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

Study Title:	**A Phase I Study of Romidepsin in Combination with Parsaclisib in Relapsed and Refractory T-Cell Lymphomas**
Principal Investigator:	**Dr Walter Hanel, MD, PhD**
Sponsor:	**The Ohio State University**
Drug Sponsor	**Incyte Corporation**

- **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 invited to participate in this clinical trial, a type of research study, because you have lymphoma that has come back (relapsed) or that has not responded to standard treatment (refractory).

This research study is a Phase 1 clinical trial. Phase 1 clinical trials find the best dose of a new or investigational drug with the fewest side effects. "Investigational drug" means that a drug has not been approved as a marketed product (i.e., available to be prescribed or sold) by the United States (US) Food and Drug Administration (FDA) or other regulatory authority as appropriate for the treatment of T-Cell Lymphoma.

This study will test the combination of an investigational drug, parsaclisib and an approved anti-cancer drug, romidepsin for the treatment of relapsed and refractory T-Cell Lymphoma. The investigational new drug is parsaclisib and it will be given to you with another anti-cancer drug romidepsin. Both the drugs are termed as the "study drugs" in this document. This clinical trial is sponsored by The Ohio State University and Incyte Inc.

Parsaclisib: You have been offered the drug called "Parsaclisib" that is being developed for the treatment of different types of cancers, including lymphomas. Parsaclisib is a phosphatidylinositol 3-kinase-δ inhibitor (PI3K). The PI3K pathway promotes cancer cell proliferation, growth, and survival. Parsaclisib, thus, may stop the growth of cancer cells by blocking PI3K enzymes needed for cell growth.

Romidepsin: Romidepsin is approved by the US FDA as a treatment for several types of lymphomas. This drug blocks certain enzymes (Histone Deacetylases) and acts by stopping cancer cells from dividing.

Combination Therapy of Parsaclisib and Romidepsin: Results from the laboratory studies show that a combined treatment of the study drugs may be more advantageous to block cancer growth than therapy of either drug alone. We anticipate that complimentary functions of the study drugs may be effective in T-cell lymphomas.

Before you decide if you want to participate in this study, it is important for you to understand why the research is being done, how your information will be used, what the study will involve, and the possible benefits, risks and discomforts. Please take time to read the following information carefully. Some terms may be unfamiliar to you. If there is anything you do not understand or if you would like more information, please ask the study doctor or study staff. You may also discuss the study with family members, friends, and your own doctor if you wish. If you decide that you want to take part in this study, you will be asked to sign the consent statement at the end of this informed consent form (you will be a given a copy of this to take home with you). No study procedures will be done until you have read and signed this form. You will be free to withdraw from the study at any time without having to give any reason. A decision not to take part in this study, or to withdraw at any time, will not affect your health care.

1. Why is this study being done?

The purpose of the study is to find the appropriate Parsaclisib dose level in combination with a Romidepsin for the treatment of relapsed or refractory T-Cell Lymphoma. The other goals of this study are (1) to find the proportion of patients in this trial whose cancer is put into complete remission or significantly reduced by the study drugs and (2) measure the effectiveness of the study drugs in terms of patient survival.

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

Up to 20 patients will participate at The Ohio State University.

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

If you decide to take part, this is what will happen:

