[LOCAL SITE NAME] Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Network Epidemiology of Syphilis Transmission (NEST): Understanding the Epidemiology of Syphilis in the United States

Principal Investigator: [NAME of PI, qualification]

Sponsor: US Centers for Disease Control and Prevention (CDC)

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with [LOCAL SITE].
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The United States is currently experiencing an epidemic of the sexually transmitted infection syphilis. Syphilis is a major public health problem. It can increase HIV risk, and if left untreated, syphilis can also lead to serious physical complications such as blindness. In Columbus, men who have sex with men (MSM) have the highest prevalence of syphilis. This study is being done to understand how the sexual networks of MSM relate to syphilis transmission. (A sexual network is like a web, with linkages drawn between men who have had sex with each other. It can be used to answer questions about how infections spread across populations of people). Understanding how the shape and density of sexual networks relate to syphilis risk can help researchers develop more effective programs for syphilis prevention.

2. How many people will take part in this study?

About 200 men from [SITE LOCATION] will be enrolled in the study. Overall across the three cities where the study is being done, about 600 men will participate.

3. What will happen if I take part in this study?

Today, you will complete a survey that asks about your background, your sexual behaviors, your healthcare access and other topics. We will also ask you to name your recent sex partners, so that we can construct the sexual network. You will also have a physical exam, where a clinician will collect urine, blood (30ml, or about 2 tablespoons), and swabs from your throat, rectum and urethra. These samples will be tested to determine whether you have infection with syphilis, HIV, chlamydia, gonorrhea or another infection called *Neisseria meningitidis*. Some blood or blood products (such as serum or peripheral blood mononuclear cells (PBMCs)) will be sent to CDC for additional testing.

If you agree, we will also collect an additional sample of 10ml of blood to store for future research at CDC, but you do not need to agree to that sample to take part in this study.

Today we will also invite you to recruit up to 6 men to join this study. These men can be social contacts (friends or acquaintances) or sexual partners. We will describe this process in more detail during today's visit. Recruiting potential participants is not a requirement to take part in this study.

We will ask you to download a smartphone application that will prompt you to answer brief questions about your behavior. (This is called 'Ecological Momentary Assessment' or EMA). The study staff will train you to use the EMA app. When it opens, you will be asked a series of questions about your recent behavior. These questions will take about 3 minutes to answer. You will be prompted to answer these questions approximately once a week.

You will return for follow-up visits every three months for the next 2 years. Each follow-up visit will be similar to today: you will complete a sexual behavior survey, name your recent sex partners, and have a physical exam with collection of blood, urine, and swabs from your throat, rectum and urethra.

If you are infected with a curable sexually transmitted infection today or during later visits, the study will inform you and will schedule a time for you to come for treatment. Participants in this study will receive regular care for infections. There is no change to treatment or follow-up as a result of being in this study.

This study does not provide HIV-related treatment or care. If you are found to be HIV-positive, you will be linked to care with the [LOCAL PROVIDER] or to another provider of your choice. Being "linked to care" in the context of this study means connecting you to a provider or healthcare facility who agrees to see you for HIV care.

4. How long will I be in the study?

After your visit today, you will return every three months for two years. Each visit will take about one hour of your time.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with [LOCAL SITE].

6. What risks, side effects or discomforts can I expect from being in the study?

There is a risk of feeling uncomfortable or embarrassed when answering sensitive questions about your sexual behavior. Some people may feel discomfort when a clinician collects biological samples such as blood, or swabs from your throat or genitals. There is also a risk of loss of confidentiality, though study staff will make every effort to keep your information confidential. In particular, some information for this study is transmitted through the Internet, so there is a chance (as with all online activities) that someone could access your information without permission. In some cases, this information could be used to identify you.

7. What benefits can I expect from being in the study?

There may be no direct benefit to you from participating. Some potential benefits could include increasing awareness of risk-taking behavior and learning whether you are infected with sexually transmitted infections (including syphilis, HIV and other infections). This testing may allow you to be diagnosed with these infections earlier than you otherwise would. You may also benefit from the knowledge that you may help develop future programs to improve sexual health among MSM.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs to you to participate in this study.

10. Will I be paid for taking part in this study?

Yes. You will receive $75 after this visit and $75 after each follow-up visit (3, 6, 9, 12, 15, 18, 21 and 24 months after enrollment). For each new participant you recruit who joins the study, you will also receive $20. You will receive $3 for each weekly smartphone survey that you complete.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at [LOCAL PROVIDER OR CARE FACILITY].

The cost for this treatment will be billed to you or your medical or hospital insurance. [LOCAL SITE] has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at [LOCAL SITE] reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information private to the extent permitted by law. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- [LOCAL SITE] Institutional Review Board or Office of Responsible Research Practices;
- The sponsor of the study, the US Centers for Disease Control and Prevention (CDC), its agents or study monitors; and
- Your insurance company (if charges are billed to insurance related to care sought outside of this study).

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - HIV, syphilis and other sexually transmitted infections
  - Other reportable infectious diseases

Physical exams
Laboratory and other test results
Questionnaires

II. Who may use and give out information about you?

Researchers and study staff with approved access to study data.

III. Who might get this information?

- Authorized [LOCAL SITE] staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

IV. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

V. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VI. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VII. What if I decide not to give permission to use my health information?

In that case, you will not be able to be in this research study. However, this decision will not lead to a loss of benefits to which you are otherwise entitled.

VIII. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

IX. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact the researcher leading this study, [NAME OF LEAD RESEARCHER], at [PHONE NUMBER] or by email at [EMAIL ADDRESS].

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Privacy Officer [NAME OF PRIVACY OFFICER], at [PHONE NUMBER]; or by email at [EMAIL ADDRESS].

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact [NAME] in the Office of Responsible Research Practices at [PHONE NUMBER].

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact the researcher leading this study, [NAME OF LEAD RESEARCHER], at [PHONE NUMBER] or by email at [EMAIL ADDRESS].

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	Signature of subject
	Date and time AM/PM

Consent to store biological samples for future testing

The study team would like to keep blood (including blood products such as serum, plasma or peripheral blood mononuclear cells (PBMCs)) from each participant, from each visit, for future sexual health research. These samples will be kept at the CDC Roybal campus, LRRB, 3rd floor of building 23, LER 435, Atlanta, Georgia. Security clearance is required to gain access to this building. Blood samples will be labeled only by study ID number, not by participant name. You can still participate in the study even if you do not permit storage of these samples.

I agree that the study may store 10ml additional blood/blood products from each study visit for future sexual health research. ☐ Yes ☐ No

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of subject	Signature of subject
	Date and time AM/PM