Title: Parrying the Pitfalls of PrEP: Preventing Premature PrEP Discontinuation and STIs among MSM

Date: 03/26/2024

NCT # NCT05072093

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 200 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question of how we can maximize the benefits of HIV pre-exposure prophylaxis (PrEP) for HIV-negative men who have sex with men (MSM). We also plan to study how use of sexually transmitted infection (STI) post-exposure prophylaxis (PEP) can prevent new infections. You are being asked to be in this research study because our focus for this study is men who have sex with men who are HIV negative and who could benefit from PrEP and STI post-exposure prophylaxis (STI PEP).

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 2 years. The researchers will ask you to do the following: (1) decide if you want to start Daily Oral PrEP, On-Demand Oral PrEP, Injectable PrEP (must be initiated outside study) and/or STI PEP (use of an antibiotic after unprotected sex); (2) attend a combination of in-person and remote study visits as often as every 3 months depending on study activities you choose; (3) provide laboratory specimens for HIV, STIs and other lab tests related to PrEP and STI PEP use; (4) keep track of use of PrEP and/or STI PEP in study's mobile app; and (5) complete online behavioral surveys. You will be paid for most study procedures.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. Additionally, you could benefit if you choose to use PrEP and/or STI PEP since both of these are prevention strategies for HIV and STIs.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious, such as the side effects of PrEP and STI PEP, loss

of privacy and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
If you choose not to participate in this study, there are still ways to obtain PrEP from community providers and/or your physician.

Costs
You might have to pay for some of the optional study activities, in particular those that are not covered by your medical insurance. There are patient assistance programs that the study team will help you explore if your insurance won't cover the cost or if you don't have health insurance.

The study team can help you work out how much you might have to pay. There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Take time to consider this and ask any questions you would like.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Parrying the Pitfalls of PrEP: Preventing Premature PrEP Discontinuation and STIs among MSM

IRB #: 00000608

Principal Investigator: Patrick Sullivan, DVM PhD, Epidemiology Department, Rollins School of Public Health, Emory University

Sponsor: National Institutes of Health

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you.
- Please listen to the study doctor or study staff explain the study to you.
- Please ask questions about anything that is not clear.

You can take a copy of this consent form to keep. Feel free to take your time thinking about whether you would like to participate in the study. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?
The purpose of this study is to learn how we can maximize the benefits of HIV pre-exposure prophylaxis (PrEP) for HIV-negative men who have sex with men (MSM). PrEP is a medication people at risk for HIV take to prevent getting HIV from sex or injection drug use. We also plan to study how use of sexually transmitted infection (STI) post-exposure prophylaxis (PEP) (e.g., taking doxycycline after unprotected sex) can prevent new STI infections.

What will I be asked to do?
You will be asked to participate in a research study and to download the study app to your smartphone. You will be offered voluntary opportunities to start PrEP and/or STI PEP and we will ask you to take brief surveys about your use of them. All study participants, regardless of their PrEP and STI PEP use, will attend study visits and will provide laboratory specimens for HIV, STI and non-prescription drug testing. The duration of the study is 24 months.

Initial Procedures: Your first (baseline) study visit will involve study counselors providing an overview of the study, confirming your eligibility, and engaging you in the informed consent process. The baseline study visit will last between 2-3 hours. You will complete a behavioral survey on the computer. Staff will assist in downloading and orienting you to the study app on your smart phone. After a detailed explanation of the study intervention options—daily, on-demand or injectable PrEP and STI PEP—you will be given the option to start these. If you elect to start any of them, staff will assist you by completing the paperwork, if necessary, to help obtain financial assistance for Oral PrEP use, and to receive STI PEP at no cost. If you elect to start PrEP and/or STI PEP, the study counselor will explain the weekly and/or monthly surveys you will receive and how to complete them through the study app. These surveys will ask questions about your experience taking the medications. You will be prescribed Oral PrEP and/or STI PEP through the study if you choose to start them. If you choose to start Injectable PrEP, counselors will provide you with a list of local providers. You will have to contact these providers on your own to start the medication. Study counselors will explain the Injectable PrEP monthly surveys you will receive and how to complete them through the study app. If you do not choose to start PrEP and STI PEP at the baseline study visit, you can choose to begin them at a later point when study staff will ask you about your interest in starting.

