Defining Antiretroviral Pharmacology Within HIV-1 Reservoirs of Males and Females

NCT02924389

Date: September 8th, 2020

IRB00089025

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 40 people who are being studied, at Emory.

Why is this study being done?

This study is being done to is to find out how well dolutegravir (DTG/Tivicay), a FDA approved HIV medication for the treatment of HIV infections, gets into different parts of the body: including blood plasma, special blood cells, and rectal tissue. Specifically, we want to compare how fast dolutegravir lowers the HIV viral load in these three different sites. In addition, we want to see if there are any differences in how dolutegravir acts in males and females. Results of this study will give us more information about HIV medications and their limitations. In the future, this could help us create better HIV medications that can get into these hard-to-reach places and eventually cure HIV infection.

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 for your condition. 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 be asked to begin a regimen of Triumeq, Dolutegravir and Descovy, or Dolutegravir and Truvada. You will need to get the prescription from your provider. Your participation is voluntary and will not influence the care you receive from Grady or Emory. During this study, you will have 5 study visits over 6 months: one 8-hour visit at Grady Hospital and 4 visits at the Grady Ponce IDP Clinic. Study procedures at each of the Ponce visits will take about 1-2 hours. We would ask you some questions, perform a physical examination, collect some blood, and perform a rectal biopsy at the 8-hour visit at Grady Hospital and during three of the visits at the Ponce clinic. There is no cost to you for any of the study procedures.

It is important to know that for this study, the study drug, dolutegravir (DTG/Tivicay) is FDA approved for the treatment of HIV infections and can be given in combination with other antiretrovirals (ARVs), as a standard therapy for HIV. It is also important to know that this study will not provide nor will the study pay for the study medication. Your HIV medication will be determined by your primary HIV provider you will be responsible for obtaining it and bringing it to the study visits.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question how well the HIV medication Dolutegravir gets into different parts of the body including blood plasma, special blood cells, and rectal tissue.

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, feeling uncomfortable answering some questions, some discomfort or bruising from the blood draw and mild discomfort or minimal bleeding from the anus during and after the rectal biopsy procedure. An addition risk is new information regarding STI and pregnancy status. For these procedures, experienced staff will perform the tests and provide necessary counselling. 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.

Costs
You WILL NOT have to pay for any of the study procedures. The study will not be paying any additional evaluations or follow up care needed after completion of study activities or related to a finding that requires follow up with your provider or a referred to Clinician/Specialist.

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.) Make sure you understand the expectation of the study and if you can commit to participating in them. Take time to consider this, and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: Defining Antiretroviral Pharmacology Within HIV-1 Reservoirs of Males and Females

IRB #: 00089025

Short Title: Dolutegravir in Reservoirs

Principal Investigator: Cecile Delille Lahiri, MD

Sponsor: National Institutes of Health (NIH)

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.

What is the purpose of this study?

Even with strong HIV medications, there is no known cure for HIV infection. When a person is infected with HIV, studies have shown that the virus enters many different parts of the body, including the brain, lymph nodes, the gut (including the rectum), and special cells in the blood. HIV medications are very good at getting into blood plasma and killing the virus, but may have limited ability to get into some of these other places. In sites such as special blood cells and the gut, the virus can hide from HIV medications.

The dose of HIV medication needed for good HIV control is decided by studies that look at drug levels in the blood plasma of patients. While the dose of medication may be good enough to control HIV infection in blood plasma, it may not be good enough to control HIV infection in these other hard-to-reach sites.

