Screening # _____

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

Study Title:	**EXT608 in Human Healthy Adults; A First-in-Human, Randomized, Double-blind, Placebo-controlled, Single Dose Escalation Study**
Sponsor:	**Extend Biosciences Inc.**
Protocol Number:	**EXT608-101**
Principal Investigator: (Study Doctor)	[redacted]
Telephone:	
Address:	

KEY INFORMATION

You are invited to take part in a research study because you are a healthy adult man or woman 18 to 55 years of age who might meet the study participation requirements. This research study involves the use of a new investigational drug called EXT608. An investigational drug is one that is not approved by the United States Food and Drug Administration (FDA) for human use. It is not available for sale or prescription and can only be used in a study like this one. The study has received approval from the institutional review board. EXT608 is a version of a hormone found naturally in the body called parathyroid hormone that is being studied as a possible treatment for a rare clinical syndrome called hypoparathyroidism. This is the first time that EXT608 will be used in humans.

Extend Biosciences Inc. is sponsoring this research study, and has contracted Pharmaceutical Research Associates Inc. (PRA) to conduct the research.

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. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking

to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

Extend Biosciences Inc. is developing the study drug EXT608.

The purpose of this research study is to:

- Determine the safety and tolerability of a single dose of EXT608
- Determine how EXT608 is absorbed and eliminated by your body; also known as pharmacokinetics
- Determine the effect(s) of EXT608 on your body, particularly changes in calcium levels in the blood and urine; also known as pharmacodynamics
- Determine the effect of EXT608 on vitamin D metabolism
- Determine if there is an immune system effect from EXT608

WHAT WILL HAPPEN DURING THE STUDY

The study will enroll up to approximately 30 healthy adult male and female participants in 6 groups with approximately 4 participants in each group. In each group, 3 participants will be given one dose of EXT608 in a subcutaneous (under the skin) injection, and 1 participant will be given one dose of the placebo in a subcutaneous injection. The placebo will look the same as EXT608 but will not have any active ingredients in it. Whether you receive EXT608 or placebo will be decided by randomization, in other words, by chance (like flipping a coin). Neither you nor the study staff directly involved in your care will know whether you are assigned to receive the study drug or the placebo, although in an emergency, if needed, the study staff can find out.

The planned doses of EXT608 for each group of participants will be determined based on the safety information (blood tests results and any adverse reactions) of the prior dose level. The starting dose will be 4 micrograms, and each participant will receive only one dose of EXT608 or matching placebo. The dose levels for the subsequent groups are planned to be higher than the starting dose, but based upon the review of safety information, may be the same or lower than the previous group's dose.

Your participation in this study will last up to approximately 8 weeks, depending on the duration of the screening period:

Screening visit

Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this informed consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- A negative SARS-CoV-2 test or proof of vaccination may be required prior to your study screening procedures per the site's procedures at the time of your visit.
- You will be asked about your medical history
    - For females of current reproductive potential, this history will include current or plans of pregnancy, and for males of current reproductive potential, plans of conceiving or donating sperm during the course of or within 3 months of completing this study.
- You will be asked about all medications, including over-the-counter, vitamin and/or herbal medications, that you have been, or are currently taking.
    - If you are taking certain medications that, in the opinion of the study doctor, cannot be discontinued or avoided for 4 weeks prior to receiving the study treatment through 1 month after, you will not be eligible for participation.
- You will be asked to confirm your age, month and year of birth, race and ethnicity.
- You will be asked about your drug, alcohol, and smoking history.
- Your blood pressure, pulse rate, breathing rate, and body temperature will be measured.
- You will have a full physical examination.
- Your height and weight will be measured to determine your body mass index.
- An electrocardiogram (recording of your heart's electrical activity and rhythm) will be done
- Blood and urine samples will be collected to assess your general health.
    - Part of the blood test will include a test for the HIV virus (which causes AIDS), and hepatitis B and C viruses. If the test shows you are positive for HIV or hepatitis, you will not be included in this study, but you will have follow-up counseling and medical advice. If your test results are positive, the study doctor may be required by state law to notify the local health department. Signing and dating the consent form means you agree to have this testing. It will not be done without your consent.
- A urine sample will be collected to assess your general health and to test for drugs of abuse and cotinine (a test for nicotine use). If you are female it will also be used to check if you are pregnant.

