APPROVED BY
[redacted] IRB
DECEMBER 19, 2019

INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY

NAME OF SPONSOR:	Biomedical Advanced Research and Development Authority (BARDA)
PROTOCOL NUMBER AND TITLE OF STUDY:	BP-C-19010; "A Randomized, Three-Sequence, Three-Period Crossover Study to Assess the Bioavailability and Pharmacokinetics of a Single Dose of Atropine Administered Sublingually in Healthy Adult Volunteers"
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (INVESTIGATOR/STUDY DOCTOR):	[redacted]
TELEPHONE NUMBER(S), DAYTIME: 24 HOURS:	[redacted]

KEY INFORMATION

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Please take time to review this information carefully. After you have finished, you should talk to the study doctors and nurses about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you. Your participation in this study is voluntary – you can choose whether to participate or not.

This research study is a pharmacokinetics or PK study. This means that what is being studied is how your body processes, and eliminates the study drug. This study is comparing the pharmacokinetics (PK) of 2 different forms of atropine sulfate; atropine sulfate eye drops, delivered under the tongue, and atropine sulfate injection form, delivered in a needle in your vein (intravenously or IV). The goal of this study is to find out if the body processes the atropine sulfate eye drops under the tongue like it does the atropine given through an IV. 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.

If you choose to participate in this study, you will have 4 study visits and one telephone call over a period of about 35 days. Study visit procedures will occur in a single day, and the study visits will last about 8 hours for each visit. A screening visit will determine if you are eligible to participate in the study. If you pass the screening visit you will be asked to return for Visit 1 within the next two weeks. Everyone who participates in this study will receive 2 different dosages of atropine sulfate under the tongue and one dosage of atropine sulfate by vein over the course of the study. The order in which the three different dosages are given will be randomly assigned (like a flip of a coin) during Visit 1. During the study visits, a variety of procedures will be performed including physical exams, blood draws, and drug tests. You will be asked to complete two questionnaires, and information about your medical and substance use history will be collected.

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After Visit 1, you will be released from the clinic and will return to the clinic in about 6 days for Visit 2. The time between clinic visits is called a washout period. This time is necessary to allow your body to remove all traces of atropine from the previous dose. Visit 2 will be similar to Visit 1, and Visit 3 will be similar to Visit 1. The difference between the visits will be the amount of atropine you are given and how it will be given to you (under your tongue, or through an IV). You will have one follow-up phone call about 6 days after Visit 3 where you will be asked about any new symptoms and medications.

Atropine sulfate and the study procedures have risks and side effects that you should be aware of. The main risks you should be aware of are: a fast heart rate, temporary blurry vision, dry mouth and a temporary feeling of warmth. A complete list of known risks is listed later in this informed consent form.

If you choose to participate in this study and are eligible, you will be expected to attend all study visits and follow instructions for all study procedures.

INTRODUCTION

You are deciding if you would like to volunteer for a medical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. Do not sign this form if you have any questions that have not been answered.

The investigator is being paid by the sponsor, Biomedical Advanced Research and Development Authority (BARDA), to conduct this research study. BARDA is part of the U.S. government Department of Health and Human Services.

You must be honest with the study doctor and study about your health history or you may harm yourself by participating in this study. It is extremely important to your health and safety to tell the truth about your medical history and any and all medications that you are currently taking or have taken within the time required for the study. For your continued safety, if you develop any new conditions or start any new medications during the study, you should inform the study doctor right away. A list of people who will have access to this information is listed in the Confidentiality section below.

PURPOSE OF THE STUDY

This study drug (atropine sulfate eye drops) is an approved, marketed drug for the use of dilating the pupils in the eyes to allow for eye examinations. Atropine sulfate is also an approved, marketed drug in an injectable form for the treatment of poisoning by mushrooms and is also used for treatment of nerve gas poisoning. This research study is not intended to treat any condition. This research study is a pharmacokinetics or PK study. This means that what is being studied is how your body absorbs, processes, and eliminates the study drug. This study is comparing the pharmacokinetics (PK) of 2 different forms of atropine sulfate; atropine sulfate eye drops, delivered under the tongue, and atropine sulfate injection form, delivered with an IV. The goal of this study is to find out if the body processes the atropine sulfate eye drops under the tongue like it does the atropine given through an IV. 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.