The purpose of this study is to find out how well dolutegravir (DTG/Tivicay), a FDA approved HIV medication for the treatment of HIV infections, gets into different parts of the body: including blood plasma, special blood cells, and rectal tissue. Specifically, we want to compare how fast dolutegravir lowers the HIV viral load in these three different sites. In addition, we want to see if there are any differences in how dolutegravir acts in males and females. Results of this study will give us more information about HIV medications and their limitations. In the future, this could help us create better HIV medications that can get into these hard-to-reach places and eventually cure HIV infection. It is important to know that for this study, the study drug, dolutegravir (DTG/Tivicay) is FDA approved for the treatment of HIV infections and can be given in combination with other antiretrovirals (ARVs), as a standard therapy for HIV. It is also important to know that

this study will not provide nor will the study pay for the study medication. Your HIV medication will be determined by your primary HIV provider you will be responsible for obtaining it and bringing it to the study visits.

Our target enrollment consists of 20 women and 20 men for this research study.

Procedures

Where is the study taking place, and how long will the study last?

- The research procedures will be conducted within the Grady and Emory Health Systems. The sites will include
  - The Grady IDP (Ponce Clinic)
  - Grady Memorial Hospital
- You will be in the study for six study visits over the course of 6 months

What will I be asked to do?

If you are eligible for this study and do volunteer to take part, you will be asked to do the following:

1. Sign this combined consent/HIPAA Authorization Form and a medical release form.
2. Have a screening visit for the study and, if eligible, make 6 additional visits at the Ponce Clinic or Grady Memorial Hospital, over a course of 6 months which include:
   a. One 8-hour visit at either Grady Memorial Hospital or Emory University Hospital
   b. 4, 2 -hour visits at the Ponce Clinic.
3. Undergo thorough medical evaluations. This will include:
   a. Review of your medical records
   b. Comprehensive medical history
   c. Physical examination
4. Specimen collection including
   a. Blood
   b. Urine
   c. Rectal swab collection
   d. Rectal Biopsy collections during anoscopy procedure. Anoscopy is a procedure that uses a lighted scope called an anoscope to look at the anal canal and the lower rectum.
5. Receive from your provider a prescribed supply of the drug, Tivicay® (dolutegravir/DTG), with either Triumeq, or Truvada or Descovy as determined by your primary HIV provider. It will be taken by mouth as prescribed. The dose and its administration will be determined by your provider. You will be responsible for bringing these medications with you to your study visits.

IF YOU ARE FEMALE:

Females of childbearing potential (FCB) must agree to either commit to continued abstinence from heterosexual intercourse or to use a reliable form of birth control such as oral contraceptive pills, intrauterine device, Nexplanon, DepoProvera, permanent sterilization, or another acceptable method, as determined by the investigator for the duration of the study. FCB are defined as sexually mature women who have not undergone hysterectomy or bilateral oophorectomy or have not been naturally postmenopausal for at least 24 consecutive months (i.e have had their menses/a period at any time in preceding 24 months. A pregnancy test will be done at each visit.

Study Visits:
The screening visit will determine whether you are eligible for the study. During this visit, a qualified member of the research team will review your medical and medication history to determine your eligibility. In addition, you will give a urine sample for a pregnancy test (if you are a female of child bearing potential) and may have blood collected to check your blood counts, liver, and kidney function.
You should let the study staff know if you have any reason to suspect that you may be pregnant during this visit.

A. Screening visit: (Grady IDP/Ponce Clinic)

- You will be evaluated to see if you are eligible for the study based on the study's criteria.
- You will be asked to sign the informed consent, HIPAA form, and medical release form.
- Your medical record will be reviewed.
- Medical/medication history and demographic characteristics will be recorded.
- Urine will be collected for a pregnancy test (females of child bearing potential).

This visit should last for about 1 hour.

The subsequent six study visits will occur over 6 months and will include one 8-hour long visit at Grady Memorial Hospital- CRN (5th Floor), immediately followed by a next morning visit (24 hours) at the Grady IDP/Ponce Clinic.

