I.D. #:_____

Consent to Participate in a Research Study

KEY INFORMATION FOR: A Phase 4 Comparative Trial of Benzathine Penicillin G 2.4 Million Units Administered as a Single Dose versus Three Successive Weekly Doses for Treatment of Early Syphilis in Subjects with or without HIV Infection (DMID Protocol #: 17-0101)

Taking place at: LSU-CrescentCare Sexual Health Center

We are asking you to choose whether or not to participate in a research study that will compare the effect of 1 dose of benzathine penicillin G (BPG) to 3 weekly doses of BPG and to determine whether the effects of 1 dose of BPG or 3 weekly doses of BPG are different in HIV-infected and HIV-uninfected subjects. Syphilis is a bacterial infection that can be transmitted through sexual contact. People infected with syphilis may have sores, rashes, fever, headache, or sore throat. There are 4 stages of syphilis: primary, secondary, latent, and tertiary. This research study will include people who have untreated primary, secondary, or early latent syphilis. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Please ask the research team any questions you have as you read this document. If you have questions later, the contact information for the research investigator in charge of the study is listed below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to understand how well BPG received once or weekly for 3 weeks works against syphilis infections. This study will enroll subjects who have untreated primary, secondary, or early latent syphilis. Your participation in this research will include a total of 8 visits, including today's visit, over the next 12 months. The second visit will be 6 to 12 days from today, and the third visit will be 12 to 24 days from today. The remaining 5 visits will be about 1 month, 3 months, 6 months, 9 months, and 12 months from today. The study procedures for today's visit will take about 90 minutes in addition to any non-study procedures you may be completing at the clinic. The study procedures for each of the future visits will take about 60 to 75 minutes in addition to any non-study procedures you may be completing at the clinic. During each visit, you will have about 1-2 tablespoons of blood drawn. For a complete description of what will be done with the blood samples, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY?

The main reason you might choose to participate in this study is that you would be volunteering to contribute information about how our understanding of how well future patients with syphilis may better be treated. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICIPATE IN THIS STUDY?

The main reason you may not want to volunteer for this study is that you may get no direct benefit from being in the study. For a complete description of benefits, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to participate. You will not lose any services, benefits or rights you would normally have if you choose not to participate.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr Stephanie Taylor of the Louisiana State University Health Sciences Center of New Orleans, Department of Medicine. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is Phone # (504) [redacted] (Office).

If you have questions about your rights as a subject, or want to discuss problems, concerns or questions, or obtain information or offer input, you can contact the Chancellor of the LSU Health Sciences Center of New Orleans at (504) 568-4801.

LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER – NEW ORLEANS

Informed Consent Form

1. **Study Title:** A Phase 4 Comparative Trial of Benzathine Penicillin G 2.4 Million Units Administered as a Single Dose versus Three Successive Weekly Doses for Treatment of Early Syphilis in Subjects with or without HIV Infection (DMID Protocol #: 17-0101)

2. **Performance Sites:** LSU-CrescentCare Sexual Health Center
3308 Tulane Ave., 5th Floor
New Orleans, LA 70119

3. **Investigators:** Principal Investigator: Stephanie N. Taylor, MD
1542 Tulane Ave., [redacted]
New Orleans, LA 70112
Phone: 504-[redacted] (Office)

Co-Investigator: Rebecca A. Lillis, MD
1542 Tulane Ave., [redacted]
New Orleans, LA 70112
Phone: 504-[redacted] (Office)

In case of research injury during business hours contact Dr. Stephanie N. Taylor at 504-[redacted]. After hours, or on weekends and holidays contact Dr. Taylor at the 24-hour number: 504-[redacted]

Sponsor: Division of Microbiology and Infectious Diseases (DMID), National Institutes of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH).
Bethesda, MD
United States

4. **Purpose of the Study:** Syphilis is a bacterial infection that can be transmitted through sexual contact. People infected with syphilis may have sores, rashes, fever, headache, or sore throat. There are 4 stages of syphilis: primary, secondary, latent, and tertiary. This research study will include people who have untreated primary, secondary, or early latent syphilis.

Treating syphilis with an effective antibiotic is important because untreated infection can affect the central nervous or cardiovascular systems and can be passed to sexual partners or to babies born to mothers who have syphilis. Syphilis infection might also increase the risk of HIV-uninfected people getting HIV, or HIV-infected people transmitting HIV to others.

