subject populations

Immunogenicity testing: These samples will be used to assess if TRL345 has the potential to cause an immune reaction (immunogenicity) in a person's body. Immunogenicity testing is done by measuring antibodies against TRL345 in your blood. Antibodies are proteins produced by the body in response to foreign substances. Even though TRL345 is a human monoclonal antibody, it may be recognized as a foreign substance by a person's immune system.

2. NUMBER OF SUBJECTS AND LENGTH OF STUDY

This study will enroll about 16 subjects. The entire study will last about 77 days plus up to 14 days for screening. There is 1 confinement period where you will stay in the clinic the entire time. The confinement period will last about 4 days. There are 5 return visits to the clinic.

3. SCREENING VISIT

The following procedures will be done during this visit(s) to help the Study Doctor determine if you qualify for this study. This is called the screening visit. Screening may consist of 1 or more visits and involves the following procedures.

- Read, sign, and date the Informed Consent Form (ICF).
- Provide your medical history including all medications, vitamins, herbal products or supplements you are taking.
- Provide information such as your name, age, date of birth, sex, race, ethnicity, address, social security number or tax identification number, and phone number.
- An ECG - electrocardiogram (a test that measures and records the electrical activity of your heart) will be done.
- A physical examination will be done.
- Height and weight will be measured.
- Vital Signs (for example, blood pressure, pulse rate, respiratory rate, and body temperature, obtained by mouth) will be done.
- Blood and urine samples will be collected. Your blood and urine sample will be used for routine laboratory tests including fasting blood sugar and HbA1c, a measure of blood sugar control. In addition, your blood will be analyzed for the presence of exposure to HCMV, which is often positive in adults. Your urine sample will be tested for drugs of abuse and alcohol and cotinine (nicotine exposure). If you are female and able to become pregnant, your blood will be used for a pregnancy test.
- Your blood will also be used to test for HIV and hepatitis B and C. If your results are positive, the laws require that your name and positive result be reported to

the local health department. Your HIV and hepatitis B and C results must be negative to be in the study. If you are not selected to be in the study, for any reason, it is possible that we will not complete this testing on your blood. You can call the study staff to find out if your blood was tested for HIV and hepatitis B and C and the test results, if applicable.

4. SUBJECT RESPONSIBILITIES

You must:

- Follow all clinic rules and instructions of the study staff.
- Follow the study restrictions.
- Report any side effects.
- Give true and complete answers to any questions.
- Comply with the terms of the Informed Consent Form.

5. GENERAL CLINIC RULES AND STUDY RESTRICTIONS

Meals and snacks will be served at scheduled times during your stay in the study clinic. You can eat only the food and drink provided to you. You can eat only at the times food is provided. You may be awakened during the night for scheduled events such as vital signs or blood draws.

Some drugs, foods, drinks, or activities can increase or decrease the effect of the study drug. This can be a risk to your health or lead to false study results. Some of the restrictions and requirements for this study are listed below.

You must not:

- Be pregnant or breastfeeding, if female.
- Have unresolved gastrointestinal symptoms (for example, diarrhea [loose stools], vomiting).
- Have serious or long-lasting infections (for example, viral infections, except chronic recurrent herpes simplex infections).
- Abuse alcohol within one year prior to the Screening Visit defined as more than fourteen units of alcohol per week [one “unit” is equal to about ½ pint [200 mL] of beer, 1 small glass [100 mL] of wine, or 1 measure [25 mL] of spirits).
- Donate blood or plasma during the study.
- Use any prescription drugs or over-the-counter (OTC) products (including natural food supplements, vitamins, herbs) within 14 days prior to dosing and through the last study visit.
- Have received any vaccine or booster within 14 days prior to Day 1 or have a planned vaccination or booster within 4 weeks after study drug dosing. The study staff can give you specific examples of these.
- Be a Celerion employee or study staff that is contracted to work on this study.
- Have received an investigational product, or participated in another study involving a marketed or investigational drug within 30 days of Day 1.
- Use tobacco or nicotine within 4 hours prior to the ECGs.

