The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: **A Single Arm, Open Label, Phase 1 Study of Novel BET inhibitor PLX51107 and Corticosteroids for Treatment-Refractory Acute GVHD**

Principal Investigator: Hannah Choe, MD

Sponsor: **National Institute of Health**

Drug provided by: **Plexxikon Inc., 91 Bolivar Drive, Berkeley, CA 94710, USA**

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

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

You are being asked to take part in a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. This consent form also gives you information about the study. You should read all of this information carefully and discuss your questions and

concerns with your study doctor or healthcare team. You may also discuss your decision with your family and friends, and anyone you choose.

The Sponsor of this study is The National Institute of Health (NIH). The study drug is provided by Plexxikon Inc.

Purpose: Researchers at The Ohio State University have found that a new oral investigation drug, PLX51107, has anti-inflammatory effects that may be useful for the treatment of Graft Versus Host Disease GVHD. The purpose of this study is to determine the safety, best dose, and effectiveness of an investigation treatment with PLX51107 for GVHD that does not respond to steroids and/or other drugs used for GVHD treatment.

Procedures: Before the treatment, you will have testing to see if you are a suitable candidate for this study. If you are found to be a suitable candidate, you will start treatment with PLX51107 around three weeks after screening. PLX51107 comes in the form of tablets and will be taken by mouth daily as tolerated for a maximum of 6 months. The treatment is organized in cycles, and each treatment cycle will last 4 weeks. The dose of PLX51107 you receive will be determined by when you enroll in the study and may be different from the dose other study participants receive.

Risks: Most of the risks you may experience are from the medication you will receive. More details can be found in the following consent.

Benefits: Information from this study may help doctors learn more about medications used to prevent GVHD for future transplant patients.

Duration: You will be in the study for 1 year. You will be treated for the first 6 months, and your study doctors will continue to watch you for side effects and follow your condition for an additional 6 months.

The procedures and treatment plan are outlined in greater detail below. Your participation in this study is completely voluntary.

1. Why is this study being done?

Acute graft versus host disease (GVHD) is the most common serious complication after receiving a bone marrow transplant. GVHD is an immune response and occurs when the donor cells (the graft) treat the recipient's body as "foreign" and attack the cells in the recipient's body. During this immune system response the donor cells damage body tissues, such as the skin, liver, stomach, and/or intestines. GVHD can be severe and potentially fatal to the transplant recipient.

Currently, the only proven effective treatment for patients with acute GVHD are steroids. Patients who do not respond to steroid treatment are at high risk for death. If patients do not respond to steroid treatment, then there is no standard next line treatment. There is one FDA approved drug, ruxolitinib, but it is not standard treatment. Other drugs may be used off-label to try and treat the GVHD.

The goal of this research is to develop safer and more effective treatments for GVHD with the ultimate goal being safer and more effective transplant therapies for blood cancers such as leukemia, lymphoma, and multiple myeloma.

This research study is a Phase 1b clinical trial. Phase 1b clinical trials test the safety of an investigation drug. Phase 1 studies also try to define the appropriate dose of the investigational drug to use for further studies. "Investigational" means that the drug is still being studied and that research doctors are trying to find out more about it. It also means that the FDA (U.S. Food and Drug Administration) has not approved PLX51107 as an effective therapy for use in patients, including people with your type of cancer or GVHD.

PLX51107 works by targeting and slowing down certain activities within cells that promote inflammation. By inhibiting these activities, PLX51107 may help to stabilize or reduce the inflammation or growth of inflammatory cells. PLX51107 has anti-inflammatory effects in laboratory studies, but it is not yet known whether it will work in humans.

We are looking for the highest dose of PLX51107 that can be given safely to patients with your type of disease, GVHD. We will also look at how your body absorbs and breaks down PLX51107 and how effective PLX51107 is in treating your disease.

PLX51107 is **not** FDA-approved nor has it been used for treatment of GVHD, and is considered an experimental drug for treating patients wth GVHD. This treatment has also not been studied in pediatric patients (patients under the age of 18) for any disease.

You may qualify to take part in this research study because you have developed acute GVHD and your doctor feels that treatment for the GVHD is necessary. If you have GVHD that is not responding to steroids, you may be eligible to take part in this research study.