For people who are not allergic to penicillin, syphilis is usually treated with benzathine penicillin G (BPG), 2.4 million units (MU). BPG is approved by the US Food & Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) recommends giving BPG once to treat primary, secondary, or early latent syphilis. Some doctors treat early syphilis with 2.4 MU of BPG weekly for 3 weeks. However, there has not been much research comparing 1 dose of BPG to 3 doses of BPG.

The purposes of this study are to compare the effect of 1 dose of BPG to 3 weekly doses of BPG in all subjects; and to determine whether the effects of 1 dose of BPG or 3 weekly doses of BPG are different in HIV-infected and HIV-uninfected subjects.

5. **Description of the Study:** Approximately 560 adults who are at least 18 years old will be enrolled in this study, which is taking place at 10 sites in the US. The LSU-CrescentCare Sexual Health Center is one of the centers where this research will be conducted. At this site, 60 individuals will be participating in this research study.

   You are being asked to take part in this research study because you have untreated primary, secondary, or early latent syphilis and are at least 18 years old. Your participation is your choice. You do not have to be part of this study. Please ask questions if there is anything you do not understand.

   If you choose to enroll in the study and sign this consent form, the following will happen:

   Visit 1 – Screening/Enrollment (Today; this will take about 90 minutes):

   - You will be asked a few questions about yourself (such as your age, education level, race, and ethnicity) and your health. Some questions are about your sexual activities, medicine use, and current symptoms. Your answers will be kept confidential.
   - We may review your medical records from the past 14 days, if available, to confirm you are eligible for the study. If you have an HIV viral load test result available in your medical record from the past six months, we may note this result.
   - You will be asked to provide contact information, including your telephone number(s), address, and email. The study staff will use the contact information to follow up with you to remind you about your appointments. The study staff may contact you by telephone, text message, or email. You may tell the study staff if you prefer one type of contact over the others.
   - You will have a physical exam that includes taking your vital signs (temperature, heart rate, respiration rate, and blood pressure) and looking at your genitals, rectum, mouth, skin, and lymph nodes.
   - If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.
   - If you are of childbearing potential, you will have a pregnancy test (urine or blood). The pregnancy test must be negative, and you must agree to use an acceptable method of birth control for the entire time you are part of the trial to participate in the study. If you are breastfeeding, you cannot participate in the study.
   - You will have about 1-2 tablespoons of blood drawn for the following:
     - syphilis testing;
     - HIV testing if you have not tested positive for HIV infection in the past (if, at any time during this study, you test positive for HIV infection, you will be immediately provided with counseling and you will be referred for confirmatory testing and clinical care);
     - storage and future testing;
     - CD4 cell count (if you are HIV-infected and have not had your CD4 cell count measured within the last 30 days).
   - You will be tested for chlamydia and gonorrhea if you have not been tested for these diseases and you have been sexually active in the past 14 days. You may also have other sexually transmitted infection testing if study staff think this is needed.

   To be in the study, you must be willing to receive 3 doses of BPG if you are assigned to Arm 2 (described below) and to return for all follow-up procedures. You will not be allowed to participate if you are allergic (or think you may be allergic) to penicillin or similar antibiotics known as beta-lactams.

   After you have completed the tests and procedures above, and if you are eligible to be in the study, you will be randomized (like the flip of a coin) to receive one or the other treatment for syphilis. If you are in Arm 1, you will receive BPG once. If you are in Arm 2, you will receive BPG weekly for 3 weeks. The arm that you will be in will be chosen by chance: half of the people in the study will receive BPG once, and half of the people in the study will receive BPG weekly for 3 weeks. We will tell you which treatment you will receive.

Arm 1: BPG 2.4 MU administered once as a divided dose in each buttock (total of 2 injections).

OR

Arm 2: BPG 2.4 MU administered as a divided dose in each buttock for 3 consecutive weeks (2 injections each week for a total of 6 injections).

At the clinic today, you will receive BPG as two 2-mL injections, one in each buttock. If you are in Arm 1, this will be the only time you will receive BPG in the study. If you are in Arm 2, you will also receive BPG again at Visits 2 and 3. After you receive BPG, while other visit activities are being completed, you will be observed for adverse events that may occur due to receiving BPG.