B. First Study Visit/Baseline (Ponce Clinic)

- This visit will take place at the:
  - Grady IDP Clinic/Ponce Clinic on the 3rd floor.
- Arrive promptly for your scheduled appointment time.
- If you are a female of childbearing potential, a urine sample will be collected for a pregnancy test .
- Medical, sexual, and reproductive history will be collected and a targeted physical exam will be performed by qualified study personnel.
- You will come to your study visit with the medication that was prescribed by your primary HIV provider for care.
  - This medication must include Dolutegravir (DTG /Tivicay®), and may be in combination with other drugs as determined by your primary HIV provider.
- Once this visit is completed, you will be started on your HIV medications.
  - These medications may include either:
    i. Triumeq (a combination medication with Dolutegravir, the study drug, + Abacavir + Lamivudine)
    ii. Or the medications Truvada or Descovy plus Dolutegravir (study drug)
- Up to eight tubes of blood (3 full tablespoons) will be collected.
- At this visit, or within seven (7) days of beginning your HIV medication(s), you will undergo a procedure called anoscopy to collect rectal fluid and tissue. During anoscopy, a small tube is inserted into the anus to look at the rectal tissue.
  - Rectal fluid will be collected on two (2) dry sterile cotton swabs to look at the types of bacteria living there.
  - Up to eight (8) small punch biopsies will be done at one time point to collect small pieces of rectal tissue to measure both HIV viral load and dolutegravir drug concentrations.
- To look at rectal tissue healing over time, digital photographs may be taken during the anoscopy procedure, and these images may be shared with investigators not listed on the study.

Your visit should last for about 2 hours. This visit may occur on the same day as the Screening visit.

C. Second through Third Study Visits (Grady IDP/Ponce Clinic)

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- Visit 2 occurs 14 days after first visit.
- Visit 3 occurs 42 days after first visit.

- These visits will take place at the Grady IDP Clinic, on the 3rd floor.
- Arrive promptly for your scheduled appointment time.
- If you are a female of childbearing potential, a urine sample will be collected for a pregnancy test.
- Targeted medical history and physical will be performed by qualified study personnel.
- Up to eight tubes of blood (3 full tablespoons) will be collected.
- At Visit 3/Day 42, you will also undergo anoscopy to collect rectal fluid and tissue, where two (2) swabs of fluid will be collected and up to eight (8) small punch biopsies will be done.
- To look at rectal tissue healing over time, digital photographs may be taken during the anoscopy procedure, and these images may be shared with investigators not listed on the study.

Your visit should last for about 2 hours for the visit that has rectal tissue collection,
And 1 hour for those studies visits that do not involve rectal tissue collection.

D. Fourth Study visit: (Grady Memorial and Grady IDP/Ponce Clinic)

- This visit will take place at the:
  a. Grady Memorial Hospital at the Clinical Research Network (CRN), located on the C-wing of the 5th floor and
  b. Grady IDP Clinic/Ponce Clinic on the 3rd floor.
- It will occur 84 days (12 weeks) after your initial visit.
- Arrive promptly for your scheduled early morning appointment time.
- You will be staying 8 hours at the CRN for this visit (meals will be provide throughout your stay) and then you will come back the next morning to the Grady IDP Clinic for your final blood collection.
- If you are female of childbearing potential, a urine sample will be collected for a pregnancy test.
- Targeted medical history and physical will be performed by qualified study personnel
- An i.v. line will be placed into a vein for blood collection.
- You will come to your study visit with the medication that was prescribed by your primary HIV provider for care.
  a. This medication must include Dolutegravir (DTG /Tivicay®), and may be in combination with other drugs as determined by your primary HIV provider.
- At the study visit you will take your HIV medications.
  a. These medications may include either:
     i. Truimeq (a combination medication with Dolutegravir, the study drug, + Abacavir + Lamivudine)
     ii. Or the medications Truvada or Descovy plus Dolutegravir (study drug)
- At the CRN, your blood will be drawn 15 minutes before you take the first dose of medications and after 1, 2, 3, 4, 6, and 8 hours.
- You will come back the next morning for your 24 hour blood draw at the Grady IDP Clinic, for a total of 8 blood draws for study tests.
- Up to eight tubes of blood (3 full tablespoons) will be collected each time.
- You will undergo anoscopy to collect rectal mucosa fluid and tissue, where two (2) swabs of fluid will be collected and up to eight (8) small biopsies will be done at one time point.
- To look at rectal tissue healing over time, digital photographs may be taken during the anoscopy procedure, and these images may be shared with investigators not listed on the study.