You must:

- Refrain from strenuous exercise within 5 days prior to your lab work (creatine kinase) drawn on Days 1, 3, 8, and 15.

6. STUDY DRUG DOSING

You will be enrolled into a study dose level group. In each study dose level group, you will be randomly assigned (by chance like flipping a coin) to take TRL345 or placebo. Out of 8 subjects, 6 will receive TRL345 and 2 will receive placebo. A placebo is a solution that looks like TRL345 but contains no study drug. The use of a placebo helps to make sure that any side effects during the study are judged fairly. Neither you nor the study staff will know who is taking TRL345 and who is taking placebo. If necessary for safety reasons, the Study Doctor can find out which study dose level you were assigned to.

The Study Doctor and the Sponsor will review the safety data of each dose level. The next dose level will not be dosed until the safety data has been reviewed of the previous dose level. The doses may be modified at any time during the study based on the safety and tolerability of the study drug. The Sponsor and/or the Study Doctor can stop the study at any time.

The Study Doctor/study staff will not tell you if you are receiving TRL345 or placebo, but they can let you know what dose of TRL345 is being used in your study dose level group prior to dosing.

- Study Dose Level 1: 1 mg/kg TRL345 or placebo
- Study Dose Level 2: 10 mg/kg TRL345 or placebo

Your weight will be taken prior to dosing to determine the correct dose of TRL345 for administration. TRL345 will be put into saline for administration. If you are assigned to placebo, you will receive saline only. All infusions will be at a total volume of 200 mL administered over approximately 60 minutes.

An intravenous (IV) infusion cannula will be inserted into a vein in your hand or arm. The study drug will be given through this IV directly into your vein. You may have discomfort or pain when the IV is inserted. There is a risk of infection, bleeding, or bruising at the IV site.

POSSIBLE SIDE EFFECTS RELATED TO THE STUDY DRUG:

This is the first study in which TRL345 will be given to humans, so the risks are unknown. In some cases, side effects may be serious, long lasting and may cause death. Some side effects may go away soon after you stop the study treatment, and some may never go away.

The possibility that TRL345 binds to gastrointestinal or pancreatic tissue cannot be excluded. Potential risks that may result from this binding include:

- Pancreatitis
- Nausea (a feeling of wanting to vomit)
- Vomiting
- Diarrhea (loose stools)
- Abdominal spasms
- Discomfort

Based upon studies with other monoclonal antibodies, following side effects might occur:

- Pain, bruising, or redness at the infusion site
- Allergic reactions from the infusion

Allergic reactions may include:

- Hives
- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating
- Anaphylaxis, which can include all of the range of allergic reactions described above.

Anaphylaxis can be potentially life threatening. Anaphylaxis represents the severe end of the spectrum of allergic reactions listed under allergic reaction (above). Your vital signs and overall clinical status will be closely monitored in case you develop any signs of not tolerating the infusion. The research unit will have the facilities to provide adequate treatment for any anaphylactic reactions, including IV injections or infusions, or need for intubation.

Please seek treatment immediately and tell the Study Doctor or study staff if you have any of these symptoms.

7. PROCEDURES AND POSSIBLE RISKS OR DISCOMFORTS

Procedures will be done during the study at assigned times. The procedures will be done to monitor your health, assess the safety of the study drug, and to see how the study drug is broken down in your body. You will be given a schedule of all study procedures.

BLOOD COLLECTIONS

A needle will be used to take blood samples from a vein in your arm about 15 times during the study. Less than 2 cups of blood will be taken. For additional information regarding blood volume please see study staff. Two cups is the amount you would give if you were donating blood. Additional samples may need to be taken.

You may have discomfort or pain when your blood is collected. You may feel faint or pass out. There is a risk of infection, bleeding, or bruising at the puncture site. You may develop a small scar at the puncture site where multiple blood samples are taken.

If the study staff has a difficult time obtaining your blood from the individual needle sticks you may be dropped from the study. On rare occasions, if blood cannot be obtained per the usual needle stick, we **may** place an intravenous (IV) catheter (a small hollow tube) in a vein in your arm to obtain the blood. Blood is then withdrawn from a port on the IV at scheduled time points. The tube will be flushed or cleaned out with a small amount of saline (salt water) before and after it is used. You may have discomfort or pain when the IV is inserted. There is a risk of infection, bleeding and/or bruising at the insertion site.