In this document, you may see the terms “medication” and “treatment”; these are terms used in research studies as mentioned above and does not mean that you will be receiving medical treatment for any condition. These terms apply to the study drugs and parts of the study where you will receive the study drug.

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If you qualify for the study, you will receive two doses (0.5 mg and 1.0 mg) of atropine sulfate sublingually (delivered under the tongue). You will also receive an injected dose (1.0 mg) of atropine sulfate. The order of the drug you receive will be assigned by chance, like the flip of a coin. Administration of the drug is described below:

- A small amount of atropine sulfate (low dose; 0.5 mg) will be dropped under your tongue on one visit;
- A slightly larger amount of atropine sulfate (high dose; 1.0 mg) will be dropped under your tongue on another visit;
- A small amount of atropine sulfate (1.0 mg) will be injected into a vein in your arm on another visit.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

The study will last about 35 days and will require 4 one day visits to the clinic. About 15 healthy men and women, ages 18 through 55, are expected to be in this study.

TO BE IN THIS STUDY

You cannot be in this study if you are in another research study or if you have been in any other research study in the last 30 days. You cannot be in this study if you are taking any controlled substances (illegal and/or prescription). A urine test will be performed to check for the use of these drugs.

Subject Responsibilities:

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. Some of the requirements and restrictions for this study are listed below.

You must agree to follow all the study restrictions and research center rules and regulations. These will be reviewed with you by the study staff. You will be given the rules and regulations to read and sign during the Screening Visit and provided with a copy of the rules. You will be required to wear an ID band for the duration of the in-patient portions of the study, as well as one during any outpatient visits (Screening and Unscheduled Visits). Failure to follow the study restrictions, rules and regulations may result in your compensation being reduced or your participation in the study coming to an end, which will require you to leave the study site.

You can be tested for illicit drug or alcohol use at any time during the study at the discretion of the investigator. If you are discharged from the study because you have a positive drug or alcohol screen result, or refusal to give a specimen or providing urine samples that do not meet temperature requirements, you will not be compensated for any of your participation in the study.

While participating in this research study, you will need to:

- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study.

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WHAT WILL HAPPEN DURING THE STUDY?

Screening:

Before the study starts, you will be asked to sign this consent form, give your health history, and tell study staff if you take any over-the-counter or prescription medicines, vitamins, minerals or herbal products. You will also be asked if you currently or have ever used tobacco or vaping products and if you do use them, how often and how much. An assessment of adverse events (AEs) also called side effects will also be done.

The investigator will do some tests to find out if you can be in the study. These tests include:

- Physical exam including height and weight
- Vital signs (blood pressure, temperature, heart and breathing rates)
- Blood collection for HIV and hepatitis B and C, laboratory tests, and pregnancy test for female subjects
- Electrocardiogram (ECG; used to assess heart rhythm): To perform the ECG, you will have stickers placed on select locations on your chest, arms and legs. The machine connects to these stickers and records the activity of your heart. If there is hair where the stickers need to be placed, small areas may need to be shaved. After the ECG is complete, these stickers will be removed.
- Dry mouth questionnaire
- Vaping and tobacco use questionnaire

The investigator will conduct safety assessments, that may include breath alcohol testing, to decide if you qualify to participate in the study. The investigator may determine that you are not suitable for the study based on protocol requirements or other concerns. If you qualify to take part in this study and go on to participate and receive the study drug, then the following will happen:

Visit 1:

After completing the screening visit, you will be asked to return to the research site some time from the next day to about two weeks later.

You will be assigned by chance to determine the order in which you will receive each of the 3 different doses of atropine at your 3 visits to the site. The order of getting the drug will be defined and is shown in the overall study design figure (Figure 1) below. You have an equal chance of being assigned to any of the 3 dosing sequences. This is an open-label study. This means that you, the Investigator, study staff, and the Sponsor will know the study drugs and the doses that you are given.