Plexxikon is providing the experimental drug and financial support to the study center and study doctor to conduct the study.

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

Design of the study:
Approximately 24-34 patients will participate in this study. There will be several dose levels of PLX51107 that will be explored to determine the best dose. At the beginning of the study, one patient will be treated with a low dose of PLX51107. If this dose does not cause

significant side effects, the drug will be given at a higher dose for the next subject who takes part in the study. Dose increases will continue until the highest dose offered is reached or until a patient develops a serious side effect. The dose levels are then adjusted based on how patients tolerate the drug. Your study doctor will tell you which dose of PLX51107 you will be receiving prior to your enrollment.

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

Study procedures:
Before the research starts (Screening)
After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of your regular care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may not have to be repeated. This screening period will happen within the 3 weeks before your first dose of PLX51107.

- Recording of demographics, including date of birth, race, and ethnicity.
- A medical history, including questions about your past and current health and any allergies.
- Performance status evaluation (ECOG Performance Status), we will ask you questions about what type of daily activities you are able to do.
- Complete physical exam, including height and weight.
- Review of past and current medications and treatments.
- Vital signs, blood pressure, pulse, body temperature, and respiratory rate.
- Electrocardiogram (ECG), which is a painless test to check your heart's rhythm.
- Approximately 3 tablespoons of blood will be drawn for:
    - Routine blood tests for hematology, chemistry, coagulation (blood clotting ability). These tests measure how well your organs are functioning.
    - Additional cancer-specific blood collections including the pharmacogenomics blood sample. These may help to determine specific biological characteristics of your cancer, such as mutations from genes in tumor cells and develop information about how each person responds or reacts to the study drug.
- Pregnancy test, if you are a woman and capable of becoming pregnant.

Confirmation that you are eligible to participate in the research study:
If these tests show that you are eligible to participate in the research study, you will begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

Study drug (PLX51107): PLX51107 comes in the form of tablets and will be taken by mouth. PLX51107 tablets should be swallowed whole and not crushed, chewed, or dissolved in water. The dose of PLX51107 you receive will be determined by when you enroll in the study and may be different from the dose other study participants receive.

Each treatment cycle will last 28 days (i.e., 4 weeks).

You will be given a Study Drug Diary to track the dates and times that you take the study drug and whether you were fasting or not. It is important you complete the Drug Diary accurately and that you bring your study drug and diary to every visit. You should take the study drug at approximately the same time each day.

Visit schedule of tests and procedures:
You will come into the clinic on Cycle 1 Days 1, 8, 15, 22, and then on Day 1 of all subsequent cycles. Your visits will typically last a few hours, though on Cycle 1 Days 1 and 8, study procedures will span an 8 hour period, and on Cycle 1 Day 15, study procedures will span a 4 hour period.

At most visits when drug levels in your blood are to be measured ("pharmacokinetic" or "PK" collection days), you should come to the clinic without eating or drinking anything (except for low calorie drinks like water or unsweetened coffee/tea) for at least the previous 8 hours. You will take your dose of study drug in the clinic. Do not take your dose of study drug at home that morning. It is important that you bring your study drug and diary to every visit.

On other days you take PLX 51107 at home you should not eat or drink anything except water 2 hours before and 1 hour after you take the study drug. However, if you feel weak or nauseous, you can have a low fat snack (i.e., dry toast, crackers).

If you agree to take part in this study, your doctor will perform a number of tests and examinations before, during and after the study. Some of these examinations, tests and procedures may be the same as those that are carried out as part of your regular medical care. You will also be asked to complete a number of questionnaires. Depending on the study visit, you may have the following tests and procedures:

- Performance status evaluation (ECOG Performance Status), we will ask you questions about what type of daily activities you are able to do.
- Physical exam, including weight.
- A review of current medications and any side effects you may be experiencing.
- Vital signs, blood pressure, pulse, body temperature, and respiratory rate.
- Electrocardiogram (ECG), which is a painless test to check your heart's rhythm.
- Depending on the study visit, approximately 1-9 tablespoons of blood will be drawn for:
    - Routine blood tests, for hematology, chemistry, coagulation (blood clotting ability). These tests measure how well your organs are functioning.
    - Blood collections for pharmacokinetics (PK), to measure how much study drug (PLX51107) is in your blood.
    - Blood collections for biomarker assessments, to measure effects of PLX51107 in your cells.