ADA (ANTI-DRUG ANTIBODY) TESTING (IMMUNOGENICITY TESTING)

Administration of certain types of drugs including TRL345 may cause your body to produce a protein against the study drug. This protein is called anti-drug antibody (ADA). Very rarely, some people already have an ADA against the study drug in their body even before being given the study drug. In general ADA do not cause problems, but it is possible that an ADA may change the clearance or weaken the effectiveness of the study drug. Sometimes it may cause an allergic reaction (for example, injection-related reaction or anaphylaxis) or adverse side effects including those similar to the study drug itself, especially if you already have the ADA and are given the study drug again.
Your blood will be tested for ADA against TRL345 to better understand your body's response to TRL345.

FUTURE RESEARCH

Blood for future research will be obtained on days blood samples are taken. These pharmacokinetics (PK looks at how your body takes, processes and removes the study drug from the body) samples and the additional serum (blood) sampling for any exploratory assessments are mandatory as part of participation in this study. The blood samples, if not required for repeat of blood assessments, may be retained for future exploratory assessments. These stored samples will remain anonymized (identifying information removed) may be used by the Sponsor or its research partners for retesting of planned tests, characterization of TRL345, further analyses to study Cytomegalovirus (CMV) infections, or clinical laboratory testing to provide additional safety data. No human genetic testing will be performed on these samples. At the conclusion of this study, these samples may be retained in storage by the Study Doctor, Sponsor or its research partners for a period up to 15 years.

URINE COLLECTION

Urine samples will be collected during the study.

VITAL SIGNS

Your vital signs will be measured at multiple times during the study. For example, blood pressure, pulse rate, respiration rate, and body temperature (obtained by mouth).

ECG

ECGs (electrocardiograms) will be done. An ECG traces the electrical activity of the heart. You may have mild irritation, slight redness, or itching at the sites on your skin

where the recording patches are placed. It may be necessary to shave the area on your chest for placement of ECG tabs directly on skin.

WEIGHT

Your weight will be taken.

PHYSICAL EXAM

Physical examinations will be done.

FASTING, CAFFEINE, AND SMOKING RESTRICTION

You will be asked to fast (having nothing to eat or drink, except water) at certain times during this study. You will not be able to ingest caffeine containing foods and beverages while confined in the clinic. You cannot smoke while in the clinic. This may cause discomfort.

PHOTOGRAPH

If you develop a skin condition (reaction or rash) while being in this study, your skin condition may be photographed as soon as it is noticed and several other times until it is gone.

If the skin condition is on your face, all reasonable attempts will be made to disguise your facial features to hide your identity. It is possible that your face may be recognizable.

Your image may be sent electronically to the sponsor. The photographs or electronic images will be labeled with your study number and not your name. People working at Celerion, the Sponsor, the FDA, and IRB will have access to your photographs if they have a valid reason for seeing them. Valid reasons include but are not limited to, monitoring or auditing the study, to assess the skin condition or to determine the cause of the skin condition. When the study is over, your photograph or electronic image will be stored with the study files indefinitely. Your picture will not be used for teaching purposes and will not be published in any medical journal. You may be asked to have additional tests to assess the skin condition. The Study Doctor will discuss this with you before any other tests are done.

COVID-19 TESTING

You will be administered the COVID-19 test at times determined by the Study Doctor and/or study plan. The tests may be performed through various methods of sample collection. The study staff collecting your sample will confirm which collection type is applicable for your COVID-19 test. You may have more than one type of test performed.

Nasopharyngeal Swab

If the test is performed through a nasopharyngeal swab, you will be asked to blow your nose in a tissue. You will then tilt your head back. The medical staff will inspect in the inside of your nose. A sterile swab will be gently inserted into the nasopharynx (the upper part of the throat behind the nose that covers the roof of the mouth). The swab will be quickly rotated and removed. This procedure may be repeated for additional samples.