Specimen collection for laboratory testing will be done in-person at the PRISM Health Research Clinic for the baseline, 12 and 24-month study visits and through a self-collected home test kit every 3 months if you choose to start Oral PrEP and/or STI PEP. If you start Injectable PrEP, you will not have 3-monthly testing through the study. Laboratory testing will have to be done by the local provider you choose for your Injectable PrEP. At each in-person visit, we will draw your blood (approximately 2 tablespoons) towards the beginning of the visit so that we can perform an HIV rapid test to confirm you are HIV-negative and eligible to take part, or continue, in the study. We will also use your blood to test for syphilis. We will have you self-collect oral, rectal and urine samples to test for gonorrhea and chlamydia, and a nasal swab for antibiotic resistance testing. All participants will have their urine screened for non-prescription drugs. If you elect to start Oral PrEP and/or STI PEP, we will test your blood to verify that you are HIV-negative with a commercial laboratory-based test. If Oral PrEP is being started, your blood will be tested for hepatitis B and creatinine (kidney function) level. At the three in-person study visits, an additional rectal sample will be collected for future microbiome research. At the baseline, 12 and 24-month visits, a nasal swab will also be collected to understand the development of antibiotic resistance. The additional rectal and nasal samples will be stored without any personally identifying information for up to 20 years and will be used to learn about, prevent, or treat health problems.

Your laboratory results for HIV, STI, hepatitis B, and kidney function will be shared with you through the study app. We will not return results of any non-prescription drugs detected. Additionally, microbiome and antibiotic resistance results are for research purposes only and will not be returned to you. We will share laboratory results with the study clinicians so that any abnormal results can be flagged, and clinical staff can follow-up. If you have an abnormal test result, a study or clinical staff member will reach out to discuss next steps for care and treatment, if needed.

Specimens for STI testing will include a self-collected rectal swab sample, a throat swab sample, and a urine sample. Rectal swab collection will involve inserting the tip of a swab about one and a half inches into your rectum to collect a sample. Throat swab collection will involve using a swab to reach the back of your throat, collecting a sample with the swab tip. Urine sample collection will involve urinating in a cup and transferring urine with a pipette from the cup to the sample tube. You will insert a swab into each of your nostrils and swirl around 10 times. Your urine sample will also be used to test for non-prescription drugs. The counselor will explain to you how to self-collect each of the specimens and there will be instructions posted in the bathroom as well. If you test positive for gonorrhea, we will ask you to provide a second sample in-person so that we can determine if your infection is resistant to doxycycline.

Home Specimen Collection: For the self-collected home testing every 3 months if you start Oral PrEP and/or STI PEP, you will receive printed instructions on self-administered finger prick blood draw methods. You will conduct 1-2 self-administered finger pricks, similar to the practice someone with diabetes might follow on a regular basis. Although this

is a smaller needle than used for a traditional blood draw, you may experience more or less pain from it. The finger prick device is spring-loaded and encased in a plastic shell, so you will not see or manipulate the needle. Following the finger pricks, you will collect blood by blotting your finger on collection paper and by using a collection tube. This will be a small amount of blood, about 6 drops total. If the sight of blood makes you feel light-headed, or if at any point you feel uncomfortable or wish to stop participating, please immediately notify study staff. You will also self-collect rectal, urine and throat samples. Collecting the specimens will take you at most one hour. You will receive detailed printed instructions regarding how to self-collect each of these samples and how to ship them to the laboratory with the postage paid mailer. If you start Injectable PrEP, you will not have 3-monthly testing through the study. Laboratory testing will have to be done by the local provider you choose for your Injectable PrEP.