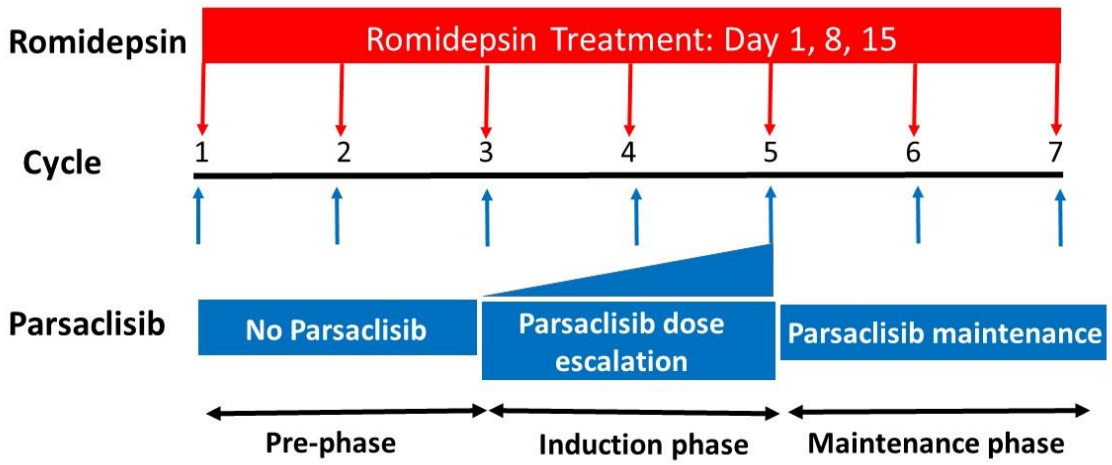
The study drugs will be given in cycles with each cycle lasting 28 days. The dosing for the study drug, parsaclisib, will vary during the course of the study while the dose and administration of romidepsin will remain the same. The dosing for this trial is divided into three phases:

1) **"Prephase"-** Two cycles of romidepsin treatment on days (D) 1, 8, 15 of a 28 day cycle. No parsaclisib will be given during prephase.

2) **"Induction phase"-** Parsaclisib dosing will begin on the third cycle of the study. This will include two cycles of increasing doses of parsaclisib (daily dosing from 5 mg up to 20 mg) along with romidespin on days 1, 8, 15 of a 28 day cycle.

3) **"Maintenance phase"-** constant dosing of parsaclisib at 2.5 mg daily along with romidespin on days 1,8,15 of a 28 day cycle. There is no maximum number of cycles planned in the "maintenance phase", you will remain on both parsaclisib and romidepsin until you are no longer able to tolerate the treatment, your lymphoma is no longer controlled on the treatment, or you decide to come off the the clinical trial for other reason.

A graphical timeline of the drug administration is shown below:



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 regular cancer 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 or may not have to be repeated.

- **Medical history,** which includes questions about your health, current medications, and any allergies.
- **Performance status,** which evaluates how you are able to carry on with your usual activities.
- **Physical examination** including height, weight, heart rate, temperature, respiratory rate, blood pressure and oxygen levels.
- **Determination of Body Surface Area (BSA):** Your height and weight will be calculated to determine your body surface area. BSA is collected to calculate dosing of the study drugs
- **Blood tests:** A Blood sample (about 2-3 teaspoons) will be taken from a vein in your arm to check your blood counts, liver function, total protein, Hepatitis B, C, and HIV tests, and chemistry including calcium, magnesium and phosphorus.
- **Computerized Tomography (CT) scan** of chest, abdomen, and pelvis.
- **Bone marrow biopsy:** A small sample of a soft tissue inside your hip bone will be tested for lymphoma
- If you have Cutaneous T cell lymphoma (CTCL), additional skin tests will be done as follows:
  - **mSWAT score:** Skin assessment and scoring to decide stage of your cancer

- **Skindex-16 Score**: A questionnaire about your skin condition
- **Detection and counting** of lymphoma cells in your blood.
- **Clinical exam** of lymph node, liver, and spleen

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 Procedures:

If you are eligible to participate in this research study, the following tests and procedures will occur:

(a) Prior to each infusion of romidepsin, you will receive anti-nausea medication (ondansetron and dexamethasone) and you will receive potassium and/or magnesium, either by mouth or intravenously, if your blood levels are found to be low. This is considered standard procedure if you are treated with standard of care romidepsin (outside a clinical trial)

(b) **Combination treatments**:

