UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: Efficacy, Safety, and Tolerability of Bictegravir/Emtricitabine/Tenofovir Alafenamide in Adults with HIV-HBV Coinfection.

Study No.: HP-00083844

Principal Investigator: Joel Chua, MD 410-706-5704

CONCISE SUMMARY:
This is a research study to find out if a drug called BIKTARVY® is safe and effective for the treatment of patients with both HIV and hepatitis B virus. Participation in this research study is voluntary. All eligible participants will take BIKTARVY® one pill once daily for the duration of this 48-week treatment study. During each of the 8 study visit, your blood will be tested for both HIV and hepatitis B levels. There are risk to taking this study drug that are described in detail in this document. The most common side effects include diarrhea, nausea, and headaches.

If you are interested in learning more about this study, please continue reading below.

Sponsor: Institute of Human Virology

You are being invited to take part in a research study. This Consent Form tells you all about the study. The study staff will talk to you about this information. Please read the information carefully and talk about it with anyone you want. If you have questions at any time, please ask the study staff or study doctor who will answer your questions.

Before you agree to participate in this study, you need to know the risks and benefits so that you can make an informed decision. This process is known as "informed consent". Once you have read the information and know about the study, you will be asked to sign this form before joining the study. You will get a copy to keep with you.

Your decision to participate in this study is voluntary. This means that you are free to decide to join this study or not join this study. You are also free to leave the study at any time. If you choose not to join this study, there will be no impact on your regular medical care.

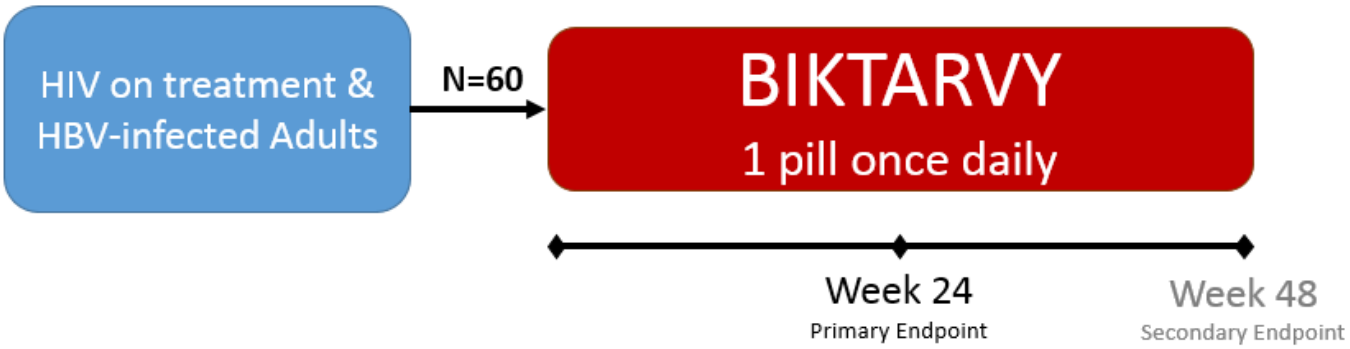
PURPOSE OF STUDY

This is a study for adults who are infected with both HIV and hepatitis B virus. The purpose of this research is to determine how safe and how effective a medication called BIKTARVY® is on patients that have both HIV and hepatitis B infection. BIKTARVY® is a fixed-dose combination drug containing Bictegravir, Emtricitabine, and Tenofovir Alafenamide, and is approved by the Food and Drug Administration (FDA) for the treatment of HIV infection. Tenofovir Alafenamide, which is a component of BIKTARVY®, is FDA-approved for the treatment of hepatitis B infection. BIKTARVY® has not been well studied in patients with both HIV and hepatitis B.