  - Blood collection for inflammation markers, to track if the study drug is affecting your body's response to inflammation.
  - Additional disease-specific blood collections, these may help to determine specific characteristics of your cancer, such as mutations from genes in inflammatory cells and develop information about how each person responds or reacts to the study drug.
- Drug Diary, you will be sent home with your study drug diary to accurately track the dates and times that you take the study drug each day. It is important that you bring your study drug and completed diary to every visit
- You may be asked for additional PK blood samples to be taken after your last dose of study drug or if there is a safety concern.
- After your last day of treatment, the study center may continue to keep in touch with you (this may occur in the form a telephone call or a routinely scheduled office visit) to follow the status of your disease and to collect information on your GVHD treatments after discontinuation of treatment on this study.

Follow Up
You will be followed for up to 6 months from initiation of study drug or 30 days from drug discontinuation (end of treatment) whichever is longer.

Your follow up appointments will involve:
- A review of current medications and any side affects you may be experiencing.
- Physical exam, including vital signs.
- Performance status evaluation (ECOG Performance Status), we will ask you questions about what type of daily activities you are able to do.
- Depending on the study visit, approximately 1-9 tablespoons of blood will be drawn for:
  - Routine blood tests, for hematology, chemistry, coagulation (blood clotting ability). These tests measure how well your organs are functioning.
  - Blood collections for biomarker assessments, to measure effects of PLX51107 in your cells.
  - Blood collection for inflammation markers, to track if the study drug is affecting your body's response to inflammation.
  - Additional disease-specific blood collections, these may help to determine specific characteristics of your cancer, such as mutations from genes in inflammatory cells and develop information about how each person responds or reacts to the study drug.

You will have weekly visits for the first two cycles of study drug and monthly thereafter until study drug discontinuation. You will have additional evaluations at 6-months from the start of the study drug, and end of treatment (30 days after the last dose of the study drug). You might have additional evaluations if study doctor determines that they are needed, All visits will be

done in-person with the exception of Cycle 2 Days 8, 15, and 22, which may optionally be done via secure video, per the doctor's determination.

4. How long will I be in the study?

Duration of the study
You may continue receiving study drug until one of the following happens:

- Your study doctor determines that you should stop receiving the study drug due to side effects
- Your blood disorder (e.g., leukemia, lymphoma) relapses
- Your GVHD worsens or has no response by 28 days
- Your GVHD response and completely resolves and you require less than ≤ 10mg/day or prednisone. The study drug is then tapered by 20 mg over one month.
- You decide to stop receiving study drug
- You decide to stop being part of the study.
- The study Sponsor (Plexxikon Inc.) or the IRB decides to end the study
- You reach a maximum of 6 months from initiation of study drug. If the dose is greater than 20 mg, the study drug should be tapered over maximum one additional month.

You will be in the study for 6 months. After you have stopped taking PLX51107, your study doctors will continue to watch you for side effects and follow your condition.

5. Can I stop being in the study?

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

You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

If you decide to stop being part of the study altogether, no additional tests will be done as part of this study. Any data or blood samples obtained prior to your decision to stop participation in the study will still be analyzed by the Sponsor. The study staff may still use publicly available information to find out how you are doing.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available • If you do not follow the study rules
- If the study is stopped by the sponsor or Institutional Review Board (IRB), a group of people who review the research with the goal of protecting the people who take part in the study
- If the study is stopped by the Food and Drug Administration (FDA) you may ask your study doctor about alternative methods of treatment at any time. The total length of time that you will be on study depends on how you respond to the study drug you receive. If your disease worsens or if you stop study drug dosing because your disease has worsened or you stop dosing due to side effects, you will be asked to return to the study center for an end of treatment visit.

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

Risks:
You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effect, however, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study drug. In some cases, side effects can be serious, long lasting, or may never go away.

There is a great deal of variability among side effects of different drugs and between individuals. For PLX51107, not all of the risks are known at this time. Since the effect of the study drug taken with other medications is not known, it is important that you tell the study doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate in this study. You may be asked to sign a new informed consent form that shows that you have been informed of new information relating to this research study. You should talk to your study doctor about any side effects which you experience while taking part in the study.