If you have a positive test for HIV or an STI, state law requires us to report that positive test to the State Health Department for the purposes of statistics and service planning. Study staff will assist you in linking to care and treatment as soon as possible and will order some additional labs to check your immune status and viral load. Individuals testing HIV positive will not continue in the study once diagnosed. It is possible that the Health Department could contact you to offer referrals for care or help with getting your partners tested. These procedures are the same as if you were tested at a doctor's office or a clinic outside of this research study.

Follow-up Procedures: You will be emailed a link to complete an online behavioral survey at home at months 4, 7, 12, 19 and 24. The surveys will take you approximately 20-30 minutes to complete. You will also participate in an in-person study visit at months 12 and 24. At these study visits, you will be tested for HIV, STIs and non-prescription drugs in the same way as the first (baseline) study visit. The 12 and 24-month study visits will last approximately 90 minutes. If you are on Oral PrEP at the 12 and/or 24-month study visit, you will have your creatinine (kidney function) level tested again and we will draw a blood sample to test the level of PrEP in your body. PrEP levels are for research purposes only, and these results will not be returned to you.

Oral PrEP/STI PEP 3-Monthly Clinical Monitoring: If you begin Oral PrEP and or STI PEP, you will have 3-monthly clinical monitoring testing similar to what would be done in the non-research setting. You will self-collect specimens at home to test for HIV and STIs so that clinical study staff can monitor your health. Since PrEP and STI PEP are recommended in combination with safer sex practices, you will also be encouraged to have sex with condoms throughout the duration of your participation in the study and at all times that you are on PrEP and/or STI PEP. If you start Injectable PrEP, you will not have 3-monthly testing through the study. Laboratory testing will have to be done by the local provider you choose for your Injectable PrEP.

Peer counselor: If you are having challenges taking daily Oral PrEP, a peer counselor will be available to provide support and help you work through any personal challenges that may be interfering with your ability to take it consistently. Even if you choose not to take daily Oral PrEP, the peer counselor will be available to provide you support should you request it.

Timeline of Study Visits, Activities and Labs

	Baseline	3 months	4 months	6 months	7 months	9 months	12 months	15 months	18 months	19 months	21 months	24 months	Key
Study visit for all participants													All participants
4, 7, 12, 19 & 24-month online surveys													
HIV, STI, urine drug screening; nasal and rectal swabs for future research													
Additional HIV and STI testing every 3 months and testing for level of PrEP, if indicated													Oral PrEP and STI PEP participants. Schedule will shift if someone starts after baseline.
Kidney function testing at Oral PrEP start and every 12 months													Reflects a participant starting Oral PrEP at baseline. Schedule will shift if someone starts after baseline.
Hepatitis B testing at Oral PrEP start													
Resistance testing for persons with positive Gonorrhea test													Could occur at any time during the study.
Weekly surveys for Oral PrEP/STI PEP users													Start/duration of these activities will vary by participant.
Monthly surveys for daily PrEP and injectable PrEP users													
Peer support for Oral PrEP users													

How will my medicine be provided?

Oral PrEP medicine that you choose to take will be dispensed by the pharmacy of your choice. Injectable PrEP will be dispensed by the local provider who administers it. If you have questions about PrEP, you should ask the principal investigators, clinicians, or study staff. You may also call the pharmacy if you have questions about the medicine. STI PEP medicine will be shipped to you directly from the Emory Investigational Drug Service. If you have questions about STI PEP medicine, you should ask the principal investigators, clinicians or study staff.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may still be used for this study. If you withdraw from the study and would like your data not to be used and your samples to be destroyed, inform the study staff.

What are the possible risks and discomforts?

There are minor risks associated with this study. You may experience physical discomfort from the laboratory-based and/or self-administered specimen collection, including the blood draw, finger prick, rectal swab, throat and nasal swabs. You may also experience bruising around the site of the blood draw and finger prick. You may find out that you are infected with HIV or another STI which can be upsetting. If you are infected with HIV or another STI, we will help you find a doctor.