Study staff will review the study requirements with you and will schedule Visit 2. Study staff will give you a checklist to use to keep track of any side effects you have after receiving the BPG. You will be asked to have this checklist handy for the Non-Visit Contact described below and to bring it with you to Visit 2. If you feel feverish any time between Visit 1 and the Non-Visit Contact described below, you will be asked to take your temperature using a thermometer at home, if possible, and note the highest temperature to report to study staff during the Non-Visit Contact.

Non-Visit Contact (about 24-48 hours after Visit 1):

- Study staff will contact you to ask if you have had any side effects after receiving the BPG. Based on the preferred contact method you indicated at Visit 1, this contact may be a phone call, text message, or email. If you are contacted by text message or email, the message will provide a phone number to call if you have had any side effects.

Visit 2 – Week 1 (Day 7 to 13; this will take about 60 to 75 minutes):

- Study staff will determine if you still have signs of syphilis.
- You will be asked about your health, including questions about your sexual activities, medicine use, and symptoms since your last visit. You may have sexually transmitted infection testing if study staff think this is needed.
- We may review your medical records since your last study visit, if available. If you have an HIV viral load test result available in your medical record since your last study visit, we may note this result.
- If study staff could not contact you by phone call, text message, or email after Visit 1, they will review any side effects that you may have had.
- If you are of childbearing potential, you will have a urine pregnancy test.
- Study staff will ask you if you had any problems.
- You will have a physical exam like at Visit 1.
- If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.
- You will have about 1-2 tablespoons of blood drawn for the following:
    - syphilis testing;
    - storage and future testing.
- If you are in Arm 2, you will receive BPG for the second time as two 2-mL injections, one in each buttock. After you receive BPG, while other visit activities are being completed, you will be observed for adverse events that may occur due to receiving BPG.
- Study staff will review your contact information and schedule you for Visit 3.

Visit 3 – Week 2 (6 to 12 days after Visit 2; this will take about 60 to 75 minutes):

- Study staff will determine if you still have signs of syphilis.
- You will be asked about your health, including questions about your sexual activities, medicine use, and symptoms since your last visit. You may have sexually transmitted infection testing if study staff think this is needed.
- We may review your medical records since your last study visit, if available. If you have an HIV viral load test result available in your medical record since your last study visit, we may note this result.
- If you are of childbearing potential, you will have a urine pregnancy test.
- Study staff will ask you if you had any problems.
- You will have a physical exam like at Visit 1.
- If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.
- You will have about 1-2 tablespoons of blood drawn for the following:
    - syphilis testing;
    - storage and future testing.
- If you are in Arm 2, you will receive BPG for the third and final time as two 2-mL injections, one in each buttock. After you receive BPG, while other visit activities are being completed, you will be observed for adverse events that may occur due to receiving BPG.
- Study staff will review your contact information and schedule you for Visit 4.

Visit 4 – Month 1 (Day 30 ± 7 days; this will take about 60 to 75 minutes):

- You will be asked about your health, including questions about your sexual activities, medicine use, and symptoms since your last visit. You may have sexually transmitted infection testing if study staff think this is needed.
- We may review your medical records since your last study visit, if available. If you have an HIV viral load test result available in your medical record since your last study visit, we may note this result.
- If you are of childbearing potential, you will have a urine pregnancy test.
- Study staff will ask you if you had any problems.
- You will have a physical exam like at Visit 1.
- If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.
- You will have about 1-2 tablespoons of blood drawn for the following:
    - syphilis testing;
    - storage and future testing;
    - CD4 cell count (if you are HIV-infected and have not had your CD4 cell count measured within the last 30 days).
- Study staff will review your contact information and schedule you for Visit 5.

Visit 5 – Month 3 (Day 90 ± 21 days; this will take about 60 to 75 minutes):

- You will be asked about your health, including questions about your sexual activities, medicine use, and symptoms since your last visit. You may have sexually transmitted infection testing if study staff think this is needed.
- We may review your medical records since your last study visit, if available.
- If you are of childbearing potential, you will have a urine pregnancy test.
- If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.
- You will have a physical exam like at Visit 1.
- You will have about 1-2 tablespoons of blood drawn for the following:
    - syphilis testing;
    - storage and future testing;
    - HIV testing (if you have not tested positive for HIV infection in the past).
- Study staff will review your contact information and schedule you for Visit 6.