One of the most serious side effects could be Differentiation Syndrome. Differentiation syndrome is a condition that affects your blood cells which may be life-threatening or lead to death if not treated. In an acute GVHD patient population with no concern or evidence of active disease or suspicion of relapse, there is no known basis for the development of Differentiation Syndrome. Subjects with active disease/relapse are excluded from enrolling (exclusion criterion 3), and all enrolled subjects undergo a weekly physical examination with vital sign assessment and laboratory monitoring. In the event that an enrolled patient develops

relapse of disease, PLX51107 must be discontinued immediately and the patient withdrawn from study.

Risks associated with PLX51107
PLX51107 is a new investigational drug and has been tested in a small number of patients with cancer.

Side effects identified to date with patients who took PLX51107 are as follows:

Common side effects (experienced by greater than or equal to 10% of patients) associated with the use of PLX51107 include the following:

- Nausea
- Fatigue
- Vomiting
- Diarrhea
- Increase in blood tests that monitor for and indicate liver damage
- Decreased appetite
- Low red blood cells
- Low platelets
- Increase in blood tests that monitor risk of bleeding
- Dizziness
- Muscle aches
- Cough
- Shortness of breath
- Constipation
- Blood in urine
- High blood sugar
- Decrease in blood tests that measure the protein (albumin) in your body
- Low levels of electrolytes in the blood

Less common side effects (experienced by 5% to less than 10% of patients) associated with the use of PLX51107 include the following:

- Headache
- Chills
- Blood creatinine increased
- Low white blood cells
- Protein in urine
- Itching
- Fever
- Rash
- Urinary tract infection
- Decreased weight
- Dry mouth

- Muscle spasm
- Irritation of the mucus membranes (the lining inside areas of your body such as your mouth, nose, and digestive tract).

Rare but serious:
One patient with leukemia developed Differentiation Syndrome. Because patients with active underlying diseases (like leukemia, lymphoma) will not be eligible for the study, we do not anticipate that this will be a risk. Patients with any evidence of relapse of disease will be removed from study.

Side effects identified in preclinical animal studies:

- Gastrointestinal erosion and/or mucosal inflammation (erosion and/or inflammation affecting moist tissue lining parts of the inside of your body, such as mouth, nose, lungs, and digestive tract)
- Toxicity affecting the bone marrow (responsible for producing red blood cells, white blood cells, and platelets) and lymphatic tissues (responsible for white blood cells) which may decrease the number of some or all of these cells and may make you feel weak or fatigued, may increase risk of infection, and/or may increase risk of bleeding.
- Alteration in function of the tests which could result in reduced fertility
- Increase in blood tests that monitor risk of bleeding

Risks Associated with Study Procedures in This Study:

- Electrocardiograms [ECGs]: To perform the test, electrodes, i.e., stickers with wires attached, will be placed on your skin to record your heart's activity. No pain or other side effects are expected to be associated with these tests, but you may feel some discomfort, similar to pulling off an adhesive bandage, when the technician removes the electrodes after the procedure.
- Blood Samples: Side effects of having your blood taken may include pain, redness, swelling, and/or bruising where the needle enters the body. Rare instances of fainting, excess bleeding, blood clotting, or infection have occurred.

Unknown/Unexpected risks and discomforts
In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of PLX51107, including severe or life-threatening allergic reactions, interactions between study medications or interactions with another medication. You will be informed in a timely manner, both verbally and in writing of any new information, findings, or changes to the way the research will be done that might influence your willingness to continue your participation in this study.

Pregnancy risks
There also may be other side effects or discomforts that we cannot predict, especially to a fetus or embryo. Because the drugs in this study may affect an unborn baby, you should not become pregnant or father a baby while on this study.

For women of child-bearing potential, a pregnancy test will be performed during the screening period and must be negative before starting the study medication. Women of child-bearing potential must agree to use an acceptable method of birth control from the time of the negative pregnancy test to 6 months after the last dose of study drug. Effective forms of contraception include abstinence, hormonal contraceptive in conjunction with a barrier method, or a double barrier method. Women of non-childbearing potential may be included if they are either surgically sterile or have been postmenopausal for 1 year or longer. Fertile men must also agree to use an acceptable method of birth control while on study drug and for 6 months after the last dose of study drug. You should discuss your birth control with the study doctor. Let your doctor know immediately if you think you have become pregnant or if you think you have fathered a child during the research study or within 6 months after your last dose of study drug.