- *Romidepsin:* Romidepsin will be given in your vein [by intravenous (IV) infusion] weekly on Day 1, Day 8 and Day 15 of a 28 day each cycle as an outpatient IV infusion over 4 hours. For your convenience, and after discussion with the study doctor, D8 and D15 of romidepsin may be given in a local oncologist office if no side effects were observed during the first 2 cycles
- *Parsaclisib:* Starting with the third cycles and continuing through the fouth cycle, you will start taking parsaclisib by mouth daily in increasing doses (5mg, 10 mg and 20 mg). After the dose escalation cycles (third and fourth cycles), you will continue to take 2.5 mg parsaclisib daily. The drug manufacturer, Incyte, has decided to discontinue production of the medication, so there is a limited supply of the study drug parsaclisib and it is very possible the drug will run out during the course of your participation. In the event that you are doing well on the study drug and deriving benefit but the supply of drug is no longer adequate for you to continue, your doctor will discuss with you potential options, including reaching out to the manufacturer prior to running out of drug to access further study drug for compassionate use basis, continuing on the standard of care portion of the treatment (romidepsin) without parsaclisib, or changing to an alternate standard of care treatment or clinical trial treatment.

(c) **Other medications:**

- You may be at a higher risk of infections, including a special type of pneumonia called Pneumocystis Jirovecii pneumonia (PJP). Your doctor will prescribe a medicine that prevents this type of pneumonia (DS Bactrim tablet or dapsone).
- Your doctor will avoid treating you with medications that may lower your blood cell counts.

- Use of pain medications and transfusion of blood or blood products are allowed at the discretion of your doctor.
- In case of temporary side effects (painful lymph nodes, fever and rash), your doctor may prescribe corticosteroids.

(d) **Clinic visits:** Clinic visits will occur every 4 weeks and will involve the following:
- You will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- A physical exam
- Vital Signs: weight, heart rate, temperature, respiratory rate, blood pressure and oxygen levels.
- Performance status evaluation: which evaluates how you are able to perform your daily activities
- We will check your heart activity by EKG
- If you have Cutaneous T cell lymphoma (CTCL), skin evaluations and tests (mSWAT test, Skindex-16 test and counting of abnormal and cancerous cells as described earlier) will be repeated every 8 weeks.

(e) **Scans:** We will monitor your cancer by CT or FDG-PET scan of chest, abdomen and pelvis sometime between day 15 and day 21 after cycles 2, 4, 6, and 9. After that, we will perform a CT or FDG-PET every 6 months or sooner if we feel your lymphoma is progressing.

(f) Blood tests:
Your blood cell counts and chemistry will be routinely checked on day 1, 8 and 15 of each cycle. You will also have extra blood taken on day 1 of cycles 1, 3, 5, 7, and in the event that your lymphoma progresses while you are on the study. These will be used for research studies.

(g) Biopsies:
If you have CTCL, you will undergo a skin punch biopsy on four separate occasions during the course of the study:
1) prior to your first treatment with romidepsin (cycle 1, day1)
2) prior to your first treatment with parsaclisib (cycle 3, day1)
3) after receiving parasaclisib for two cycles of treatment, just prior to receiving romidepsin for the next cycle of treatment (cycle 5, day1)
4) if your lymphoma progresses while on the clinical trial

If you have CTCL, one punch biopsy will be required during each of these times. We will also ask you if you want to provide a second punch biopsy during each of these times, however, this second biopsy will be optional.

If you have PTCL, we will not require you to undergo a biopsy as part of this study. However, if you have had a biopsy of a diseased site performed prior to enrolling on

the study, we will request tissue from this biopsy for research studies. If you have a biopsy of a diseased site performed while you are on study or in the event that your lymhoma progresses while you are on study, we will also request tissue from these biopsies for research studies.

Research Study Calendar:

Assessment	Screening	Day 1 of each cycle	Day 8 of each cycle	Day 15 of each cycle	End of Study	Follow up
Informed consent	X					
Medical history	X					X
Physical examination, vital signs	X	X			X	X
Concomitant medications	X	X			X	
Tissue collection	X	X			X	
Body Surface Area	X	X			X	X
Skin Assessment (mSWAT score)		X			X	
Questionnaire about your skin (Skindex-16)	X					
Skin photography	X					
Lymph node biopsy	X					
Bone marrow and organ biopsy	X	X				
Skin biopsy	X	X				
Blood tests	X	X	X	X		
Electrolyte repletion		X	X	X		
EKG		X	X	X		
Hepatitis B, C, HIV testing	X					
Pregnancy testing	X	X			X	
Peripheral blood flow		X			X	