Your visit should last for about 24 hours (8 hours at the Grady Memorial Hospital CRN and 1 hour at the Ponce Clinic).

E. Fifth Study Visit (Grady IDP/Ponce Clinic)

- This visit will take place at the:
  - Grady IDP/Ponce Clinic on the 3rd floor.
- It will occur 168 days (6 months/week 24) after your initial visit.
- Arrive promptly for your scheduled appointment time.
- If you are a female of childbearing potential, a urine sample will be collected for a pregnancy test.
- Targeted medical history and physical will be performed by qualified study personnel.
- Up to eight tubes of blood (3 full tablespoons) will be collected.
- You will also undergo anoscopy to collect rectal fluid and tissue, where two (2) swabs of fluid will be collected and up to eight (8) small punch biopsies will be done.
- To look at rectal tissue healing over time, digital photographs may be taken during the anoscopy procedure, and these images may be shared with investigators not listed on the study.

Your visit should last for about 2 hours

Optional Study Section 1: Genetic Testing

Investigators are also studying how genes (a patient's DNA) may affect HIV and other viruses, as well as other outcomes that may be of concern in HIV-infected women. If you agree, your stored left over samples may be used as a source of DNA for genetic testing that is not yet planned but may be done at a later date. This testing may include studies of HIV, studies of other diseases that affect people with HIV, studies of your cells, proteins, and other chemicals in your body, and studies of your DNA. Your blood specimen will be used to extract DNA and other biological markers, which will be studied for research purposes only. The results of the DNA testing will not be revealed to your health care provider or you either during or after the completion of this study.

Optional Study Section 2: Contact for Future Studies/Research Opportunities

We would like to contact you in the future for participation in other research studies that you may be eligible for. Please take your time to think about it and discuss any questions you may have.

If you agree, we would like to store your name and contact information in an electronic database, specifically designed to contact those who are interested in future opportunities to participate in research. The database will be maintained by authorized members of Dr. Lahiri's team and you may be contacted by Investigators or Research Staff under this study.

Confidentiality of your information will be maintained in the following manner:

- Access to the database will be restricted and limited to Investigators or Research Staff under this study.
- Limited information may be shared with Investigators or Research Staff under this study and other researchers at Emory University.
- The following information: name and phone number will be provided to Investigators or Research Staff outside this study, so they may contact you.
- Information on your mailing address, HIV status, date of birth and clinic of care will not be shared with Investigators or Research Staff outside this study.
- This database will be retained indefinitely and if destroyed it will be done to ensure your privacy and confidentiality are kept.
- The information in the database may be inspected by an Emory University Research Ethics Board to ensure that your information is being collected and maintained in an ethical manner.

Your decision to allow your information to be in the database is completely voluntary. While there may be no benefit to you, your information will help researchers to quickly identify individuals who may be suitable for a particular research study. If you change your mind after agreeing to this, your information can be removed from the database. You will not be penalized in any way if you refuse to participate, or if you change your mind and ask that your information be removed.

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. Your specimens will be kept indefinitely and will only be used for research purposes. If you withdraw from the study, data and samples that were already collected may be still be used for this study. Your samples will be kept secure and stored at the local laboratory and will only be used for research related to this study. The samples stored will not have any data written on them or records stored with them that could identify you.

What are the possible risks and discomforts?

The most common risks and discomforts expected in this study are:

1. **Questionnaire/Comprehensive Medical Review:**

Participation in the mental tasks may lead to fatigue, boredom or frustration. Assessment of sexual behavior will be done at each visit using a brief questionnaire. The responses to these questions may make one uncomfortable.
All interviews will be done in private room, with adherence to protecting the privacy and the confidentiality of data through the use of trained interviewers and other study staff

2. **Physical Exams:**

Physical examinations may cause both physical and emotional discomfort. Though mild discomfort may occur, there are no known serious adverse effects expected and only experienced health care practitioners will conduct the physical examinations.