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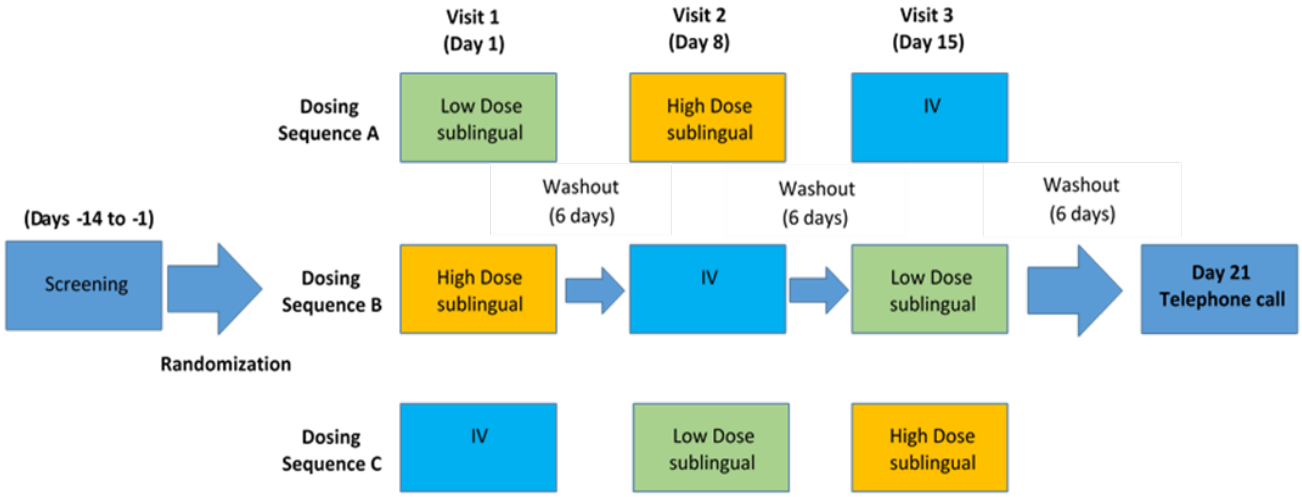
Figure 1: Overall Study Design



There are also periods between the treatments that are called washout. The washout is designed to allow your body to remove all of the drug before getting the next dose. The washout periods are about 6 days long.

When you return to the clinic (Visit 1), the study drug will be administered to you and you will stay for about 8 hours after completion of dosing. During this visit, the following procedures will occur in this order:

Visit 1: Prior to study drug administration

The following will be obtained prior to each dose:

- Medical history
- Whether you have taken any prescription or over-the-counter medicines, vitamins, or herbal preparations.
- If you currently use tobacco or vaping products, the last time you used them.
- Weight
- Vital signs
- Blood collection for PK assessment, before receiving atropine
- Urine collection to test for pregnancy, if female
- Assessment of side effects (AEs) and medications
- Dry mouth questionnaire
- Vaping and tobacco use questionnaire

In addition, the investigator will conduct safety assessments that may include breath alcohol testing, to decide if you should receive each dose.

Study drug administration

You will not be allowed food or drink 1 hour prior to receiving the atropine dose. After 1 hour, you will receive either the low dose or high dose atropine sulfate under your tongue or the atropine in an IV. The

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order of the atropine doses will be based on your assigned dosing sequence. The low and high dose atropine sulfate will be placed under your tongue and you will be asked to try and not swallow for 30 seconds. After 30 seconds, you can swallow as normal. The atropine injection will be performed via an IV in a vein in your arm.

After study drug administration

The following information will be collected and procedures performed:

- Blood pressure and heart rate every 10 minutes for the first hour, every 20 minutes at the second hour, and every 30 minutes for the next 2 hours.
- Blood collection for PK assessments at 2, 4, 6, 10, 15, 20, 30, 45, and 60 minutes, and 2, 4, 6, and 8 hours post-dose from a catheter in your arm; if for some reason the catheter cannot be used, blood sample(s) may be drawn by needle stick
- Dry mouth questionnaire every 10 minutes for one hour
- Assessment of sides effects (AEs) and medications
- Electrocardiogram within 5 minutes, if your dose was the IV dose of atropine. The electrocardiogram may be repeated if the investigator believes it is necessary.

The dry mouth questionnaire will be done by asking you to rate from 1-10 (10 being most dry) the dryness of your mouth, lip and tongue.

You will not be allowed to drink water for 1 hour after dosing. After 1 hour, you will be allowed to drink as much water as you want. Also, based on the dry mouth questionnaire, you may receive water earlier than one hour if certain conditions are met. You will be discharged from the clinic after you have finished all the study assessments.

Visits 2 and 3:

After Visit 1, you will return to the clinic in about 6 days for Visit 2. This is called a washout period and is necessary to allow your body to remove all traces of atropine. Visit 2 will be similar to Visit 1 with respect to dosing and procedures.