The long-term goal of our research is to find a highly effective, convenient (one pill once daily), and safe medication for the treatment of patient with both HIV and hepatitis B infection. BIKTARVY® is a one pill once daily drug that can be taken without regards to food, and has a high barrier of resistance against both HIV and hepatitis B – that is to say, these viruses have a hard time developing resistance against BIKTARVY®.
We believe that by patients switching to BIKTARVY®, both their HIV and hepatitis B will remain well controlled throughout the study. If you are interested and found to be eligible, you will be asked to switch your current HIV drugs to BIKTARVY® for the duration of the study, which is 48 weeks. The manufacturer, Gilead Sciences, Inc., will provide the study drug and funding for this study led by Dr. Joel Chua.

PROCEDURES

This multicenter study is conducted in the Clinical Research Unit of the Institute of Human Virology (IHV) and Newlands Health Clinic (Philadelphia PA). We estimate that we will need to screen 75 people for this study in order for 60 people to complete the study treatment. If you decide to participate in the study and found to be eligible for the study treatment, you will be asked to stop taking your current HIV medications, and in its place, you will start taking BIKTARVY one pill once daily for 48 weeks.



If you participate in this study, you will be in the study for about 15 months (1-3 months for screening and 12 months taking the study treatment. There will be about eight scheduled study visits, most lasting for 30 minutes to 2 hours. Approximately 150 teaspoons of blood will be drawn over the course of the study and is approximately the amount of blood drawn during a standard blood donation. Please refer to the attached detailed study schedules.

If you are a woman of childbearing potential, you will have blood collected for a pregnancy test during the screening visit. The pregnancy test must be negative for you to enroll in the study. A urine pregnancy test will be performed during each study drug treatment. You will need to stop taking study drugs if you are found to be pregnant. If you think you are pregnant, you must notify study personnel immediately.

Screening Visit

During the screening visit, the study doctor or nurse practitioner will take a complete medical history and perform a physical exam. Study staff will perform some tests or procedures to see if you meet the requirements for being in the study. An electrocardiogram (ECG) will be done to look at your heart rhythm. Blood tests will be done to find out about your health, and we will collect approximately 11 teaspoons of blood. We will also ask you questions about your health. If you meet the requirements, you will have up to 90 days from this Screening Visit to start the study drug treatment. This screening visit lasts approximately 2 hours.

Day 1 (Start of BIKTARVY)

If you meet all the requirements to participate in the study, and if you agree to do so, you will return to start the study. A study doctor or nurse practitioner will take a medical history and perform a physical exam on you. We

will check your starting HIV and hepatitis B levels, CD4 cell count, complete blood count, chemistries, and research labs. You will be told to stop your current HIV medications and start taking BIKTARVY® once daily with a cup of water every morning for the duration of the study. You will take the first dose of BIKTARVY® (one tablet) with a cup of plain water, while being observed by a study staff. You will be sent home with the remainder of the 60-day supply of BIKTARVY®. You will also be provided a Patient Diary to take home and where you will record the date and time when you take your study drugs. This visit will last approximately 2 hours. We will collect approximately 25 teaspoons of blood during this Day 1 visit.

For IHV site only: You will also undergo a FibroScan test (a non-invasive ultrasound-based device that measures liver stiffness and therefore able to tell the level of scarring from hepatitis B) prior to your first BIKTARVY® dose. This test can be done either on your Day 1 visit or as early as 30 days prior to your Day 1 visit. During the Fibroscan test a trained study staff member will apply a water-based gel to the skin and place the non-invasive probe over the liver area. In preparation for this procedure, you will be advised not to eat or drink (including water) for at least 3 hours prior to procedure. This procedure will last approximately 5-10 minutes.

Week 4 and 8

A study nurse will assess you for any side effects and check your current medications. Blood will be collected to test for HIV and hepatitis B levels, CD4 cell count, complete blood count, chemistries, and research labs. You will return with your Patient Diary and remaining study drugs and bottle. You will be sent home with 30-day and 60-day supply of study drug for Week 4 and Week 8, respectively. Approximately 15 teaspoons of blood will be collected for these visits. These visits will take about 30-60 minutes.

