Informed Consent Form

Title: Combo-PEP Multipurpose Prevention of Post-exposure Prophylaxis Regimens

NCT Number: NCT04860505

IRB Approval Date: February 22, 2022

You Are Being Asked to Be in a Research Study

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 40 people who are being studied, at Emory University Hope Clinic.

Why is this study being done?
This study is being done to answer the question: How well does one dose of oral doxycycline (DOX) and one dose of Biktarvy® reach parts of the body that could be exposed to sexually transmitted infections? You are being asked to be in this research study because you are HIV-negative, between the ages of 18-59 and expressed interest in participating.

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. Your choice will not affect your access to medical care. 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 a minimum of 2 weeks (10 study visits). The researchers will ask you to: take a dose of doxycycline (an antibiotic) and Biktarvy® (and anti-HIV drug), provide blood, urine, penile swabs, urethral swabs, rectal and/or vaginal swabs, and vaginal, cervical, or rectal biopsies.

What are the risks or discomforts I should know about before making a decision?
The drug provided in this study will not protect you from sexually transmitted infections, including HIV, or treat any active infections. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, the drug that is tested has been shown to be well tolerated, but can include common side effects such as, diarrhea, headaches, and hives. The risks of loss of privacy and breach of confidentiality are rare but can occur. 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
Since this is not a treatment study, the alternative is not to participate or to consider participating in another study.

Costs
You WILL NOT have to pay for any of the study procedures while participating in this study. There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: Combo-PEP Multipurpose Prevention of Post-exposure Prophylaxis Regimens

IRB#: 2242

Principal Investigator: Colleen Kelley, MD, MPH

Sponsor: Center for Disease Control and Prevention (CDC)

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 on 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. 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 more about how doxycycline is absorbed into different tissues and fluids in the body when paired with Biktarvy®, and for how long the drug stays in those areas. The drugs might be considered for a post-exposure prophylaxis (PEP) drug combination for the prevention of HIV and/or STIs in the future. However, the study drug provided is not meant to protect you from HIV or any STIs or to treat any active infections while taking part of the study.

This study will consist of 10 healthy, HIV-negative men, aged 18-59 and 10 healthy, HIV-negative women, aged 18-59. The study is designed to look at how one dose of doxycycline in combination with one dose of Biktarvy® are absorbed at different body sites at 1 hour, 2 hours, 4 hours, 8 hours, 24 hours, 48 hours, 72 hours, 96 hours, and 7 days after people take the drug. The staff will take samples from participants and measure the amount of drug in the samples. Samples that will be taken include blood, urine, penile swabs, vaginal swabs, rectal swabs, and rectal or vaginal and cervical biopsy collections.

What will I be asked to do?

If you decide to take part in this study, you will be asked to come to the Hope Clinic to complete 10 visits over a period of 2 to 8 weeks.

If you decide to take part in this study and sign the consent form, we will ask you to complete the following study visits.

Screening Visit 1a: At this visit, you will be asked questions to see if you are eligible for the study. We will ask you to sign this consent form if you agree to take part in the study. You will be asked about your medical history, undergo a physical exam with study clinician, and we will perform a rapid HIV test using blood drawn from your arm. Before and after HIV testing, we will counsel you about the test and results. We will draw about 14 mL of blood from your arm for tests to see if you have Hepatitis B, HIV, whether your kidney function is normal or if you could be at increased risk for bleeding from a biopsy. If you are a woman of childbearing potential, we will ask you to provide a urine sample to perform a pregnancy test to see if you are pregnant. Lastly, we will schedule you for your second study visit 1-6 weeks after your first visit.

Screening Visit 1b: After all screening (Visit 1a) labs are received and returned within normal range, study staff will instruct you to return to clinic to receive one dose of each study drug, doxycycline and Biktarvy®**.** Prior to administering dose, we will ask you to provide a urine sample and swab to test for gonorrhea and chlamydia. We will draw about 10 mL of blood from your arm. Once all samples are collected, we will give you one dose of each study drug to take home. You will need to take the study drugs at home **1 hour before Visit 2**. Staff will give you further instructions on how and when to take dose. You will be asked not to eat or drink, except water, after midnight before your dose. You will also be asked to photograph or videotape yourself taking the study drug with the timestamp included on your smartphone and bring with you to your next visit as proof of dosing. You will also have the option to send a text to a specified number with the time and date of dose if your phone device does not have video/photo capabilities. We will also ask you not have receptive anal or vaginal sex between the time you take the study drug and 7 days after your biopsy procedure.