- This is a study requirement and the results will remain confidential. The tests may reveal that you have previously used illegal drugs. That information will be stored in a re-identifiable (or coded) format. If you test positive for any of these substances, you will be excluded from further participation in this study.

It is possible that more participants will be screened in this study than are needed. This means that it is possible that you could successfully complete the screening phase and are ready to begin the study, but would not be admitted in the study if the target number of participants is achieved and your participation will then not be necessary anymore.

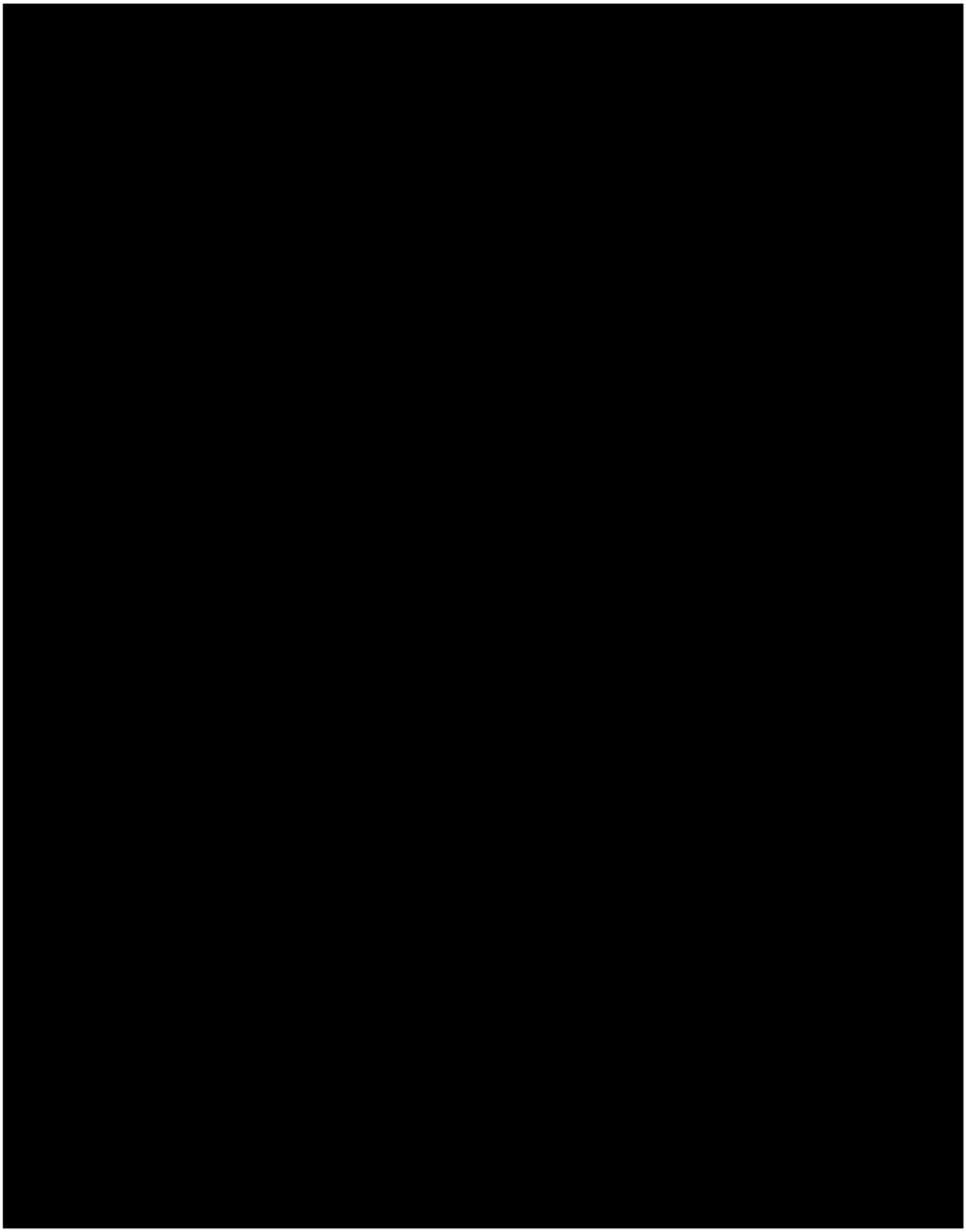
Study Treatment

The study treatment period will include an admission, study treatment, and in-patient follow up period.