Visit 6 – Month 6 (Day 180 ± 21 days; this will take about 60 to 75 minutes):

- You will be asked about your health, including questions about your sexual activities, medicine use, and symptoms since your last visit. You may have sexually transmitted infection testing if study staff think this is needed.
- We may review your medical records since your last study visit, if available.
- If you are of childbearing potential, you will have a urine pregnancy test.
- You will have a physical exam like at Visit 1.
- If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.
- You will have about 1-2 tablespoons of blood drawn for the following:
    - syphilis testing;
    - storage and future testing;
    - CD4 cell count (if you are HIV-infected and have not had your CD4 cell count measured within the last 30 days);
    - HIV testing (if you have not tested positive for HIV infection in the past).
- Study staff will review your contact information and schedule you for Visit 7.

Visit 7 – Month 9 (Day 270 ± 28 days; this will take about 60 to 75 minutes):

- You will be asked about your health, including questions about your sexual activities, medicine use, and symptoms since your last visit. You may have sexually transmitted infection testing if study staff think this is needed.
- We may review your medical records since your last study visit, if available.
- If you are of childbearing potential, you will have a urine pregnancy test.
- You will have a physical exam like at Visit 1.
- If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.
- You will have about 1-2 tablespoons of blood drawn for the following:
    - syphilis testing;
    - storage and future testing;
    - HIV testing (if you have not tested positive for HIV infection in the past).
- Study staff will review your contact information and schedule you for Visit 8.

Visit 8 – Month 12 (Day 360 ± 28 days; this will take about 60 to 75 minutes):

- You will be asked about your health, including questions about your sexual activities, medicine use, and symptoms since your last visit. You may have sexually transmitted infection testing if study staff think this is needed.
- We may review your medical records since your last study visit, if available.
- If you are of childbearing potential, you will have a urine pregnancy test.
- You will have a physical exam like at Visit 1.
- If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.
- You will have about 1-2 tablespoons of blood drawn for the following:
    - syphilis testing;
    - storage and future testing;
    - CD4 cell count (if you are HIV-infected and have not had your CD4 cell count measured within the last 30 days);
    - HIV testing (if you have not tested positive for HIV infection in the past).
- Study staff will review your contact information.

Unscheduled Visit
You may be asked to come to the clinic if you have new or worsening symptoms, or if a study doctor feels you should be seen for any reason. At that visit, the following may occur:

- You may be asked about your health, including questions about your sexual activities, medicine use, and symptoms since your last visit. You may have sexually transmitted infection testing if study staff think this is needed.
- We may review your medical records since your last study visit, if available.
- You may be asked to confirm your contact information.
- If you are of childbearing potential, you may have a urine pregnancy test.
- Study staff may ask you if you had any problems.
- You may have a physical exam like at Visit 1.
- If you have one or more lesions (sores), we may swab one or more of them with a cotton swab.

You will only have 8 visits unless:

1. You have a new problem found during a physical examination. If you have a new problem, we may contact you to refer you to another care provider for appropriate treatment outside of the study.
2. You become pregnant during the study. If this happens, you will not receive any more BPG as part of the study, and the Early Termination Visit described below will be completed. Study staff will also contact you to ask about the outcome of your pregnancy, and your baby will be monitored for up to 2 months after birth.

After all tests required for this study are finished, instead of discarding leftover blood samples, we will save them for possible future research related to syphilis. You do not have to agree to allow us to store your samples for future research in order for you to participate in this study. If you choose not allow us to store your samples for future research, they will be destroyed after completion of the study.

You will be asked to confirm your willingness to allow your leftover samples to be stored for future research at the end of this consent form.

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

The National Clinical Trials number for this study is NCT03637660.

6. **Benefits to Subjects:** You may get no direct benefit from being in the study. However, the study may help us understand how well BPG received once or weekly for 3 weeks works against syphilis infections. The study will provide information that might benefit future patients.

7. **Risks to Subjects:** You may become embarrassed, worried, or nervous when answering questions about your sexual activity. All information will be confidential. You may feel worried or anxious while waiting for your test results. Trained study staff are available to help with any feelings or questions you may have.