Types of Samples Collected

Standard Biological Samples

There are a set of biological samples that will be collected from all participants at most visit (Visits 2, 3, 4, 5, 7, 8, 9 & 10). We will refer to them as “standard samples” for the rest of this document. The standard samples include:

- Blood: We will draw approximately 14 - 20mL (about 2 ½ - 4 teaspoons) of blood from your arm.
- Self-Collected Rectal Fluid: We will ask you to gently rub a cotton swab on the inside of your rectum.
- Self-Collected Vaginal Fluid: If you have a vagina, we will ask you to gently rub a cotton swab on the inside of your vagina.
- Urine Sample: We will ask you to urinate into a cup.

Biopsy Visit Samples

At the biopsy visit (Visit 6), additional samples will be taken. If you do not have a vagina, you’ll undergo the rectal biopsy procedure described below. If you have a vagina, you will undergo the vaginal biopsy procedure described below. Those who complete the vaginal biopsy will also have the option of completing the rectal biopsy procedure in addition to the vaginal biopsy procedure.

- Rectal Tissue Sample: For rectal tissue sampling, we will insert a plastic tube into your rectum. Once the tube is inserted, we will collect rectal fluids with cotton swabs and remove small samples of tissue, about the size of a grain of rice, from your rectum (10-12 samples total). Tissue samples will be taken with clean forceps. Forceps are a metal tool to help get the tissue from inside your rectum. You may feel discomfort. We will check to make sure that there is no bleeding from where the samples are taken before taking the tube out. If there is bleeding, we will apply pressure with a cotton swab until the bleeding has stopped. The procedure will take 5 to 10 minutes. We will ask that you refrain from putting anything in your rectum for 7 days to allow time for healing.

- Vaginal and Cervical Tissue Samples: We will not collect vaginal and cervical samples if you are on your period or pregnant or if we think you may have a cervical or vaginal infection. To ensure that you are not on your period, your enrollment visit (Visit 2) will be scheduled 7 to 10 days after your last cycle. We will do a pregnancy test to make sure you are not pregnant before starting the vaginal and cervical biopsy procedure. We will first insert a speculum into your vagina. A speculum is a metal or plastic tool that looks like a bird's beak and is routinely used at gynecology doctor's visits. It is used to help open your vagina a few inches. After the speculum is put into your vagina, the vaginal wall will be cleaned with a clean cotton swab. A pelvic exam will be done to make sure it is safe to collect vaginal and cervical tissue samples. We will then collect vaginal fluids and remove small samples of tissue, about the size of a grain of rice, from your vagina and cervix (1-2 samples from each). Tissue samples will be taken with clean forceps. Forceps are a metal tool to help get the tissue from inside your vagina. You may feel cramping, pain, or discomfort. We will check to make sure that there is no bleeding from where the samples are taken before taking the speculum out. If there is bleeding, we will apply pressure with a cotton swab until the bleeding has stopped. The procedure will take about 10 minutes. We will ask that you do not have vaginal sex or place anything in your vagina, including tampons for 2 days before the procedure and 7 days after the procedure to allow healing. Do not douche or use anything around your vagina with spermicide, lubricants, or medication for 7 days after the procedure, as well.

Visit 2 (Enrollment): This visit will take place **1-6 weeks** after visit 1a. You will be asked to come to the clinic 1 hour after taking your at-home dose. Standard biological samples will be collected at this visit.

Visit 3: This visit will take place **2 hours** after your at-home dose (1 hour after Visit 2). Standard biological samples will be collected at this visit.

Visit 4: This visit will take place **4 hours** after your at-home dose (2 hours after visit 3). Standard biological samples will be collected at this visit.

Visit 5: This visit will take place **8 hours** after your at-home dose (4 hours after visit 4). Standard biological samples will be collected at this visit.