3. **Drawing Blood:**

The needle used to collect blood may cause a bruise at the insertion site, and in very rare circumstances, an infection may develop. Other uncommon risks related to the blood draw include pain, bleeding, blood clots, discomfort, swelling, lightheadedness, and fainting. These risks are uncommon.

4. **Collection of rectal swabs**

During the anoscopy procedure to look at the anal canal and the lower rectum we will collect rectal swabs. It is expected that you may have some mild discomfort during the procedure.

5. **Anoscopy with tissue collection/biopsy**

During the anoscopy procedure to look at the anal canal and the lower rectum we will collect rectal tissue (biopsy). It is expected that you may have some mild discomfort and minimal bleeding from the anus during and after the procedure. Less common risks are small anal tears or bleeding for several days with bowel movement.
Though rare, there is also the possible risk of colonic infection/perforation. However, only trained and experienced health care practitioners will conduct these collection procedures.

Minimization of Risk

To minimize these risks:

- Physical examination, drawing blood, and rectal tissue collection will be performed by experienced health care practitioners trained and certified in these procedures.

- To minimize any discomfort you may feel during the rectal tissue collection, you may want to take some over-the-counter pain medication, such as Tylenol, Motrin, or Aleve, before and/or after the procedure.

Risk of New Information Regarding: sexually transmitted infections and pregnancy status

If a test result is positive, individuals diagnosed with an STI or vaginitis may experience emotional discomfort upon receiving their diagnosis, or upon notifying sexual partners, as this would be recommended by study staff during counseling. If you have an infection, a qualified health care practitioner will give participants counseling, and a prescription for treatment, or a referral to a clinician for further testing and/or treatment.
A pregnancy test will be administered to avoid any risk posed to a fetus. Should a participant be found to pregnant in the process of screening or during the study they will be given referrals to medical care and the necessary education. Referrals will include: prenatal care, adoption and abortion care services.

Experience health care practitioners will perform all tests, examinations and counseling. Furthermore this study requires documentation of HIV infection status. If you have not had a recent test, assessment of status prior to enrollment and throughout the course of the study requires the performance of FDA-approved HIV antibody tests. All staff participating in these studies is trained in the provision of HIV pre- and post-test counseling in accordance with the standards set out in the US department of Health and Human Services HIV Counseling, Testing and Referral Standard and Guidelines. HIV test counseling and HIV risk behavior counseling will be provided to all potential participants and to those volunteers enrolled in the study.

Risks of Sample Storage
There are few risks related to storing your samples. The greatest risk is to your privacy.

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there are known risks to you, the embryo, or fetus. Recently, guidelines have indicated that there is an increased potential risk of neural tube defects in infants born to women taking DTG-based regimens. Given this new information, FCB must agree to either commit to continued abstinence from heterosexual intercourse or to use a reliable form of birth control such as oral contraceptive pills, intrauterine device, Nexplanon, DepoProvera, permanent sterilization, or another acceptable method, as determined by the investigator for the duration of the study. For women of childbearing potential, pregnancy tests will continue to be performed at all study visits. You and the study doctor must agree on a method of birth control to use throughout 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.

If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the study drug. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking 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.

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 well the HIV medication dolutegravir gets into sites of the body including blood plasma, special blood cells, and rectal tissue. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

We consider your participation in this study entirely voluntary, and appreciate your time and commitment to research. As compensation for your time, inconvenience, and to assist with the cost of transportation, you will get the following:

- Twenty dollars ($20) for completing the screening visit.
- One hundred and fifty dollars ($150) for the completed 24-hour study visit (week12/Day 84).
- Thirty dollars ($30) for each completed non-overnight study visit that does not have a rectal biopsy procedure (2 visits).
- An additional fifty dollars ($50) for each completed non-overnight study visit that has a rectal biopsy procedure (3 visits)
- Twenty-five dollars ($25) if you return to the clinic for a repeat procedure from a previous visit.
- If you complete all six study visits and arrive within 15 minutes of your scheduled appointment time for each visit, you will be given a $25 gift card at the end of your sixth visit. If you complete the screening and all six study visits you will receive a total of $495. If you do not finish the study, you will be paid for the visits you have completed.