Nasal Swab
If the test is performed through a nasal swab, a sterile swab will be gently inserted into your nostril about an inch. The swab will be rolled several times and removed. This procedure may be repeated in the other nostril or for additional swab samples.

Throat Swab
If the test is performed through a throat swab, you will be asked to tilt your head back, open your mouth, and stick out your tongue. A swab will then be inserted into your mouth and moved around to collect cells from your throat. This procedure may be repeated for additional samples.

You may have discomfort when the nasopharyngeal and/or nasal swab collection is performed. It may make your eyes water or produce a small amount of blood on the swab. The throat swab collection may cause discomfort and stimulate your gag reflex.

There is also a risk of being exposed to COVID-19 due to being in a confined area with other subjects and study staff. Celerion has added additional precautions during this time which include following Centers for Disease Control and Prevention (CDC) and local authority guidance; however, due to the highly transmissible and infectious nature of the virus, Celerion cannot entirely eliminate your risk of exposure to the virus.

If your COVID-19 test is positive, Celerion may be required to report this finding to the Health Department. There will be no charge to you for the COVID-19 test. If you test positive for COVID-19 it will be your responsibility to pay for your health care costs and to follow up with your personal health care provider or clinic. If you test positive for COVID-19, you will not be allowed to be on the study. If you test positive after you have dosed, you may be discontinued from the study.

8. STUDY RE-CHECKS AND BLOOD EXPOSURE PROCEDURE

You may be asked to return to the clinic after the study is complete to follow up on abnormal laboratory tests. The study staff may also call you to follow up on any unresolved adverse events (side effects). It is important for your safety that you comply with study staff requests to return and/or respond to any telephone calls. You may not be able to do future studies if we are unable to ensure that all your abnormal results have returned to acceptable levels and all of your adverse events have resolved.

If a study staff member sustains an exposure to your blood, tissue or body fluids by needle stick, cut or splash to mucosa or damaged skin, your name, address, telephone and date of birth will be given to the private doctor who is treating the study staff member. You may be contacted in order to collect your blood or to ask your permission to use an existing blood sample to test for HIV and hepatitis B and C. If your blood is tested, you will receive a copy of the results.

This is to enable the study staff member to receive appropriate counseling, monitoring and treatment if necessary. If your blood tests positive the results will need to be reported to the local health authorities.

You will incur no costs for any of these assessments.

9. UNKNOWN RISKS

There is always a chance that an unexpected or serious side effect may happen. This can happen to people who take this or any other drug. You must report any new symptoms/signs of illness to the study nurses any time after you have signed and dated this Informed Consent Form.

10. POSSIBLE RISKS TO AN UNBORN BABY OR CHILD WHO IS BREASTFEEDING

The risks of using TRL345 during pregnancy are not known. It is possible that this study drug may cause harm to an unborn baby. This includes death, congenital malformations or other unforeseen health problems for the baby.

Men and women that are able to become pregnant, must practice a highly effective method of birth control for 28 days before Screening and through Day 76. Highly effective methods of birth control may include, but are not limited to the following:

- Abstinence (not having sex)
- Sex only with persons of the same sex
- Monogamous relationship (sex with only one person) with a vasectomized (cutting or blocking two tubes, called the vas deferens, so that sperm can no longer get into the semen) partner
- Vasectomy
- Hysterectomy (removal of all or part of the uterus)
- Bilateral tubal ligation (cutting, burning, or removing section of the fallopian tubes)
- Licensed hormonal methods
- Intrauterine device (IUD)

Men must not donate sperm from Day 1 through Day 76.

All pregnancies that occur during the study, including female partners of male subjects will be followed to its conclusion.

11. SIGNIFICANT NEW SAFETY FINDINGS DURING THE STUDY

You will be told of any significant new safety findings that Celerion is made aware of by the Sponsor that might influence your willingness to continue your participation in this study.

12. POSSIBLE BENEFITS FROM THE STUDY

You will not receive any health benefits from being in this study. The tests provided may help you learn about your general health. They may also help you discover an unknown medical condition. This study may help doctors and scientists learn things about the study drug that will help others.