After Visit 2, you will return to the clinic in about 6 days for Visit 3. Visit 3 will be similar to Visit 2 with respect to dosing and procedures.

Blood Samples:

Blood samples for screening will be taken from your left or right arm using a needle and a collection vial. The total amount of blood dawn at screening will be about 4 teaspoons (20 mL).

Two teaspoons (10 mL) of blood will be collected each time a PK sample is taken at Visits 1, 2 and 3. The blood will be taken from a flexible tube called a catheter in your left or right arm. If the catheter cannot be used, blood may be drawn by needle stick. You cannot choose how the blood is taken. There will be 14 blood draws in a single dosing visit for the PK samples. The total amount of blood drawn for PK samples over the study will be about 2 cups (440 mL). For comparison, the standard blood donation is about 2 cups (480 mL). Because a catheter is being used to collect the PK blood samples, a small amount of blood will be drawn and discarded to clear the line before each PK blood draw. The amount drawn to be discarded is approximately 84 mL (about 1/3 cup).

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Telephone follow up:

After Visit 3, you will be released from the clinic and about 6 days later will have a follow-up telephone call from the clinic. During this call you will be asked if there were any changes to your general health, and if you have taken any over-the-counter or prescription medicines, vitamins, minerals or herbal products. An assessment of side effects (AEs) will be collected.

HIV AND HEPATITIS TESTING

As required by the study, you must have your blood tested for the hepatitis viruses and for HIV. HIV is the virus that causes AIDS. If you have a positive HIV or hepatitis test you cannot be in the study.

If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be told in private and you will also be told about counseling.

In the interest of public and participant safety, if we cannot reach you by phone to provide you with the HIV, Hepatitis B and/or Hepatitis C results, or you do not respond to the return receipt letter; we will mail positive results to your address of record via certified mail.

It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

Positive test results are required to be reported to the State Department of Health. If you have any questions about what information is required to be reported please ask the investigator or study staff.

Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

POSSIBLE SIDE EFFECTS AND RISKS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Below is a list of the most common side effects of atropine sulfate ophthalmic solution, USP 1%, when administered as eye drops:

- Sensitivity to light
- Blurred vision
- Eye pain/stinging
- Reduced tears
- Dry skin, mouth and throat
- Increased blood pressure
- Increased heart rate
- Restlessness
- Irritability

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- Confusion
- Flushed skin
- Allergic reactions

In published medical articles, atropine sulfate ophthalmic solution has been given safely to over 400 people under the tongue. The most common side effect has been dry mouth.

Below is a list of the most common side effects of atropine sulfate injection solution, USP 1%:

- Increased heart rate (with recurrent use)
- Increased blood pressure
- Dry skin, mouth and throat
- Blurred vision
- Increased eye pressure
- Intestinal problems like constipation and in rare cases a blockage
- Trouble urinating
- Thickening of mucus
- Flushed skin
- Trouble with producing sweat

These effects are generally short-lived and go away within hours. You will be monitored closely after you have received atropine at each visit

Administration of the study drug, like any medication, may cause an allergic reaction. Symptoms of any allergic reaction can include a rash, hives, itching, and/or difficulty breathing, closing of the throat, and swelling of the lips, tongue, or face. It may rarely cause death. You will be monitored carefully after administration of the study drug for signs of an allergic reaction. There are trained medical staff and emergency equipment and medicines available at the study site to treat you in the event of an allergic reaction. If you experience any of the above symptoms or any other significant symptoms, dial 9-1-1 and seek medical attention immediately, and notify the study staff listed on the first page of this consent document.

Subjects who develop any visible skin reaction may have the area photographed to document the extent of the reaction. These photographs will only be labeled with your subject ID number and will not contain any personal information.

Until you know how the drug(s) will affect you, you should use caution by avoiding stairs, not driving a car or working with machinery.

ADDITIONAL RISKS OR DISCOMFORTS

<u>Blood collection:</u>

There are side effects of having blood drawn during the screening visit and for PK samples.

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There may be side effects of having blood drawn such as:

- Fainting
- Redness
- Pain
- Bruising
- Bleeding
- Infection
- Nerve damage
- Blood clots, which may cause inflammation, swelling and pain

If you feel faint, tell the study staff right away.