Week 12, 24, and 36

A study nurse will assess you for any side effects and check your current medications. Blood will be collected to test for HIV and hepatitis B levels, CD4 cell count, complete blood count, chemistries, and research labs. You will return with your Patient Diary and remaining study drugs and bottles. You will be sent home with 90-day supply of study drug. Approximately 18 teaspoons (23 teaspoons for Week 24) of blood will be collected for these visits. These visits will take about 30-60 minutes.

For IHV site only: In addition, on Week 24, you also undergo a FibroScan test (same as to the one described on Day 1 visit). This test may be done during the Week 24 visit, or within 2 weeks (before or after) of Week 24 visit. This procedure will last approximately 5-10 minutes.

If your HIV and/or hepatitis B levels rebound during study drug treatment, we will ask you to the clinic for a blood draw to recheck the virus levels to confirm if this is a true rebound or not. Blood may also be taken to test for genotype and resistance tests.

Week 48 (End-of-Study Visit)

This is the end of study visit. You will be asked to return all bottles and pills. You will also be asked to bring and return your Patient Diary, which will be kept in your study records. A study nurse will assess you for any side effects and check your current medications. If needed, a study doctor or nurse practitioner may perform a physical examination. Blood will be collected to test for HIV and hepatitis B levels, CD4 cell count, complete blood count, chemistries, clotting labs, and research labs. You will return with your Patient Diary and remaining study drugs and bottles. Approximately 25 teaspoons of blood will be collected during this visit. This visit will take about 60 minutes.

For IHV site only: You also undergo a FibroScan test (same as to the one described on Day 1 visit). This test may be done during the Week 48 visit, or within 2 weeks (before or after) of Week 48 visit. This procedure will last approximately 5-10 minutes.

Your long-term HIV and Hepatitis B care after this end of study visit will remain the responsibility of your primary treating doctor. Your doctor may decide to continue you on BIKTARVY® or switch you to a different regimen after completion of the study.

RESEARCH STORAGE SAMPLES

To help with this research, we will be collecting blood samples (research storage labs) for use in current and future laboratory research. These samples will be stored by the University of Maryland, Institute of Human Virology researchers indefinitely and may be used in future research to learn more about HIV, hepatitis B, and their interaction with the immune system. All samples will be stored with coded numbers. No identifying information will be sent to Gilead Sciences, Inc. for further HIV and hepatitis B research including drug development. You would not receive payment for any new drug discoveries. If samples are tested for genetic markers, the results will not be labeled with your name. We will not be using the samples to generate a cell line for genetic testing. Samples and data will be stored without your name, but will be coded with a special study number that does not identify you. Only study staff will have access to the code-breaker that links your name and code. Samples will be kept in secure facilities with limited access. No results of this future laboratory research will be provided to you. If you withdraw from this study, the stored samples will not be removed from storage unless you specifically request that they be destroyed.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you decide to take part in this study, you will be responsible to:

- Take all study drugs as directed by your study staff and doctor.
- Follow all instructions given to you. If you are unsure about what you are supposed to do, ask your study team.
- Come to all your scheduled study visits and procedures. Let your study team know as soon as possible if you are not able to attend a study visit so he/she can work with you to make other arrangements.
- Inform the study team of all information regarding your health and medications.
- Consult with the study doctor before starting any new medications or herbal/natural supplements.
- Take and store your study drug as instructed, and return the unused study drug and/or empty bottles to the study doctor's office as instructed.
- Do not share your study drugs with anyone. You are the only person allowed to take the study drugs.
- Keep the study drugs out of the reach of children and persons of limited ability to read or understand.
- If you see a doctor or health care provider outside the research study, tell that doctor or health care provider that you are in an investigational research study, as certain medications could interact with the study drugs.
- Fill out your Patient Diary (study drug dosing card) completely and honestly, and bring your Patient Diary with you to each study visit as instructed by the study team.
- Tell the study staff if you wish to stop taking part in the study.
- While on the study, avoid getting pregnant or prevent your partner from getting pregnant. Effective contraception methods includes the following:
  - Complete abstinence (avoiding heterosexual contact)
  - Hormonal contraception (pills, implant or injected)
  - Vasectomy
  - Hysterectomy (removal of uterus)
  - Tubal ligation/occlusion ("tubes tied")
- Tell the study staff immediately if you are pregnant or suspect to be pregnant.