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

Possible benefits of the study
Taking part in this research study may or may not make your health better. We hope the information learned from this research study will help doctors learn more about PLX51107 as a treatment for GVHD in the future.

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

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

Treatment options:
You are being asked to take part in this study because you have a type of inflammatory condition called acute Graft-versus-Host Disease (GVHD) that has not responded to treatment. You may ask your study doctor about alternative drugs or treatments available for your specific condition. There are benefits and risks to taking other drugs, which you should discuss with your study doctor. You will be made aware of any new findings that become available during the course of the study that may affect your willingness to take part.

If you decide not to take part in this study, you have other choices. For example:

- Alternative treatments
    - FDA approved: ruxolitinib
    - Off-label: including but not limited to alpha-1 antitrypsin, anti-thymocyte globulin, alemtuzumab, tocilizumab, infliximab, extracorporeal photopheresis
- Choosing to not receive treatment
- Participate in another research study

- Comfort care, also called palliative care. This type of care may help to reduce pain, tiredness, appetite problems and other problems caused by GVHD. It does not treat the GVHD directly but instead tries to treat the symptoms.

Please talk to the research doctor about your options before you decide whether you will take part in this research study.

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

There are 2 types of procedures that will be done during this study. Some are part of your routine medical care and others are only for research.

You or your insurer will be billed for the routine medical care, because you would receive it even if you were not participating in this study. You will be responsible for your copayments, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all routine medical care costs. Before participating in this study, we recommend that you ask your insurer if there are any limitations to your particular plan.

Any procedures done only for research will not be charged to you or your insurer. This includes serial EKGs and research testing on your tissue and blood by a central lab. Your study doctor or coordinator can tell you, specifically, which costs are covered by the study.

PLX51107 will be supplied at no charge while you take part in this study.
It is possible that PLX51107 may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

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

You will not receive any payment for participating in this study.
By agreeing to participate in this study, you agree to waive any claim that you might have to the blood/body tissues that you are providing to the study and the study's Sponsor, who will retain ownership of some of your samples for the sole purpose of research and performing the study. You will receive no payment for these samples or from any products, tests, or products that are developed in the future from the use of the samples.

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

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

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

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

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

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

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

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

13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

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

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

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

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we **will** share it with you. However, we do not anticipate finding information that will significantly impact your health beyond the routine examinations and laboratory tests anticipated as part of your routine care. The research results we are obtaining do not significantly impact your health directly. Any pertinent information would be communicated directly to your study doctor who would contact you via phone or in-person visit for notification and further discussion.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

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

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

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;

- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  HIV / AIDS
  Hepatitis infection
  Sexually transmitted diseases
  Other reportable infectious diseases
  Physical exams
  Laboratory, x-ray, and other test results
  Diaries and questionnaires
  The diagnosis and treatment of a mental health condition
- Records about any study drug you received;

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

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: Scientific Advisory Board members (Steven Devine, MD, Margaret MacMillan, MD, Corey Cutler, MD), Collaborators (OSU Department of Pathology), OSU Data Safety Monitoring Board (DSMB).

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

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

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

VI. When will my permission end?

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

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

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers at:

Hannah Choe,MD
460 W 10th Ave
1st Floor
Columbus, OH-43210-1240

If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

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

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

X. May I review or copy my information?

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

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact

Study Doctor Name: Dr Hannah Choe, MD
Daytime Telephone Number(s): 614-293-3316
24-hour Contact Number(s): 614-293-8000

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact ***HIPAA Privacy Manager, The Ohio State University Medical Center, Suite E2140, 600 Ackerman Road, Columbus, OH 43202 or at 614-293-4477***.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, tell the study doctor or the study staff as soon as possible.

Signing the consent form

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

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

Printed name of participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

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

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness** **AM/PM** **Date and time**
Printed name of witness	**Signature of witness** **AM/PM** **Date and time**