Electrocardiogram (ECG):

The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If the hair under the patches needs to be shaved, irritation from shaving could occur. Sometimes hair is almost removed when the sticky pads are removed. All efforts will be made to avoid this.

Risks of Intravenous (IV) Injection:

- Infection
- Pain
- Redness
- Bruising
- Irritation from the fluids or medication being given
- Local swelling
- Accidental injecting into a muscle
- Fainting

BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female of childbearing potential (able to become pregnant) and choose to have sex with a male partner, you must have used one of the following methods of birth control for at least 2 months prior to the Screening visit and agree to continue using an acceptable form for the duration of the study (through Telephone Follow-up {Day 21}).

Adequate contraception is defined as a contraceptive method with a failure rate of less than 1% per year when used consistently and correctly and when applicable, in accordance with the product label and includes:

- Oral contraceptives
- Injectable progestogen
- Implants of etenogestrel or levonorgestrel
- Estrogenic vaginal ring
- Percutaneous contraceptive patches

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- Intrauterine device (IUD) or intrauterine system
- Male partner sterilization at least 6 months prior to the female subject's screening visit

A female of childbearing potential is defined as post onset menarche and premenopausal female capable of becoming pregnant. This does not include females who meet any of the following conditions: menopausal (no menstrual period) > 2 years, tubal ligation (tubes tied) > 1 year, bilateral salpingo-oophorectomy (removal of both ovaries and fallopian tubes), or hysterectomy (removal of the uterus).

Even if you use birth control during the study, there is a chance you (if you are female) could become pregnant. If you or your partner are pregnant or become pregnant during the study, the study drug may involve unforeseeable risks to the unborn baby. A pregnancy test is not always right, especially in the early stages of pregnancy.

You cannot be in the study if you are breastfeeding. It is not known whether the study drug can be given to breast fed babies. Therefore, if you are breastfeeding a child you cannot participate in the study.

POSSIBLE BENEFITS OF THE STUDY

You will get no medical benefit from this study, other than the possible benefit of free medical tests. Information learned from the study may help other people in the future.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

Since this study is for research only, the only other choice would be not to be in the study.

CONFIDENTIALITY

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The investigator
- BARDA, High Point Clinical Trials Center, and Rho, Inc.; including monitors and auditors
- The United States Food and Drug Administration (FDA)
- Other state or federal regulatory agencies
- [redacted] IRB

Your information or bio-specimens will not be used or distributed for future research studies even if identifiers are removed.

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.

The Institutional Review Board (IRB), [redacted], and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

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IN CASE OF STUDY RELATED INJURY

If you become ill or are injured while you are in the study, seek medical attention right away, and notify the study staff listed on the first page of this consent document. You should inform the healthcare professional treating you that you are participating in this study.

The study doctor may ask you to stay longer at your current visit, have additional testing or return to the clinic for an additional visit. If you tell the study staff that you think you have been injured, the study staff may ask you to visit the office or refer you to other medical providers for medical care, even after you have completed your regular study visits.

If you are injured as a result of taking the study drug(s) or from 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. You will not lose any of your legal rights or release the sponsor, the Investigator, the study staff, or study site from liability for mistakes by signing this consent document.

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

LEGAL RIGHTS

You will not lose any of your legal rights by signing this consent form.

CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact:

[redacted]

If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room and then notify the study staff listed on the first page of this consent document.

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact [redacted]. [redacted] is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies. [redacted]'s policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

Mailing Address:	OR	Email Address:
[redacted]		[redacted]

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

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If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

[redacted]
between 8 a.m. and 5 p.m. Central Time

[redacted] has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean [redacted] has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

PAYMENT FOR BEING IN THE STUDY

You may receive up to [redacted] for being in the study. You will be paid per completed visit as follows:

Visit	Compensation (amount)
Screening	[redacted]
Visit 1	[redacted]
Visit 2	[redacted]
Visit 3	[redacted]
Follow-up Telephone Call	[redacted]

Total compensation for study completion will be up to [redacted] for completion of all study visits and the Follow-up Telephone Call. If it is determined by your study doctor that you should stop the study early, or you choose to withdraw from the research study, study payment will be prorated based on the study visits you complete as detailed in the table above; this means you will only be paid for the study days you participate in. If you check-into the facility for Visit 1, 2 or 3 and are discharged from the study prior to that day's dosing, therefore not completing that day's activities, you will receive [redacted] compensation for that day's visit within seven (7) days of the visit.