POTENTIAL RISK AND DISCOMFORTS

Potential Risk with BIKTARVY®
The most common adverse events reported in at least 5% of patient who have taken BIKTARVY® are diarrhea, nausea, and headache. The proportion of subjects who discontinued treatment with BIKTARVY® due to adverse events, regardless of severity was 1%. The majority (87%) of adverse events associated with BIKTARVY® were mild.

The most common side effects (occurring in more than 5% of people) reported were:
- Diarrhea (3% to 6%)
- Nausea (3% to 5%)
- Headache (4% to 5%)

Severe worsening of hepatitis B have been reported in patients who are coinfected with both HIV and hepatitis B and have discontinued their medication, and this may occur with discontinuation of BIKTARVY®. It is therefore important that you inform study staff is you wish to be taken off BIKTARVY® in order that a safe plan for monitoring and appropriate anti-hepatitis B therapy may be started.

Risk of Viral Resistance
Treatment with drugs that directly inhibit the HIV and/or hepatitis B can lead to development of HIV and/or hepatitis B virus that is resistant to that drug and other drugs with the same type of action. These resistance mutations (changes in the virus) have been observed in the body as late as 4 to 5 years after treatment has ended. Some resistance mutations may reduce the chance of treatment success with future drugs with the same type of action or with different types of action. It is possible that if you are treated with the drugs in this study and treatment does not work, you will develop resistance mutations that would make future treatment less successful.

Risk of FibroScan Test (will be done for IHV site only)
FibroScan is a noninvasive diagnostic ultrasound-based device used to measure liver scarring, or fibrosis, caused by various diseases including hepatitis B. It provides a non-surgical alternative to liver biopsy to assess liver damage. In preparation for this procedure, subjects will be advised not to eat or drink (including water) for at least 3 hours prior to procedure. The FibroScan test usually takes about 5-10 minutes. During the procedure, the subject will lie on his/her back with the right arm raised behind his/her head and the right abdominal area is exposed. A trained study staff member will apply a water-based gel to the skin and place the non-invasive probe over the liver area. Fasting prior to procedure can result in hypoglycemia, lightheadedness or fainting. During the procedure, there is a small but possible risk of localized allergic reaction and irritation related to the lubricating gel as well as discomfort due to positioning while in lying position.

Risk of Blood Draws
Collecting a blood sample from a vein may cause pain, bruising, lightheadedness, fainting, and very rarely, infection at the site of the needle stick.

Risk of Electrocardiogram (ECG)
After you have an ECG, you may have mild irritation, slight redness, and itching on your skin where the recording patches are placed. You may have your chest shaved for this procedure.

Risk of Allergic Reaction
Allergic reaction is always possible with a drug you have not taken. Serious allergic reactions that can be life-threatening may occur. Some things that happen during any allergic reaction to any type of medication are: rash, difficulty breathing, wheezing when you breathe, sudden drop in blood pressure, swelling around the mouth, throat, or eyes, fast pulse, and/or sweating.

Risk of Loss of Confidentiality and Privacy
There is always a potential for the loss of confidentiality and breach in privacy. This risk will be minimized by keeping all study data stored and secured behind locked doors. Electronic data will be password protected. Study visits and procedures will be performed in private exam rooms. Private information will only be given out as listed in the HIPAA form that you will separately review and sign, and only if necessary.

Unknown/Unexpected Risks and Discomforts
There may be risks in this study that are not yet known or happen rarely when subjects take these study drugs. You will be told of any new information that might cause you to change your mind about continuing to take part in this study. As with any new drug, extra care has to be taken to monitor the side effects that are not always obvious. If you feel any side effects or unusual symptoms, please notify your study doctor as soon as possible at the phone number listed in this form.