13. TAKING PART IN THE STUDY OF YOUR OWN FREE WILL

You are being asked to take part in this study because you are healthy. You will not be taking the study drug to treat any disease or condition. The only other option is not to take part in this study.

You will take part in the study by your own choice and your own free will. No one can force you to be in the study. If you enter the study, no one can force you to stay in the study. If you choose not to be in the study or if you leave the study early, there will be no penalty or loss of benefits. **If you leave or are removed from the study for any reason your stipend will be prorated to the amount of the study that you complete.** You will not lose any rights that you are entitled to as a research subject.

14. COST AND PAYMENT FOR TAKING PART IN THE STUDY

There are no costs to you for being in the study. The study drug and study procedures are provided to you at no charge.

Celerion will pay you via the payment method you select based upon the information provided by study staff. The amount you will be paid will depend on how much of the study you complete. You will earn $350 if you complete Check In Day. You will earn $500 for each full day of confinement you complete. You will earn $150 if you complete Check Out Day. You will earn $350 for the 1st return visit, $500 for the 2nd return visit, $650 for the 3rd return visit, $900 for the 4th return visit and $1,250 for the 5th return visit you complete. You will earn a completion bonus ($1,600) if you complete the entire study. You will be paid a total of $6,750 for completing the entire study.

You will receive a partial payment at the times listed below:

- $1,850 within 7 days following completion of the 1st return visit
- $500 within 7 days following completion of the 2nd return visit
- $650 within 7 days following completion of the 3rd return visit
- $900 within 7 days following completion of the 4th return visit
- $2,850 within 7 days following completion of the 5th return visit

If you leave the study early, you will receive a pro-rated amount based on the study days you completed. If you complete an unscheduled study return visit you will be paid $150 for travel and time.

To ensure that the study doses the required number of subjects, extra subjects are recruited. These extra subjects are called alternates. If you are randomly chosen to be an alternate you will be told after you check in to the clinic. As an alternate you will be asked to complete study procedures up to the time of dosing. In the event that an on study subject is unable to dose, you may be chosen to take that subject's place on the study. If you are not needed, you will be released from the clinic after dosing. If you complete all the alternate requirements, you will receive an alternate stipend of $675 within 7 days after being released from the clinic. If you are an alternate or a study subject who is released prior to the initial dosing you will receive a prorated portion of the

alternate stipend (or $150 minimum) based on the amount of the study that you complete.

Celerion will pay you an additional $250 if the study schedule requires that you return, check-in or are confined to the site on any of the following holidays: Easter Sunday, Memorial Day, July 4th, Labor Day, Thanksgiving, Christmas Eve Day, Christmas Day, New Year's Eve Day, New Year's Day. You must complete the holiday return/confinement (on the actual holiday) in order to receive this additional holiday stipend.

You understand the following:

- No deductions will be withheld from your stipend payment for tax purposes. You are responsible for reporting any payment on your state and federal tax returns. At the end of each year, Celerion will notify the IRS of all stipends you have received throughout the year.
- You will be paid through a payment vendor selected by Celerion in the method you select from the available payment options.
- In order to be paid through the payment vendor, information such as your name, home address, email address, phone number and date of birth will be provided to Celerion's vendor. Once you have access to the vendor's pay portal, you will need to provide your social security or tax identification number and the vendor may request that you provide additional information based upon the payment method you select. All of your personal information that Celerion provides to the vendor will be handled in accordance with the confidentiality and privacy section. The vendor's privacy policy is also available to you on the website and through the payment portal.
- Being in this study does not make you an employee of the Sponsor, Celerion, or the FDA.
- You will not receive the full payment for the study if you leave before it is complete or are removed from the study for any reason. **This includes leaving the study due to an adverse event.**

15. COMPENSATION FOR AN INJURY DIRECTLY RELATED TO YOUR PARTICIPATION IN THIS STUDY

There is a chance that you could become ill or injured while being in this study. Celerion will help you make arrangements if your illness or injury requires care outside of Celerion (hospital, medical specialist). Unless other arrangements have been made by Celerion, all billing will be under your name. The cost of this care will be billed to you or your insurer in the ordinary manner. If you do not have insurance, the cost of the care will be billed to you directly.