   You may feel temporary pain or discomfort during blood draws. There is a small risk of infection or bruising at the site of the blood draw.

   You may experience an emotional episode in relation to STI/HIV test results. If that happens, comfort and counseling will be provided.

BPG is the standard therapy for treating syphilis, which means it is not an experimental treatment. BPG is generally well tolerated. However, you may feel temporary pain or discomfort during the BPG injection. Potential side effects after the BPG injection could include bruising, a skin rash, an allergic reaction, or other unforeseen risks.

When patients with syphilis are treated, they may sometimes have a fever and/or flu-like symptoms (chills, muscle pain, weakness, flushing, worsening of skin rash, fast or fluttering heartbeat, joint pain, nausea, headache, or dizziness) while the bacteria causing syphilis are being killed. This is called a Jarisch-Herxheimer reaction, and it usually happens within 24 hours (most often within 6-8 hours) of the first dose. This is not an allergic reaction and usually goes away without treatment in a day. One recent study showed that less than 1 in 3 people will develop this reaction, and that it is mild in most people with early syphilis.

Previous studies have not shown harmful effects for fetuses when BPG is used during pregnancy. However, it is possible there may be some side effects for fetuses that we do not know about yet, and so you will not be allowed to participate in this study if you are pregnant. You will also not be allowed to participate if you are breastfeeding, because BPG is excreted in breast milk and could be harmful to breastfed babies.

8. **Alternatives to Participating in the Study:** You do not have to participate in this study if you do not want to. If you choose not to participate, you will be offered testing and standard treatment for early syphilis with 1 dose of BPG 2.4 MU administered once as a divided dose in each buttock (total of 2 injections) from LSU-CrescentCare Sexual Health Center.

9. **Subject Removal:** If you decide to stop being part of the study any time after you receive the first dose of BPG but before Visit 8, you will be asked to continue scheduled study procedures, if possible, to see how well the BPG worked. If you decide not to complete the remaining visits, you will be asked to return to the clinic for an Early Termination Visit. At that visit, the items listed above for Visit 8 will occur if you agree to them.

   The study doctor has the right to take you out of the study for any of the following reasons:
   - you have a side effect related to BPG;
   - the study (in the opinion of the doctor) would pose a health risk to you;
   - you are not eligible for the study;
   - you fail to follow the study requirements;
   - you receive other antibiotic therapy active against syphilis infection outside the study;
   - the study is stopped.

10. **Subject's Right to Refuse to Participate or Withdraw:** Your participation in this study is completely voluntary. Your doctor may be involved as study staff in this study. You may talk about your care with another doctor who is not part of this study. You do not have to be part of this study. You may decide to no longer participate in the study. If you decide to not allow the use of your confidential information, you will also be withdrawn from further participation in this study. Any information from your participation in this study may continue to be used. To no longer be in this study, you will need to tell the study staff. Your decision to no longer participate in this study will have no effect on your relationship or care with the LSU-CrescentCare Sexual Health Center. Should significant new findings take place during the course of the research that may relate to your willingness to continue participation, that information will be provided to you.

11. **Subject's Right to Privacy:** Participation in a research study may involve a loss of privacy. We will do our best to make sure that your personal information is kept private. Your records will be kept as confidential as possible under the law. Your individual identity will not be used in any reports or publications resulting from this study.

To help us protect your privacy, we have a Certificate of Confidentiality (CoC) from the NIH. The researchers can use this CoC to legally refuse to give information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

Because it is very important that we can contact you during the study, you will be asked to provide contact information like your address, phone number(s), and email address. We ask for at least two additional contacts (e.g., family member or friend) who know how to reach you or would have new contact information for you. The research staff may call your contact(s) if your numbers are changed or disconnected. We will not give out confidential information if we need to get in touch with your contacts.

12. **Release of Information:** The researchers will use the CoC to resist any demands for information that would identify you, except for reporting of communicable diseases to state and local health departments. The CoC will not be used to prevent disclosure to state or local authorities for child and elder abuse, sexual abuse, or wanting to harm yourself or others. The CoC cannot be used for information in your medical records.