Pregnancy and Breast-Feeding
Because the effects of BIKTARVY® on an unborn baby or a nursing infant are not known, care must be taken to avoid pregnancy in female subjects or in female partners of male subjects during this study and following completion of study treatment (30 days after completion for women, 14 days after completion for men).

If you are a woman who is pregnant, intend to become pregnant, or is currently breastfeeding an infant, you cannot be in this study. If you are a male whose partner is pregnant or who can get pregnant, you may participate in the study as long as you use condoms or abstain from sexual contact during the duration of the study. You must protect yourself or your partner from becoming pregnant before, during, and after the study. Women, and men with female partners capable of becoming pregnant, must use effective methods of birth control. Your study doctor will need to document what type(s) of birth control you are using.

POTENTIAL BENEFITS
You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. All patients with HIV infection should receive effective treatment. Selection of drugs for HIV-infected patients who are also infected with hepatitis B should take into consideration the regimen's activity against hepatitis B to prevent potentially life-threatening hepatitis B flares. Fixed dose combination BIKTARVY® has the potential to offer HIV-hepatitis B infected patients a simple, once daily regimen containing drug components that provides a high barrier to resistance against both HIV and Hepatitis B. BIKTARVY® does not require a boosting agent (less chance for drug-drug interaction), and may potentially offers an effective and safe alternative to other regimens, without need for HLA testing or close monitoring of renal or bone toxicities. In addition, patient participation in this study will contribute to the body of knowledge about treatment for HIV-Hepatitis B dual infection.

ALTERNATIVES TO PARTICIPATION
You may choose not to take part in this study. If you choose not to take part, your healthcare at the University of Maryland, Baltimore, will not be affected. The study doctor can recommend other treatments. Alternative treatments may include approved standard of care, other research studies, palliative care, or no treatment. If you have questions about alternate treatments and their potential benefits and risks, ask the study doctor for additional information. You do not need to participate in this study to be treated for your HIV and hepatitis B dual infection. Additionally, if you are an employee or student, your employment status or academic standing at the University will not be affected by your participation or non-participation in this study.

COSTS TO PARTICIPANTS
Study procedures like study visits with the doctor and staff, and blood tests, will be done for free. The Sponsor will supply the study medications. Though you and/or your insurance may be financially responsible for paying for standard of care items and services received during this study. The Participant is financially responsible for paying

any insurance co-pay and/or deductible, if applicable. The Participant will not be responsible for the costs of services that are required only because the Participant is enrolled in the research study.

PAYMENT TO PARTICIPANTS

Study participants will receive $50 cash for each completed visit, and an additional $25 for each FibroScan test you undergo (FibroScan tests are done at Day 1, Week 24, and Week 48 visits). The total compensation will be up to $475 over the course of the study. Payment will be made at each study visit.

CONFIDENTIALITY AND ACCESS TO RECORDS

Efforts will be made to limit access to your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Most of the information collected will contain a code in the place of your name, including visit records, lab test results and assessments.

Organizations that may inspect and copy your information include the Institutional Review Board (IRB), other representatives of this organization, the Food and Drug Administration ("FDA"), the sponsor and or the sponsor's authorized representative. The monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law. Any newly documented HIV or hepatitis test results from this study will be reported as required under state law.

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.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, Dr. Joel Chua at 410-706-5704.