Visit 6: This visit will take place **24 hours** after at-home dose (16 hours after visit 5). Biopsy visit samples will be collected at this visit. If you have a vagina, we will insert a cotton swab into the vaginal opening and gently rotate it. If you have a penis, we will roll a swab around the outside of the head of the penis (under the foreskin, if present) and insert a swab into the urethra. We will also draw approximately 14 mL (about 2 ½ teaspoons) of blood from your arm and ask you to urinate in a cup.

Visit 7: This visit will take place **48 hours** (2 days) after your at-home dose. Standard biological samples will be collected at this visit.

Visit 8: This visit will take place **72 hours** (3 days) after your at-home dose. Standard biological samples will be collected at this visit.

Visit 9: This visit will take place clinic **96 hours** (4 days) after your at-home dose. Standard biological samples will be collected at this visit.

Visit 10: This visit will take place **7 days** after your at-home dose. Standard biological samples will be collected at this visit.

How will my medicine be provided?
The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse. You may also call the pharmacy at (404) 712-4718, if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

When you take the study drug 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.

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 is used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study. If you decide to withdraw from the study and would like us to destroy any remaining sample, please contact Dr. Kelley in writing at:

Dr. Colleen Kelley
The Hope Clinic
[redacted]

What are the possible risks and discomforts?
You may have side effects while in the study. In some cases, side effects can be serious. You should talk to the study doctor about any side effects that you have while in this study. There may be side effects that are not known at this time.

Doxycycline Risks
Common side effects
- vomiting
- nausea
- trouble swallowing
- acne

Rare Side Effects
- liver damage
- increase in blood levels that monitor your kidney function
- anemia
- low neutrophil (a type of white blood cell) count
- low eosinophil (a type of white blood cell) count

We do not expect these side effects to occur since you will only receive one dose as part of this study.

The drug provided in this study is not meant to treat or prevent HIV and STIs. You should not expect that you will be protected from HIV or STIs by taking the drugs in this study.
Biktarvy® Risks
Biktarvy® is a combination anti-HIV medication that contains the drugs tenofovir alafenamide (TAF), emtricitabine (FTC), and bictegravir (BIC). Based on other studies, this drug appears to have few side effects.

Common Side Effects (experienced by about 5% of people)
- diarrhea

- nausea
- headache

Rare Side Effects (experience by less than 2% of people)

- vomiting
- gas
- abdominal discomfort
- abdominal pain
- rash
- depression
- kidney damage
- bone density loss
- buildup of lactic acid
- liver enlargement

We do not expect these side effects to occur since you will only receive one dose as part of this study.

Use of Biktarvy® can also cause flare-ups in those who are infected with Hepatitis B. It can cause the Hepatitis B virus to suddenly return in a worse form than before if treatment was provided. For this reason, it is important that you do not take part in the study if you are known to have Hepatitis B. Nonetheless, the dosing regimen for this study is unlikely to cause flare-ups in Hepatitis B even if not diagnosed.

If you become HIV positive while Biktarvy® is still in your system, there is a risk for HIV drug resistance. However, this is not expected to occur since you will only receive one dose of Biktarvy®. It is important to use condoms for oral or top sex to reduce your risk of HIV and other sexually transmitted infections.
The drug provided in this study is not meant to treat or prevent HIV, and you should not expect that you will be protected from HIV by taking the medications in this study. If you are interested in pre-exposure prophylaxis (PrEP) after this study ends, we can refer you to a medical provider who can prescribe PrEP.

Rectal Biopsy Risks
Common side effects of the rectal biopsy are mild discomfort and the feeling of needing to pass stool, as well as limited bleeding for 1 to 3 days after the procedure. Rare side effects can include bowel puncture, infection and bleeding. If any of these side effects occur, you may need antibiotics and/or surgical repair. The risk of infection is less than 1 in 5,000. Infection due to bowel puncture could result in death, but this is extremely rare. It is important to realize that the risk related to multiple biopsies is not known. Having anal sex during the week after the biopsies can increase your risk of a STD and HIV.