The Study Doctor will decide if an injury or illness is directly related to the performance of the protocol (study plan) or use of the study drug. If your injury or illness is directly related to the performance of the protocol or use of the study drug, the Sponsor and/or Celerion will reimburse you for your reasonable out-of-pocket medical costs (not covered by insurance) to treat a study-related illness or injury.

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

You will need to sign a "release of information" form. This form will allow Celerion to obtain your medical records related to the illness or injury. These records will help the Study Doctor determine the cause of the illness or injury. They may also help the Sponsor learn more about the safety of the study drug.

Any injury or illness that is not directly related to the performance of the protocol or use of the study drug will be your responsibility to pay and to follow up with your private doctor or clinic. This includes any injury or illness that would have occurred even if you had not participated in the clinical trial.

In no way does signing and dating this consent form waive your legal rights nor does it relieve the Study Doctor, Sponsor or involved institutions from their legal and professional responsibilities.

16. REASONS YOU CAN BE REMOVED FROM THE STUDY

You can be removed from the study at any time and for any reason without your consent. Some of the reasons you can be removed are listed below.

- You do not follow the instructions, rules, and restrictions given by the study staff.
- You do not continue to meet the requirements for the study.
- The Study Doctor decides it is best for your health.
- The Sponsor stops the study or asks that you be removed from the study.
- Difficulties with blood collection.
- You become pregnant.

17. LEAVING THE STUDY BEFORE IT IS COMPLETED

Leaving the study before it is complete may be harmful to your health. If you choose to leave the study, you must notify the study staff. It is very important that you agree to have all the necessary procedures completed for your safety and well-being, which may include, but not limited to, the following:

- Physical examination
- ECG
- Weight
- Vital Signs
- Provide blood and urine samples
- Record any side effects you may have or medications you have taken.
- You may have a follow-up phone call and/or return

Additional procedures may be done. The study staff can discuss this with you.

All data that has been collected from you will be used for its original intention. If you leave the study early or you are removed from the study, all samples collected from you before you leave will be used and analyzed as described in this consent.

18. CONFIDENTIALITY, DATA PROTECTION, AND PRIVACY

Information collected about you and your participation in this study, including all medical and health information as outlined below, will be kept confidential according to privacy laws in this country. The information in both paper and electronic format that Celerion will collect about you will include study records that may contain your name and other personally identifiable information (PII) such as your date of birth. PII is information that directly identifies you, and will also include special information such as your racial or ethnic origin, physical or mental health, sexual life, or genetic data and/or biometric data for the purpose of uniquely identifying you. These records (including any photographs) containing your PII will be kept for a minimum of either two years following the approval of the study drug, or two years after the Sponsor discontinues its research on the study drug, and may be kept for as long as the Sponsor is developing or commercializing the study drug, which may be indefinitely. Your study results will be coded with numbers and/or initials wherever possible. Celerion will keep a list that links your name to your study results. This list will be kept confidential, however it may be provided to the Sponsor and third parties listed below. Celerion may share your PII among Celerion affiliates who are located in other countries around the world. All Celerion affiliates will comply with the terms of this ICF and all Celerion policies and applicable laws and regulations at all times with respect to your PII.

The study results, including your PII, may be disclosed to, audited by, and/or monitored by the people listed below. This is to analyze the study data for the purposes of development and/or commercialization of the study drug, and also to make sure the study was done correctly. In order for this to take place, some third parties will have direct access to your PII, and may copy some of the original records that contain your PII. This includes the laboratory report linking your name to your HIV and/or hepatitis test results. Your original records maintained by Celerion and accessed by the people listed below may contain your PII. PII may be disclosed to the third parties listed below as necessary with respect to any investigation, complaint, or claim, including with respect to any investigation by a governmental authority. These third parties include:

- Regulatory authorities, such as the FDA, MHRA (Medicines and Healthcare products Regulatory Agency), EMA (European Medicines Agency) or Health Canada
- The Sponsor and third parties working with the sponsor
- Celerion and third parties working with Celerion
- Advarra Institutional Review Board (IRB is a group of people who review research studies to protect the rights and welfare of research subjects.)