Some of the questions in the surveys are personal and may make you uncomfortable. We hope you will answer all questions to the best of your ability. You can choose not to answer any question that makes you uncomfortable. We will keep information about your HIV and STI testing, and your responses to the survey questions, confidential. Although we

will take steps to reduce the chance, there is a small chance that someone other than study staff might see your study information. More information about how we will protect your confidentiality is below.

There are risks associated with taking Oral PrEP that would be the same if you took Oral PrEP outside of the study. The most common risks and discomforts associated with PrEP are possible side effects including nausea/vomiting, diarrhea, abdominal pain, abnormal blood tests, headache, and weight loss. These side effects are uncommon and usually resolve within the first month of taking PrEP. The less common risks and discomforts associated with PrEP are a decrease in bone mineral density, and moderately decreased renal (kidney) function. Rare but possible risks include acute renal injury. We will monitor your creatinine levels to decrease any potential risks related to renal function.

The most common risks and discomforts associated with Injectable PrEP are possible side effects including pain, tenderness, hardened mass or lump, swelling, bruising, redness, itching, warmth, loss of sensation at the injection site, abscess, discoloration, diarrhea, headache, fever, tiredness, sleep problems, nausea, dizziness, passing gas, stomach pain, vomiting, muscle pain, rash, loss of appetite, drowsiness, back pain, and upper respiratory infection. Persons who take Injectable PrEP may have adverse reactions to the drug. These adverse reactions are uncommon and include allergic reactions, liver problems, and depression or mood changes. The safety of Injectable PrEP has been established through multiple clinical trials and is FDA approved and indicated for HIV-1 prevention. Clinical monitoring to ensure medication is being used safely will be done by the local provider you choose to initiate the injection. The local provider will discontinue or modify use of Injectable PrEP to ensure safety.

There are risks associated with taking STI PEP or doxycycline that would be the same if you were prescribed doxycycline outside of the study. The most common risks and discomforts associated with doxycycline include nausea/vomiting, diarrhea, abdominal pain, and abnormal blood tests. It is currently not known whether taking doxycycline as STI PEP could lead to antibiotic resistance including antibiotic resistant gonorrhea or syphilis.

If you will be taking the study drug at home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about how we can prevent early discontinuation of PrEP and about how effective STI PEP is for preventing new infections. You will be tested for HIV and STIs and be linked to treatment if necessary. You will have a lower chance of acquiring HIV if you take PrEP as directed. You will also have a lower chance of acquiring chlamydia, syphilis or gonorrhea if you take STI PEP as directed. The study results may be used to help others in the future, if the information we learn helps improve HIV and STI prevention services.

Will I be compensated for my time and effort?

You will receive a $125 incentive for completing all baseline procedures including an online survey, meeting with a study counselor, and collecting specimens for laboratory testing both self-administered and by a phlebotomist. You will receive a $100 incentive for completing the 12-month survey and study visit and $100 for completing the 24-month survey and study visit. You will receive $40 for completing the online surveys at months 4, 7 and 19. If you elect to take daily Oral PrEP, you will receive $5 for completing each weekly survey for the first two weeks of use and, after that, $10 for each completed monthly survey. If you elect to take Injectable PrEP, you will receive $10 for completing each

monthly survey. If you elect to take Oral PrEP on-demand and/or STI PEP, you will receive $5 for each weekly survey you complete. Payment for monthly and weekly surveys will be done the second week of the following month. If you need to return to the clinic for a blood draw or other specimen collection outside of your scheduled study visit, we will pay you $20 for the visit. If you do not finish the study, we will only compensate you for the visits and surveys you have completed.

You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be compensated, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?

If you decide not to enter this study, there are other options to access HIV testing, STI testing, and PrEP outside of this research study. The study staff will discuss the other options with you. You do not have to be in this study to receive HIV testing, STI testing or PrEP. Taking part in this study, however, may make you unable to participate in some other research studies if they exclude people who are currently taking PrEP. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Any information about you obtained from this research will be kept as confidential as possible. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results. Any publication of this study's results will not use your name or identify you personally in any way.