The amount provided for each visit is intended to provide you with compensation for travel and the cost of inconvenience for participating in this clinical study. Please ensure you bring enough funds with you for transport home from all visits. You will receive your compensation within seven (7) days of study completion.

If it is necessary for High Point Clinical Trials Center to obtain medications; study supplies that you were supposed to provide; clothing; toiletries; or transportation outside of what is described in this consent, you will be responsible for these costs. If you are unable to pay the fees upfront, High Point Clinical Trials Center will pay for these expenses and may deduct the cost from your stipend check. High Point Clinical Trials Center is not liable for your safety during travel to and from our site.

If it is necessary for you to return to the research unit for additional safety follow up visits, you will be compensated for travel expenses at [redacted] for each completed visit. For more information, please talk to your study doctor.

No deductions will be withheld from your compensation check for tax purposes; you are responsible for reporting any payment on your state and federal tax returns; being in this study does not make you an

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employee of the sponsor or the study site; at the end of each year, the study site will notify the IRS of all stipends you have received throughout the year.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The investigator, the sponsor, [redacted], or the FDA may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health
- If you become pregnant
- At the request of the sponsor
- At the request of the IRB

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study early, an Early Termination (ET) visit assessments will be performed, when possible. The ET visit may be conducted in clinic or by phone as determined by the investigator. If the investigator determines this ET visit should be conducted in the clinic, the investigator may want to perform a physical exam, including vital signs, an ECG or perform a blood draw to conduct laboratory tests, at their discretion.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation, we will tell you. You can then decide if you still want to be in the study.

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AGREEMENT TO BE IN THE STUDY

If you do not feel that you will be able to comply with any of the restrictions or procedures, please discuss with the study staff prior to signing and dating this consent form.

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand?
❑ **Yes** ❑ **No**

B. Do you understand the information in this consent form?
❑ **Yes** ❑ **No**

C. Have you been given enough time to ask questions and talk about the study?
❑ **Yes** ❑ **No**

D. Have all your questions been answered to your satisfaction?
❑ **Yes** ❑ **No**

E. Do you think you received enough information about the study?
❑ **Yes** ❑ **No**

F. Do you volunteer to be in this study of your own free will and without being pressured by the study doctor or study staff?
❑ **Yes** ❑ **No**

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care?
❑ **Yes** ❑ **No**

H. Do you know that your health records from this study may be reviewed by the sponsor company and by government authorities?
❑ **Yes** ❑ **No**

I. Do you know that you cannot be in another study while you are in this study?
❑ **Yes** ❑ **No**

J. You are aware that the study drug is for investigational purposes only and only for your use, and you are not allowed to share it with any other person.
❑ **Yes** ❑ **No**

K. You are aware that HPCTC is a research facility and not a treating facility and therefore you should continue to obtain your routine medical care with the provider of your choice. You are also aware that HPCTC will refer you to outside medical care if treatment is needed as a result of the study drug or study procedures.
❑ **Yes** ❑ **No**

APPROVED BY
[redacted] IRB
DECEMBER 19, 2019

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS, OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS, YOU SHOULD NOT SIGN AND DATE THIS CONSENT FORM.

Printed Name of Adult Subject	Time
Signature of Adult Subject	Date
Printed Name of Person Explaining Consent	Time
Signature of Person Explaining Consent	Date

You will be given a signed and dated copy of this consent form to keep.

APPROVED BY
[redacted] IRB
DECEMBER 19, 2019

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and research 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 research team may share health data about you with authorized users. Authorized users may include:

- Representatives of BARDA, the sponsor
- Representatives of High Point Clinical Trials Center, the research center
- Representatives of Rho, Inc, a Contract Research Organization that is coordinating and monitoring the study.
- Representatives of [redacted] 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, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research, if applicable.
- A data safety monitoring board which oversees this research, if applicable.

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

- Other research activities related to the study drug.

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 permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor. 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.

APPROVED BY
[redacted] IRB
DECEMBER 19, 2019

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.

❑ I **Voluntarily Agree** to allow study staff to collect, use and share my health data as specified in this form.

❑ I **DO NOT Agree** to allow study staff to collect, use and share my health data as specified in this form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of the Person Obtaining the Authorization

_____ _____
Signature of the Person Obtaining the Authorization Date