All of the parties listed above will maintain, use, disclose, transfer and access your PII confidentially and in accordance with applicable law or regulation. While every effort will

be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

Under certain circumstances, some test results will be reported to health and regulatory authorities. This is done when required by law or regulation. If a medical emergency happens, your study results, including your PII, may be given to emergency medical staff not employed by Celerion or the Sponsor.

In addition to the purposes outlined above, Celerion or the Sponsor may utilize your study results, including your PII, for publication purposes, such as presenting on the study results at a conference, publishing in a medical book or journal, writing a white paper about the study, or used for teaching purposes. In the event of any such publication, your PII will be anonymized prior to disclosure to third parties. Neither your name nor other identifiers will be used in any publication or teaching material. Further, Celerion may use your PII to make automated decisions, such as whether or not you are eligible to participate in any other study at Celerion.

You may withdraw your consent from Celerion's collection, use, processing, disclosure, and onward transfer of your PII at any time. If you withdraw your consent, Celerion will not collect any further PII about you except as may be necessary to follow-up on any safety events that may have occurred while you were taking part in the study or as otherwise described in this Informed Consent Form, and you may be removed from the study. Any PII, information, and samples collected from you during any follow-up visits after you withdraw your consent will also remain part of the study. The data collected from you during your participation in the study cannot be deleted even if you stop participating in the study. In addition, any PII, information, and samples collected in connection with the study will remain part of the study after your participation has ended in order to guarantee the validity of the study and to comply with legal and regulatory requirements for obtaining drug authorization and approval. If you request that your PII be erased, the PII already gathered will also still be kept in the study database as necessary to comply with all laws and regulations applicable to clinical trials, however all other PII will be erased from our databases where allowed by applicable law and regulation. Any PII that cannot be erased will be used as described in this Informed Consent Form. In accordance with applicable law, you may request (in writing) to see or have a copy of the study data collected about you. You have the right to request a correction to any PII about you that is not correct. You may not be able to see some data until after the study is over.

By signing and dating this form, you are allowing the collection, processing, use, disclosure, and onward transfer of your PII as described in this consent.

If you have any questions or concerns about Celerion's collection of your PII or the information outlined in this ICF, you may contact the Celerion Privacy Officer by electronic message at privacy@celerion.com; or by mail at 621 Rose Street, Lincoln, NE 68502. In addition, you have the right to enforce the Standard Contractual Clauses against any of the parties mentioned in this ICF under the terms established in the Commission Decision 2010/87/EU (EU) 2021/914 of 4 June 2021 on standard

contractual clause. You also have a right to lodge a complaint with any applicable governmental authority if you believe we have not complied with the requirements of applicable law with regard to your PII.

19. WHOM TO CONTACT ABOUT THE 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 of compensation for being in the study, if any;
- Your responsibilities as a research subject;
- 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 subjects. If you have any questions about your rights as a research subject, 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: Pro00070792.

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.

20. YOUR CONSENT

Your signature and date below verifies that:

- You have had adequate time to read this written Informed Consent Form.
- A study staff member has explained this form to you.
- You have had the chance to ask questions about the study.
- All of your questions have been answered.
- You understand the information in this Informed Consent Form.
- You agree to follow the restrictions of the study.
- You agree to take part in the study and give your consent for study procedures.
- You are aware that nothing contained in this Informed Consent Form waives any of your legal rights as a research subject, nor does it release the Study Doctor, the Sponsor, Celerion, or its agents from any liability for negligence.
- You are aware that you have access to a copy of this signed and dated Informed Consent Form through your MyVeeva account.

Subject Name (Print):_____

Subject Signature: _____ Date: _____

21. FOR CELERION STUDY STAFF

I have discussed this study with the above subject. This person had an opportunity to ask questions. The Subject signed and dated in my presence.

Signature: _____ _____ _____
(Study Staff Member explaining study and ICF) Date Time

22. ACKNOWLEDGMENT FOR PAPER CONSENT

You have been given a signed and dated copy of this document. Initials_____