Please note 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. To comply with this federal mandate the researchers are required to obtain your social security number to complete the form.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research. The alternative to participating in this study is to not participate. There are other available FDA-approved medications to treat people with HIV. You can receive care for your HIV infection at the Ponce de Leon Center, your local health department, or AID Atlanta. The study doctor will discuss this with you. You do not have to be in this study to be treated for HIV-1 infection.

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.

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.

Storing and Sharing your Information

Your samples, genomic data and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

Medical Record

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory and Grady Health System 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 and Grady Health System's medical records system. If we aren't 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.

Emory and Grady Health System may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Grady Health System medical

record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: dolutegravir concentrations, HIV viral loads, and microbiome results.

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory and Grady Health System will help you get medical treatment. Emory and Grady Health System 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 and Grady Health System or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

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.

If you believe you have become ill or injured from this research, you should contact Dr. Lahiri at telephone number 404-616-6306. You should also let any health care provider who treats you know that you are in a research study.

Costs

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.
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.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Grady Health System may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- NIH is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - Emory University Center for AIDS Research statisticians
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Study/Storage of Data/Specimens for Future Research:

PHI That Will be Used/Disclosed for Optional Study:
The PHI that we will use and/or disclose (share) for the optional genetic testing and contact for future research opportunities includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results

Purposes for which your PHI will be Used/Disclosed for Optional Study:
We will use and disclose your PHI for the conduct and oversight of the optional or the optional genetic testing and contact for future research opportunities, including the administration and payment of any costs relating to subject injury.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:
The following people and groups will use and disclose your PHI in connection with the optional l genetic testing and contact for future research opportunities:

- The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional genetic testing and contact for future research opportunities.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must:

Cecile Delille Lahiri, M.D.
Division of Infectious Diseases,
Department of Medicine,
[redacted]

[redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.
To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact the [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, concerns or complaints about the research

Contact the Emory University 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/6ZDMW75.

If you are a patient receiving care from the Grady Health System and have a question about your rights, [redacted].

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:

1. Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

   Genetic testing _____Initials

2. Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

   Contact for future research opportunities _____Initials

TO BE FILLED OUT BY SUBJECT ONLY

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

_____

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**

APPENDIX A: Consent Comprehension Questions

At the end of consenting, research staff members will read the questions below and circle participant responses.

1. The purpose of this study is to find out how well an HIV medicine Dolutegravir (DTG) gets into different parts of the body.
   True/False

2. You will be responsible for getting your HIV medication as the study will **not** cover the cost of your HIV medication.
   True/False

3. You will be responsible for bringing your medication to the study visits.
   True/False

4. This study asks you to come in for 5 study visits over 6 months.
   True/False

5. You will have one study visit at the Grady CRN that will last approximately 8 hours.
   True/False

6. At your Grady CRN visit, the nurse will place an IV in your arm to collect the multiple blood draws over 8 hours.
   True/False

7. You will have four study visits where the doctor will place a scope in your anal canal and collect 2 anal swab samples and up to 8 anal biopsy samples.
   True/False

8. We will secure your privacy by using a study number for the samples and data collected.
   True/False

9. You have the right to leave the study at any time and can communicate with the PI or study Coordinator for any questions you may have.
   True/False

10. Women of childbearing potential will have a pregnancy test at each visit.
    True/False

_____

Interviewer Name

_____

Interviewer Signature **Date**

STUDY STAFF: Please clarify any question/s theion/s the participant has answered incorrectly.