Vaginal and Cervical Biopsy Risks
Vaginal and cervical biopsies may cause some anxiety, pain, discomfort, and an odor. Infection and bleeding are rare but can occur. If there is bleeding, we will use medication to stop it. Until the areas where the biopsies were collected are healed, you may be at a higher risk for HIV or other STIs if you are exposed. Most people heal within 5 to 14 days, but some may take longer.

Blood Draw Risks
Having your blood taken can cause temporary discomfort such as being dizzy or fainting. Bruising can also occur. It can be prevented or reduced by putting pressure on the site for a few minutes after the blood is taken. Rarely, some people get an infection where the needle was put in their arm to draw the blood. To reduce this risk, we will wipe the area clean with alcohol and use sterile supplies.

Test Result Risks
You may find out that you have HIV or a STI during this study. This could cause you some stress. Study staff will counsel you before and after your test, no matter what the results are. Also, we will refer you to a medical provider for further care. We will ask you some personal questions about your sex life during the study, which may make you uncomfortable.

If you are a woman
To protect against possible side effects of the study drugs, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use while in the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

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. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will be compensated for each study visit you complete. If you do not finish the study, we will pay you for the visits you have done. The amount for each visit is listed below.

- Screening 1a: $25
- Screening 1b: $20
- Follow-Up Visits: $50 x 8 = $400
- Rectal/Vaginal Biopsy Visit: $125
- Optional Additional Rectal Biopsy (Women Only): $50
- Unscheduled Visit (if needed): $20
- Total: $570

Compensation will be provided on a web based, reloadable, debit card (ClinCard) that automates reimbursements. The ClinCard will be provided by study staff at the initial visit (visit 1). Because Visits 2-5 take place over a span of 8 hours, we will provide you with a $15 gift card while you wait for food and/or incidentals.

There is no charge for parking at the Hope Clinic. However, participants may be provided with a MARTA card if available.

All payments are made using a personal payment card. We issue this to you for free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. The card scheme is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card.

Emory University and Grady Health System is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well.

All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card system.

We would also like the option of compensating you in the form of cash, check or gift card if ClinCard accessibility is not available. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, 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. You will need to fill out a W-9 form.

What are my other options?
If you decide not to enter this study, there is care available to you outside of this research study. The study doctor will discuss these with you.

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

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the sponsor, the Emory Institutional Review Board, the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

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
Samples collected during the study will be sent to the Centers for Diseases Control (CDC) for testing.

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, 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.

Your data and specimens from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

We will take reasonable steps to keep copies of this form out of Emory Healthcare's medical records system. If we are not successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Colleen Kelley at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory 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.

Costs

There will be no costs to you for participating in this study, other than basic expenses like travel. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

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 the study treatment. If you leave the study before the final planned study visit, the researchers may still use your samples unless you revoke your authorization.

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 or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:
- If you are unable or unwilling to follow all of the study procedures or instructions,
- You could be harmed by study drug and/or study procedures,
- You are not able to attend clinic visits or complete all of the study procedures, or
- Other reasons, as decided by the study staff.

Contact Information
Contact Colleen Kelley MD, MPH at [redacted]
- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:
- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent
Consent for Optional Studies:

Please initial below if you opt to participate in the optional studies previously described:

Optional rectal biopsy (if applicable):
Please initial below if you agree to allow us to collect rectal samples as previously described:

_____ YES, I agree to complete a rectal biopsy
(Initials)

_____ NO, I do not agree to complete a rectal biopsy
(Initials)

_____ N/A
(Initials)

Optional Videotape or Photograph You At-Home Drug Dose:
You will be asked to videotape or photograph yourself taking the dose of Doxycycline at home with your smart phone. We ask you to do this so we can verify when you took the study drug. Your other option would be to text a designated phone number when you take the at-home dose.
You will be required to do one or the other in order to participate in the study.

Your decision to videotape or photograph your dose will not affect your participation in this study. Please place your initials below (select only ONE option):

_____ YES, I agree to videotape or photograph my dose
(Initials)

_____ NO, I do not agree to videotape or photograph my dose
(Initials)

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ : ___ **am / pm**
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

_____ _____ : ___ **am / pm**
Signature of Person Conducting Informed Consent Discussion **Date** **Time**