The study staff may use your personal information to verify that you are not in any other research studies. Your personal information may be disclosed if required by law. Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents. Your records may be reviewed by:

- Study monitors
- Study staff
- Emory University employees
- The Office for Human Research Protections, the Emory Institutional Review Board, the Emory Office of Research Compliance and the Office for Clinical Research

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases.
- Giving law officials information about abuse of a child, elderly person or disabled person.

- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing Your Information

Your personally identifying information (PII) such as name, date of birth, address, phone number and pharmacy health insurance plan information (if applicable) will be shared with laboratories and pharmacies to allow you to participate in required and optional study activities. Additionally, if you test positive for an STI and/or HIV, we will share your PII to refer you to treatment if you elect to have the study assist you.

Once the study has been completed, we will send you a summary of the results and what they mean. We will not send you your individual results from this study with the exception of laboratory results that you will receive through the study app during the course of the study. All data that is entered into the app will be encrypted, which makes it unreadable unless a special password is used to make the information readable. The study team will not be able to see your mobile device activity, they will only be able to see your completion of some activities in the study app through its admin web portal. You will be required to log in to the application with a username and password as an additional app security measure. When you finish the study, we will help you remove the app from your mobile device and you will no longer be able to log in to the app.

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

In Case of Injury

If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs. The sponsor will not pay for co-payments or co-insurance that your insurer says you must pay. If you believe you have become ill or injured from this research, you should contact Dr. Patrick Sullivan at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs

Participation: There will be no costs to you for participating in this study, other than basic expenses like transportation costs to attend study visits or to go to the post office/UPS/FedEx drop-off site for mailing specimens if you will be doing at-home specimen collection. We are able to provide transportation assistance, if needed. You will not be charged for any of the research activities, including the postage costs of mailing the specimens you provide.

Oral PrEP medication: If you have health insurance, we will assist you in accessing PrEP coverage through your insurance. If you can’t afford your co-pay with your insurance, we will assist you in accessing Co-Pay Assistance Programs. If you do not have health insurance, we will help you enroll in drug access assistance programs. However, the

study does not pay for medication costs that are not covered by insurance or assistance programs. We will work with you to refer you to services that are at low or no cost. Oral PrEP will be filled through a pharmacy of your choosing.

Injectable PrEP medication: The local provider you choose for initiating injectable PrEP will assist you in accessing the medication through your insurance or available drug access programs. They study does not provide assistance in accessing coverage or paying for any injectable PrEP costs.

STI PEP medication: There will be no charge for the STI PEP medication that the study will offer as a voluntary option, which will be filled through Emory Investigational Drug Service.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to go off Oral PrEP if you are taking it daily. If you leave the study before the final planned study visit, the researchers may follow up with you on completing final study procedures. The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest, if you move away from the Atlanta area, or if you were to object to any future changes that may be made to the study plan.

Authorization to Allow PRISM Health to Store Personal Contact Information Post Study Conclusion

You will be given the option below of allowing PRISM Health to store your contact information in a confidential database for the purposes of contacting you for potential participation in other PRISM Health research studies. However, this authorization does not guarantee that you will be contacted for future studies. This authorization is completely optional and will not affect any other aspects of your involvement in the Project PEACH Study. If you choose to allow us to store your contact information, we will record your most updated name, phone number, and email address at the Baseline visit. You have the right to withdraw this authorization at any time without penalty.

I would like my contact information stored for potential contact about participation in future PRISM Health research studies.

☐ YES

☐ NO

Contact Information

Contact Patrick Sullivan at [redacted]:

- if you have any questions about this study or your part in it.
- if you have questions, concerns or complaints about the research.

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75Consent and Authorization

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Being in this study is entirely your choice. You have the right to refuse to participate or to stop taking the survey at any time.

If you agree to voluntarily participate in this study, please sign on the following page. You may take a copy of this

consent form for your own records

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study and any option you selected above for voluntary provision of specimens for future research. By signing this consent and authorization form, you will not give up any of your legal rights.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**