[redacted]

You will have the following study visits and undergo the following procedures:

[redacted]



Blood Samples
The total amount of blood drawn for tests will be about [redacted] For comparison, the standard blood donation is about 480 mL. This does not include other blood samples that may need to be taken if the study doctor thinks it is necessary for your safety.

EXPECTATIONS

If you participate in this study, you must:

- [redacted]
- Attend all scheduled visits on time.
- Avoid using the NSAIDs (non-steroidal anti-inflammatory drugs) such as ibuprofen. Please check with the study doctor first if you need to take any medications during the study.

- Males and females of child-bearing age be willing to use an approved double-barrier contraceptive method during and for 3 months after study drug administration.
- Be willing to eat only the standardized meals during the in-patient stay.
- Be willing to abstain from alcohol and drug use during study duration.
- If male, abstain from donating sperm during the course of the study.
- Abstain from intensive exercise during the study (e.g., high impact aerobics, 3-5K runs, marathon training/running, doubles tennis, CrossFit training or weightlifting).
- Abstain from using nicotine-containing products (including but not limited to cigarettes, electronic cigarettes, pipes, cigars, chewing tobacco, nicotine patch or nicotine gum) within 28 days prior to Inpatient Check-in (Day -1) and throughout the study.
- Inform the staff if you decide to withdraw from the study.

You cannot be in this study if you are currently in another research study or if you have been in another research study in the last 30 days. You cannot be in this study if you are taking any illicit drugs (testing will be performed to check for use of drugs) or if you have used prescription drugs in the last 30 days. You may have to wait longer depending upon the type of prescription medication used. You cannot be in this study if you have been a smoker in the last 28 days or have a history of drug or alcohol abuse within the past year.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

This will be the first time that EXT608 will be given to humans. All known potential risks for EXT608 are based on animal data and on the mechanism of action (the proposed way the drug works in the body). The side effects in humans are still unknown.

Potential risks

Based on the mechanism of action of EXT608 and results found in animal studies on EXT608 performed in the laboratory, as well as potential side effects described by patients who were treated with multiple injections of a similar drug, risks may include:

- Nausea
- Constipation
- Vomiting
- Dehydration/increased thirst
- Frequent urination
- Joint pain
- Depression
- Confusion
- Fatigue
- Administration site reactions
- Renal failure or altered kidney function
- Changes to bone marrow

- Altered lab values, such as increases in ALT, AST, as well as changes to liver function, changes to levels of vitamin D, serum alkaline phosphatase, and serum calcium
- Bone lesions
- Changes in red blood cells lymphocytes and eosinophils
- Muscle Weakness
- Sleepiness
- Loss of Appetite
- Dry Mouth
- Metallic Taste
- Headache
- Diarrhea
- Extremity pain
- Upper respiratory infection
- Pre-syncope (feeling light headed, faint)
- Back pain
- Neck pain
- Dizziness
- Increased heart rate
- Heart palpitations (sensation of heart beating fast and/or irregularly)
- Increased calcium in the blood
- Increased calcium in the urine
- Orthostatic hypotension (low blood pressure upon standing from a sitting or lying position)

As with taking any drug, there is a risk of having an allergic reaction. Symptoms of an allergic reaction may include:

- Rash
- Flushing (redness)
- Swelling
- Shortness of breath

Severe allergic reactions can cause dizziness, difficulty breathing or swallowing, a decrease in blood pressure, and could be life threatening. If you feel that you are having symptoms of an allergic reaction, you should notify the study doctor or the study staff immediately.

You should be aware that in laboratory studies of male and female rats, repeated dosing of the parathyroid hormone found naturally in your body caused an increase in the incidence of osteosarcoma (a malignant bone tumor). The osteosarcoma occurrence was dependent on the dose and duration of treatment. An increase in osteosarcoma risk has not been observed with repeat dosing of parathyroid hormone in humans. The risk of osteosarcoma with EXT608 has not been studied. Therefore,

participants who are at increased risk for osteosarcoma are excluded from the study. If you have concerns about your risk, please discuss this with the study staff.