If you withdraw from this study, data already collected may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include need for failure to follow instructions of the research staff, or if the person in charge decides that, the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer any study-related injury, you may seek medical care from any healthcare provider. UMB and/or one of its affiliated institutions or health care groups may help you obtain medical treatment for the specific injury and provide referrals to other health care facilities if you request this. The costs of medical care for a study related injury would be billed to your medical insurance carrier. If you incur uninsured medical costs, they will be your responsibility.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____	_____
Participant's Signature	Participant's Name (PRINTED)
Date:_____	
_____	_____
Investigator or Designee Obtaining Consent Printed Name and Signature	Witness
Date:_____	Date:_____

SCHEDULE OF EVENTS

Study Procedures	Screening (D-90 to -3)	Day 1	Study Week					
			4	8	12	24	36	48[f]
Administrative Procedures								
Informed Consent	X							
Inclusion/Exclusion Criteria	X	X						
Complete Medical History	X							
Interval Medical History		X	X	X	X	X	X	X
Administer 1st Dose of Study Drug		X						
Receive Study Drug Supply		X	X	X	X	X	X	
Check Patient Diary and Number of used and unused study drug			X	X	X	X	X	X
Clinical Procedures/Assessments								
Complete Physical Exam	X	X						X
Targeted Physical Exam, if needed			X	X	X	X	X	
Concomitant medication	X	X	X	X	X	X	X	X
Adverse event		X	X	X	X	X	X	X
Height	X							
Vital Signs	X	X	X	X	X	X	X	X
FibroScan Test[e]		X[e]				X[e]		X[e]
Electrocardiogram (ECG)	X							
Clinical Laboratory Tests								
HIV Viral Load	X[a]	X	X	X	X	X	X	X
Hepatitis B Viral Load & HBsAg level	X[a]	X	X	X	X	X	X	X
CD4 Cell Count	X[a]	X			X	X	X	X
Hepatitis B serologies	X[a]					X		X
HIV Genotype and Resistance Tests[b]		X[b]						X[b]
Hepatitis B Genotype and Resistance Tests[c]		X[c]						X[c]
Hepatitis C and D testing	X[a]							
Complete Blood Count	X[a]	X	X	X	X	X	X	X
Blood Chemistries	X[a]	X	X	X	X	X	X	X
Clotting Factor Tests	X[a]							X
Urinalysis	X[a]							
Urine Pregnancy Test[d]		X	X	X	X	X	X	X
Blood Pregnancy Test[d]	X							
Research Laboratory Tests								
Research labs and storage		X	X	X	X	X	X	X
Blood Volume (in teaspoons)	11	25	15	15	18	23	18	25

LEGEND:

[a] Screening labs - ok to use available labs from clinic if < 90 days old.

[b] If HIV-1 RNA is >500 copies/mL.

[c] If HBV DNA is >500 IU/mL.

[d] For Women of Childbearing Potential.

[e] Baseline (Day 1) FibroScan test may be conducted within 30 days prior to Day 1 Visit.
FibroScan on Week 24 and Week 48 can be done on day of visit OR 2 weeks before or after the visit.

[f] Week 48 Study Visit procedures will be used for Early Termination/Study Withdrawal Visits

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Volunteer: _____

Date of Birth: _____ **Medical Record Number**: _____

NAME OF THIS RESEARCH STUDY: Efficacy, Safety, and Tolerability of Bictegravir/Emtricitabine/ Tenofovir Alafenamide in Adults with HIV-HBV Coinfection (BEST-HBV).

UMB IRB APPROVAL NUMBER: HP-00083844

RESEARCHER'S NAME: *Joel Chua, MD*

RESEARCHER'S CONTACT INFORMATION: *Institute of Human Virology*
University of Maryland School of Medicine (UMSOM)
725 West Lombard Street
410-706-5704

This research study will use health information that identifies you/your child. If you/your child agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Clinical laboratory tests*
- *Physician or Provider notes*
- *Research tests*

Federal laws require this researcher to protect the privacy of this health information. He/she will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. Joel Chua and his research team.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations, and the Food and Drug Administration (FDA)

THIS AUTHORIZATION WILL NOT EXPIRE. HOWEVER, YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. He/she will stop collecting health information about you. This researcher might not allow you to continue in this study. He/she can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
    - University Physicians, Inc. (UPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you/your child are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him/her.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your/your child's rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.