Assessment	Screening	Day 1 of each cycle	Day 8 of each cycle	Day 15 of each cycle	End of Study	Follow up
PMBC collection		X				
Plasma cytokines		X				
CT chest abdomen pelvis or FDG-PET	X	X (after cycles 2, 4, 6, and 9)			X	X`
Parsaclisib		Daily on days 1-28				
Romidepsin		X	X	X		

Planned Follow-up:
After you complete the study treatment you will be monitored as follows:
- **Safety Follow-up:** You will be followed for 30 days after your last dose of study treatment. Your doctor may order tests as necessary to check on your side-effects.
- **Disease Follow-up**: After you complete the study treatment, your disease status will be followed every 3 months for the first 2 years.

The study ends 30 days after your last dose of study treatment (romidepsin and/or parsaclisib). We would like to follow you at least twice a year until the study ends to keep track of your medical condition. We would like to do this by reviewing your medical records and/or calling you on the telephone. Checking on your condition helps researchers look at the long-term effects of the study treatment on your diagnosis.

4. How long will I be in the study?
You will remain on study treatment as long as you are tolerating the treatment well and your disease is controlled, and if the sponsor continues to provide sufficient investigational drug (parsaclisib).

When you come off the study, you will be followed for about 24 months after study treatment. Your doctor may recommend stopping study treatment early if you get serious side effects from the treatment or it is the opinion of your doctor that you are not benefiting from the treatment.

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. All blood, skin, and marrow samples that you provided as part of study procedures will continue to be stored and/or analyzed at the primary investigator discretion and may be

shared with collaborators at outside institutions. None of your identifying information will be shared with any third party if such samples are shared.

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

All cancer treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different cancer treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.** Everyone in the research study will be watching you carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts. If you experience side effects, they may go away after you stop taking the study drug. Some side effects can be mild; but others can be long lasting and may never go away as noted below. Some may be life-threatening or fatal and are noted below. You will be monitored closely for any severe, life-threatening side effects listed below. Some of these side effects may be permanent. Appropriate medical care will be provided, if necessary, including additional treatment, hospitalization and/or surgery.

Possible risks and discomforts you could experience during this study include:

Risks and side effects related to Romidepsin

Likely risks of Romidepsin: (events occurring in more than 20% of patients)
• Nausea • Fever • Low blood pressure (possible dizziness and / or fainting) • Fatigue • Headache • Skin rash • Itching • Shedding and scaling of the skin (possible fatal loss of bodily fluids) • Abnormal levels of salts, minerals, and / or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental state, and / or seizures) • High blood sugar (possible diabetes) • Loss of appetite • Vomiting • Abnormal taste • Constipation • Diarrhea • Low red blood cell counts causing fatigue and anemia • Low white blood cell counts (causing an increased chance of infection

- Low platelet counts in the blood (causing an increased chance of bleeding such as nosebleeds, bruising, strokes, and / or digestive system bleeding)
- Abnormal liver test results (possible liver damage)
- Weakness
- High levels of uric acid in the blood (which can cause painful joints and / or kidney damage)
- Coughing
- Difficulty breathing

Less likely risks of Romidepsin: (events occurring in 3-20% of patients)

- Swelling of the arms or legs
- Fast heartbeat
- Chills
- Weight loss
- Abdominal pain
- Blisters or sores in the mouth (possible difficulty swallowing)

Exact frequency unknown: (events occurring in fewer than 10% of patients)

- Chest pain
- Irregular heartbeat
- Blood clots in a vein (possible pain, swelling, and / or redness) that can travel to the lung causing life-threatening lung damage
- Fainting
- Allergic reaction
- Severe life-threatening infection (possible low blood pressure, kidney failure, and / or heart failure)

Rare but Serious risks: (occurring in fewer than 3% of patients)

- Heart failure
- Kidney failure

Romidepsin may also cause reactivation of Hepatitis B (liver damage) that can lead to liver failure.