The possible risks and/or discomforts associated with the procedures described in this study include:

- **Blood samples:** You may experience discomfort from blood sampling, and/or placement of the canula, including pain, bleeding, burning swelling, infection or a bruise at the site of the blood draw/canula placement. You could also experience dizziness or faint.
    - In the rare event a PRA employee is accidentally exposed to your blood, we will draw about ½ tablespoon of blood from you and have it tested for HIV, Hepatitis B, and Hepatitis C at a local clinic. The results of the test will be shared with you, the PRA employee involved and the medical team counseling/treating the employee.
- **Electrocardiogram (ECG):** The ECG procedure may cause discomfort during the attachment and removal of the leads to and from your chest, including mild irritation, slight redness, or itching. To reduce discomfort, the study staff may need to shave the hair at the attachment sites.

Unforeseen or Unexpected Risks

Because the study drug EXT608 is investigational and has not previously been administered to humans, there may be other risks that are unknown. Some of these may be life threatening. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed.

Reproductive Risks

The risks to a pregnancy, embryo, or unborn baby (fetus) are unknown. This is why all females of child-bearing age and all males must agree to use approved double barrier contraception during the study and for 3 months after study drug administration. Male participants must also refrain from donating sperm for the duration of the study.

ALTERNATIVES TO PARTICIPATION

This study is for research purposes only. The only alternative is to not participate in this study.