    The NIH, as the sponsor of this research study, the FDA, and the LSUHSC-NO Institutional Review Board (IRB) of the institution where the study is being conducted may review and obtain information (which may include your identifiable medical information) related to this study. (An IRB is a committee that watches over the safety and rights of research participants.) The sponsor has an agreement with a company that will be the monitoring group to review the research study. Staff from the clinical monitoring group may review study information (which may include your identifiable medical information) for accuracy and completeness.

13. **Financial Information:** The medicine that you get as part of this study will be provided free of charge. There will be no cost to you to take part in the study. Your insurance will not be billed for any of the study procedures. Treatments or procedures done according to local clinic practice may be charged to your insurance.

    If you complete the procedures, you will receive the following for your time, transportation, and other expenses: **Visit 1**: $40.00 debit card; **Visit 2**: $50.00 added to same debit card; **Visit 3**: $50.00 added to same debit card; **Visit 4**: $50.00 added to same debit card; **Visit 5**: $50.00 added to same debit card; **Visit 6**: $50.00 added to same debit card; **Visit 7**: $50.00 added to same debit card; **Visit 8**: $50.00 added to same debit card.

    The reloadable debit card will be activated by your study doctor or nurse within 48 hours of your Visit 1, and money will be added to the same debit card by your study doctor or nurse within 48 hours of each visit. This will be done by computer using the card company's website. If the card is lost or stolen, you will have to contact the Greenphire Company at 215-[redacted]. You will have to pay $7.00 for a new card if it is lost or stolen. Clinic staff will not be able to help you get another card. You must call the company yourself. No follow-up visit will be required.

    The staff at LSU-CrescentCare Sexual Health Center makes efforts to prevent and treat any injuries that might happen. If you think you are hurt because of this study, contact the study staff at LSU-CrescentCare Sexual Health Center right away.

    Emergency care for injuries related to this study will be done by the staff of LSU-CrescentCare Sexual Health Center. It is possible that LSU-CrescentCare Sexual Health Center may bill your insurance for the cost. If your injury needs more medical care, you may be responsible for the costs. The NIH will not pay for treatment or provide any compensation in the case of injury. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the federal government. You do not give up any legal rights by signing this form.

14. **Signatures:**

The study has been discussed with me and all my questions have been answered. Additional questions regarding the study should be directed to the investigators listed on page 1 of this consent form. If I have questions about subject's rights, or want to discuss problems, concerns or questions, or obtain information or offer input, I can contact the Chancellor of the LSU Health Sciences Center New Orleans at (504) [redacted]. I agree with the terms above, acknowledge I have been given a copy of the consent form, and agree to participate in this study. I have not waived any of my legal rights by signing this consent form.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

After all tests required for this study are finished, instead of discarding leftover blood samples, we will save them for possible future research related to syphilis. We may also collect additional blood for future research related to syphilis. The swab samples we take from syphilis lesions will be used to sequence syphilis bacteria DNA but not your human DNA. No genetic testing will be done on left over specimens.

We may share some of these samples and the information we collect about you with researchers outside of the study. The samples could be tested in the future to research topics related to syphilis. The samples and the information we collect about you will not have your name or other identifying information on them at any time; they will only have a coded number on them. These specimens will not be linked to your identity. We will share only information that was collected as part of the study.

You do not have to agree to allow us to store your samples for future research. If you choose not to allow us to store your samples for future research, they will be destroyed after completion of the study. There is no time limit on how long your samples will be stored. Your medical care at this clinic will not be affected if you do not allow us to store your samples for future research.

If you decide at any time that you do not want the samples stored for future research, you must contact the study staff who will then notify the laboratory/specimen archive staff. Laboratory staff will mark the samples with a "destroy" label and destroy them at the end of this study, or they will remove the samples from storage and destroy them as soon as possible.

Please write your initials in one of the spaces below. You will be treated the same no matter which you choose.

I give permission for my specimens to be stored for future use as described above.

Yes _____ (Initial – **Do not check**) No _____ (Initial – **Do not check**)

I may withdraw my consent for storage of my samples by submitting a request in writing to the investigator.

_____ _____
Signature of Subject Date

The study subject has indicated to me that the subject is unable to read. I certify that have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part.

_____ _____
Signature of Reader Date

_____
Printed Name

_____ _____
Signature of Witness Date

_____
Printed Name

CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date