Risks and side effects related to Parsaclisib:

If you experience any of the described side effects, you must immediately tell the appropriate study staff member or the study Doctor. These side effects include but are not limited to diarrhea, signs of infection (e.g., fever ≥38ºC or 100.4ºF, chills, or coughing), spontaneous

bleeding (e.g., the appearance of small red or purple spots or patches on the skin, unexplained nose bleeds or bruising, or a sudden, extremely painful headache that peaks within a minute), or redness and peeling of the skin. The Doctor will determine what should be done if these things happen. If the Doctor or study staff are unreachable, seek immediate medical assistance from the nearest available health care facility.

Common Side Effects: (Events occurred in more than or equal to 5% of patients)

- Diarrhea*
- Nausea
- Cough
- Fatigue
- Fever
- Rash
- Constipation
- Decreased appetite
- Vomiting
- Loss of strength
- Swelling caused by fluid in the legs/arms
- Headache
- Abdominal pain
- Joint pain
- Labored breathing
- Itching
- Upper respiratory tract infection
- Low levels of potassium
- Dizziness
- Back pain
- Urinary tract infection
- Abnormal liver test results
- Inflammation of the large intestine*
- High blood pressure
- Eczema
- Skin infections
- Shingles
- Neutropenia (low white blood cell levels

*Diarrhea and inflammation of the intestine are also serious side effects that are considered to be expected.

Serious Side Effects that are Considered to be Expected

- CMV (cytomegalovirus) infections; signs may include fever, fatigue, shortness of breath, weakness, blurry/loss of vision, stomach pain, nausea, vomiting, bloody stool, diarrhea, seizures, headaches, and confusion
- Severe rash, hives, peeling, or other skin reaction
- Lower blood counts (red and white blood cells, platelets)
- Severe diarrhea or colon inflammation

Uncommon Side Effects

- Irregular bowel movement- increased fecal volume, frequent bowl movements, inability to control bowl movements
- Skin irritation- acne, peeling, scaliness, bumps
- Ear, eye, or sinus infections
- Interstitial lung disease, which can make your lungs stiff and cause breathing difficulties
- Pneumocystis jirovecii pneumonia (pneumonia caused by a fungus)
- Chickenpox

Infection risk of Parascaclisib:
Based on the way in which the parsaclisib works, your body may not be able to fight off an infection as well as it would otherwise. You may be at a higher risk of an infection, including reactivation of a previous viral infection (some viruses can remain in the body after an infection) or Pneumocystis jirovecii pneumonia (PJP), a form of potentially life threatening pneumonia caused by a fungus. All participants will be asked to take a preventative medication to assist your body with fighting this potential infection. You will need to take this medication while you are in the study and for 2 to 6 months after you take your last dose of parsaclisib. Your doctor will tell you which medication to take and will discuss with you the risks for the medication you are prescribed. You will be closely monitored for any infections and the study drug may be temporarily interrupted for infections that can be easily treated. If you get an infection that is serious or requires prolonged antibiotic therapy, you may not be able to continue the study.

Potential Risks Associated with Pneumocystis Jirovecii Pneumonia Prevention
Your doctor and/or study staff will give you the approved package leaflet for the pneumonia prevention medicine and will explain to you the possible side effects and the safety information related to this medicine.

Risks associated with combined therapy of romidepsin and parsaclisib:
It is possible that combination of the two study drugs may cause unexpected side effects that so far have not been seen when either medication is taken alone.

Risks Associated with Blood Draw

Risks of blood draws include mild pain or discomfort, bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).

Risks Associated with Skin Biopsy
The risks associated with a skin biopsy include a feeling of burning when the medicine used to numb your skin is injected. There is a possibility that you will have an allergic reaction, including rash, hives, and shortness of breath, to the numbing medicine, but it could be treated immediately. If you have a known allergy to the numbing medicine, you may not give a skin sample. Bleeding, bruising, discomfort or pain, and rarely infection may occur. It should heal with a small, flat scar.

Risks Associated with Bone Marrow Biopsy
A feeling of pressure and temporary pain are the most likely adverse events experienced with bone marrow biopsies. Bleeding, bruising, and rarely infection may occur.

Reproductive Risks:
We do not know whether the study drugs (romidepsin and parsaclisib) used in this research study might hurt an unborn child.