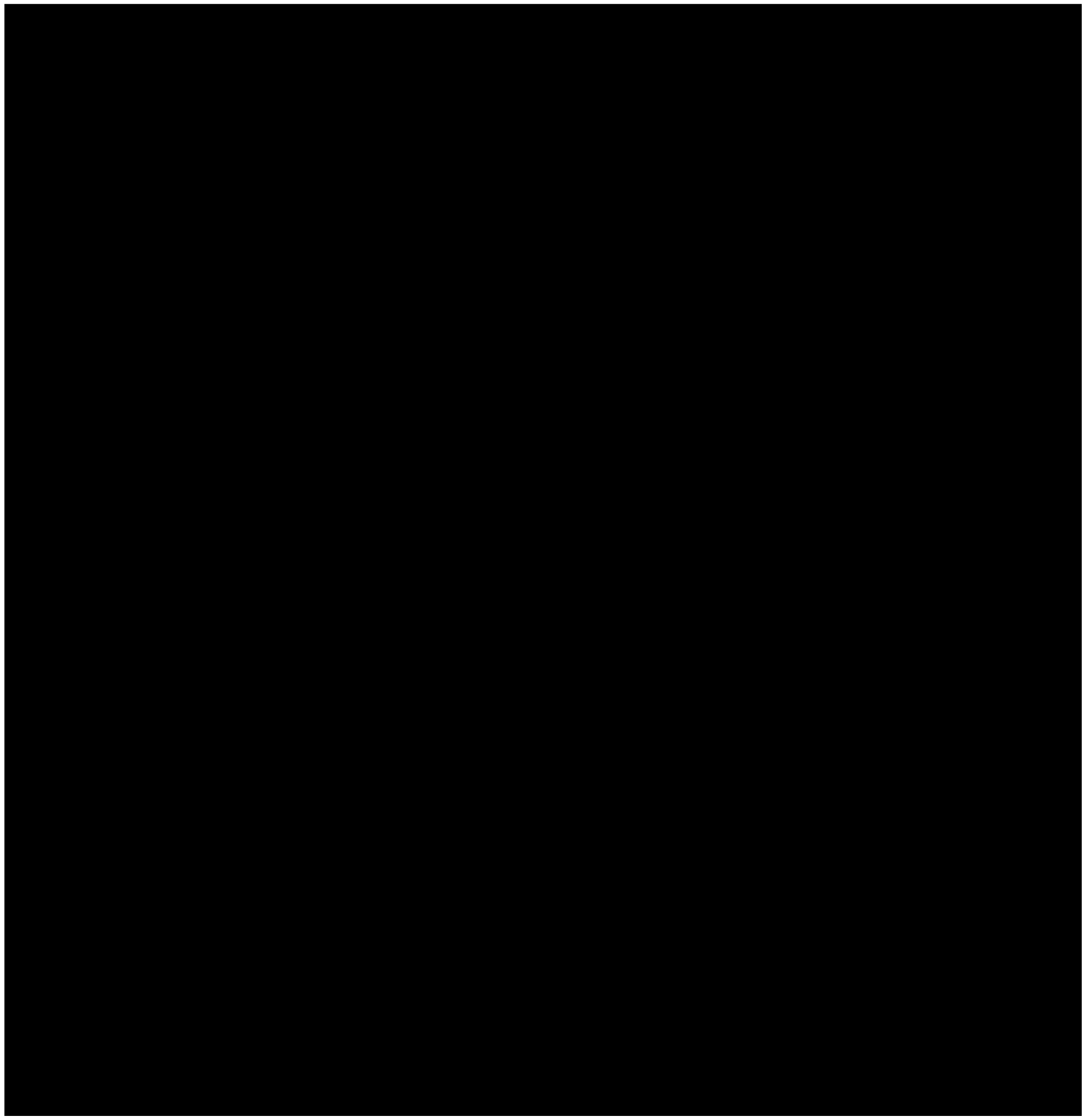
NEW FINDINGS

Any new important information that is discovered during the study that may influence your willingness to continue participation in the study will be provided to you, and in which case, you may be asked to sign a new consent form.

BENEFITS

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION



CONFIDENTIALITY

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent form. The study doctor, the Sponsor or persons working on behalf of the Sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records that identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

Photographs
Some medical conditions are documented by taking digital photographs. If any changes occur anytime during this study, digital photographs of the affected area(s) may be taken to document the condition. If photographs are taken, the photos will be identified only by your subject number and initials and only involve the area where the condition is located. Your face will not be visible.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. Tell the study staff that you think you are ill or have been injured so that they will help you get the care you need.

If you are injured as a result of the proper administration of the study drug(s) or from properly performed procedures done for the purpose of this study, the Sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. The Sponsor will not pay the cost of your medical care that is unrelated to the clinical study drug or the procedures in the treatment plan, or that are pre-existing medical conditions.

Neither PRA nor the Sponsor assumes any independent liability for any injury suffered which is the result of any of the following: pre-existing condition or illness (whether or not the condition or illness has been previously diagnosed); substance abuse or withdrawal from any addictive substance; an accident in the parking lot of PRA; travel to or from PRA for screening, admission, study procedures; any other factor outside the control of the Sponsor, PRA, and their respective employees or agents.

By signing this consent form, you will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes.

COSTS

There will be no charge to you for your participation in this study. The study treatment, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a study-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or if hospitalization is required, alert the treating physician that you are participating in this research study.

An Institutional Review Board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights

as a research participant, and/or concerns or complaints regarding this research study, contact:

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled, and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study and can continue to be used.

If you decide to withdraw from the study, please notify your study doctor or study staff before you withdraw. This notice will allow the study doctor to discuss any health risks or special requirements linked to withdrawing.

The study doctor or the Sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you
- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled
- For administrative reasons

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).
❒**YES** (If yes, please complete the information below)
❒**NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed and dated consent document.

_____	_____
Participant's Printed Name	Time
_____	_____
Participant's Signature	Date
_____	_____
Printed Name of the Person Conducting the Consent Discussion	Time
_____	_____
Signature of the Person Conducting the Consent Discussion	Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study team will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study team may share health data about you with authorized users. Authorized users may include:

- The Sponsor of the study, Extend Biosciences, Inc.
- Extend Biosciences' research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study drug.
- Other qualified researchers, approved by Extend Biosciences, Inc., who may receive individual research results that do not identify you
- Representatives of the Clinical Research Organization (CRO) conducting the study, ICON.
- Representatives of the IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV and hepatitis) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the study team and Sponsor and need to access your information to conduct this study.
- Other study doctors and medical centers participating in this research, if applicable.
- A data monitoring board which oversees this research, if applicable.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your health data will be used to conduct and oversee the research, including for instance:

- To conduct the study, to monitor your health status, to measure the effects of the study drug being studied, and to determine the research results.
- To compare the study drug to other drugs
- For other research activities related to the study drug
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- For regulatory filing purposes
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease

Your permission to use and share health data about you will not end unless you revoke it (take it back).

You may revoke your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

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

_____	_____
Participant's Printed Name	Time
_____	_____
Signature of Participant	Date