While participating in this research study, you should not become pregnant, should not nurse a baby, should not father a baby or donate sperm while in the study and for 6 months after last dose of study drug(s). We will provide counseling about preventing pregnancy for either male or female study participants. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

If you have any reason to suspect you are pregnant, you must IMMEDIATELY tell your doctor.

If you are pregnant or nursing a baby, you cannot take part in this study.

You must use **TWO** reliable methods of birth control at the same time (one highly effective method and one additional effective method) or practice complete abstinence while you are being given study treatment and at least 6 months after you discontinue study treatment.

The following are the acceptable birth control methods:

Highly Effective Methods	Additional Effective Methods
Intrauterine device (IUD)	Latex condom
Hormonal (birth control pills, injections, implants)	Diaphragm
Tubal ligation	Cervical Cap
Partner's vasectomy (for men)	Sponge used with spermicidal gel or foam

Hysterectomy (for women)

Other Risks:
Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

Since the effect of the study drug(s) taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods and vaccinations that you should avoid while on this research study and your research doctor will review this information with you.

Risks associated with Breach of Confidentiality:
Just as with your standard health care, we will take all measures necessary to make sure your personal health information is kept private while you are on the clinical trial in accordance with the health insurance portability and accountability act (HIPAA). However, there is a small risk that people who are not connected with this study will learn your identity or your personal information.

7. What benefits can I expect from being in the study?
There is no guarantee that you will receive any benefits from this study. The possible benefit of the study drug in the treatment of your diagnosis is not known. If you decide to participate in this study, your health will be monitored very closely. By being in this study, you will give doctors more information about how well the study drug works. It may help doctors understand your condition better and may help future patients with this medical condition.

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

Taking part in this research study is voluntary. Instead of being in this research study, you have other options that may include the following:

- Have the usual approach for your cancer, which may include romidepsin by itself, other targeted therapies, or chemotherapy
- Receive no further treatment
- Take part 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 the cancer. It does not treat the cancer directly, but instead tries to treat the symptoms.

9. What are the costs of taking part in this study?
Parsaclisib will be provided by Incyte Inc and will not be billed to you or your insurance company. It is possible that Parsaclisib 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.

Romidepsin is a treatment which has been approved by the FDA for use in T-cell lymphoma and will be the responsibility of you and/or your insurance carrier.

Neither you nor your insurance carrier will be responsible for the research procedures related to this study.

However, you or your insurance company will be responsible for paying for procedures, tests and possibly medications that are part of standard care for patients with your type of cancer. You are responsible for any co-payments, co-insurance, and deductibles as required by your insurance company or charges your insurance company does not pay.

Participating in this research study may lead to additional costs to you. Your insurance company may not pay for costs associated with research studies like this one. Please feel free to contact your insurance company to review benefits provided by your insurance policy.

If you become sick as a result of this study, any medical care that you require will be billed to your insurance company and you may have to pay for any medical care, including hospitalization that your insurance company does not pay for.

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

You will not receive any payment for taking part in this study.

If you agree to participate, your samples will be considered a gift to The Ohio State University. The university may sell or share your samples and clinical information with others, such as private companies, government agencies, or other universities. The university will be paid if your samples and personal information are sold.

- Your samples and clinical information may be used to make new products or technologies. You will not be paid if these new products or technologies are sold or make money.
- You cannot choose how your samples and clinical information will be used. If you do not want to let others decide how your samples and clinical information will be used, then you should not donate your samples.

Possible Commercial Products

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose. Donors of blood, tissue and other biological materials do not retain any property rights to the materials. Therefore, you would not share in any money or other benefits that any entity might receive for these inventions or discoveries

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 on 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).

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
- 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;
- The research sponsor The Ohio State University and Incyte Inc. (supplier of Parsaclisib) and its employees, agents or contractors who are involved in the administration of the study

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. 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 **Dr Walter Hanel at 614-293-9588 or 614-293-8000 (24 hours).**

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, you may contact **Dr Walter Hanel at 614-293-9588 or 614-293-8000 (24 hours).**

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