Consent and Authorization Document

HCI IIT CHARGE

A Phase I/Ib Trial of the CDK4/6 Antagonist Ribociclib And The HDAC Inhibitor Belinostat In Patients With Metastatic Triple Negative Breast Cancer And Recurrent Ovarian Cancer With Response Prediction By Genomics (CHARGE)

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You are being asked to take part in a research study. Once you learn more about the study, you will make a decision about whether to take part. Before you decide, it is important for you to understand why the research is being done and what it will involve. This document may contain words and information that you do not understand. Please ask your study doctor or study staff to explain anything that is not clear to you. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

Summary
You are being asked to participate in this research study because you have been diagnosed with advanced breast or ovarian cancer. In this study you will be given a combination of two drugs, ribociclib and belinostat. The combination of the drugs used in the study is investigational. Although each drug has been approved by the FDA, the combination has not been approved by the U.S. Food and Drug Administration (FDA).

The purpose of this consent form is to help you decide if you want to be in this research study. You should not join this research study until all of your questions are answered. Once you know about the study, you will decide about whether to take part. If you decide to take part, you will be asked to sign this form. Your decision to take part in this study is voluntary which means you are free to decide to join this study or not to join this study.

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Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue your participation.
- **Purpose**. The purpose of this research is determine safety of the combination of treatments and associated side effects. We will also study the effect the combination treatment has on your disease.
- **Duration.** Your participation may last for up to 3 years.
- **Procedures and Activities.** You will be asked to undergo a number of tests (Screening) to be certain that you are able to participate and that you are healthy except for your tumor. During the Treatment period you will also undergo additional testing to evaluate your disease, the study treatment, and safety. The schedule is described below.
- **Risks.** There are side effects that may occur from taking ribociclib and belinostat. The side effects range from very common to rare. The side effects vary in seriousness. Both drugs can affect your blood counts including your immune system or the ability of your blood to clot. Both drugs can also increase the risk of abnormal heart rhythms.
- **Benefits**. We do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have cancer.
- **Alternatives.** As an alternative to participation, you could receive standard of care treatment, take part in another study, choose to receive comfort care, or choose to have no further treatment.

The main reason for you to take part in this study is to help in answering the following research questions:

1. How safe is ribociclib in combination with belinostat? What, if any, side effects that you might have when you receive the combination treatment.
2. What effect the study treatment combination may have on your disease.

The study drugs, ribociclib and belinostat will be given to you in segments of time called “cycles”. For this study, a cycle will be 28 days. Ribociclib will be given to you as a pill that you will take at home. Belinostat will be given to you as an intravenous (IV) infusion for the first 5 days of each cycle. The study treatment will continue as long as it is working on your cancer and the side effects are tolerable. 30 days after your end of treatment visit, you will have a safety follow-up. You may continue to have additional follow-ups for up to 2 years after you end treatment. A detailed description of the study procedures is explained later in this document.

The combination of ribociclib and belinostat has not been approved by the U.S Food and Drug Administration (FDA) so this combination is being considered “investigational” for use in this study. An investigational drug is a drug that is being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration (FDA).

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Ribociclib is an anti-cancer agent which is approved in the United States (US) to treat patients with estrogen receptor-positive breast cancer. However, it has not been FDA approved to treat patients with triple negative breast cancer or ovarian cancer.

Belinostat is approved by the FDA for the treatment of lymphomas. However, it has not been FDA approved to treat patients with triple negative breast cancer or ovarian cancer.

The study is being conducted by Dr. Theresa Werner at the Huntsman Cancer Institute of the University of Utah and one additional site.

What is expected from you?
If you participate in this study you will be expected to:

- Attend all your appointments and follow all instructions given to you by the study doctor and/or study staff.
- Tell the study doctor or study staff how you feel and possible side effects that you are experiencing.
- Tell the study doctor or study staff about any changes in your health.
- Tell your study doctor about any medical treatments that you plan to receive during the study (such as elective surgery or radiation).
- Tell the study doctor or study staff about any medication that you take while you are in this study, including any new prescription, over the counter medications or herbal supplements, even if they are prescribed by another doctor. You may not be able to take certain medications while you are participating in this trial. Your study doctor will inform you what these are.
- You should not eat grapefruit, grapefruit hybrids, pomelos, star fruit or Seville oranges while taking study drugs. This includes any juice derived from these fruits.
- Tell your study doctor or study staff if you change your address, telephone number, or other contact information.

STUDY PROCEDURES
If you decide to take part in the study and you sign this informed consent form, you will have some screening tests and procedures done to make sure you are eligible to enroll.

The CT (Computed Tomography) scans that are to be performed as part of this study are considered standard of care and would be done regardless of your participation in this research study.

Screening Period

- Medical history will be collected, including smoking history, as well as details about what medications and vitamins you are currently taking.
- You will have a physical exam and a measure of your vital signs, including weight and height.
- An evaluation of your ability to perform everyday activities (performance status) will be done.
- You will have an electrocardiogram (ECG) done. An ECG measures the electrical activity of your heart, including the rate and rhythm of your heartbeat.

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- You will have a CT scan. This is considered standard of care and would be done even if you were not participating in this study.
- If you are female with the potential of becoming pregnant, you will have a pregnancy test.
- You will have your blood drawn and a urine sample taken for standard lab testing to ensure you are healthy enough to take part.
- You will have a biopsy of at least one tumor and at most three tumors. The locations of the biopsies will be determined by your doctor and the radiologist doing the biopsies.
- At the time of biopsy you will also have additional blood taken for genetic testing related to this study.

Treatment Period

Once it is decided that you are able to enroll into this study, you will begin study treatment. The study drugs, ribociclib and belinostat will be given to you in segments of time called "cycles". For this study, a cycle will be 28 days. Ribociclib will be given to you as a pill that you will take at home. Whether you take ribociclib every day or only some days will depend on what group is available when you enroll. You will be given a "dosing diary" to track when you take your ribociclib dose at home. Belinostat will be given to you as an intravenous (IV) infusion on the first five days of every cycle. Your doctor will give you more information about your treatment plan.

You will come to the clinic on Day 1 of each cycle for various procedures. Some of the procedures are being done as part of your routine cancer care. Some are being done because you are participating in this study. For Cycle 1 and Cycle 2 you may also come to clinic on Day 8 and Day 15. You will continue on the study treatment for up to 1 year unless your disease gets worse, you have intolerable side effects, you decide to stop, or if your doctor decides it would be in your best interest to stop or the study ends. If your disease responds well to the drug, your treatment may be extended, you will discuss this with your doctor at that time.

If you experience any changes in your body or develop any new or worsening side effects during or after the study treatments, you should inform the study doctor or study staff immediately

Study Procedures during the Treatment Period:

- You will have physical exams and measures of your vital signs, including weight, during your clinic visits. You will also be asked about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects.
- Evaluations of your ability to perform everyday activities (performance status).
- You will have CT scans to check how your disease is responding to treatment. This will be done every 8 weeks (2 cycles). These scans are considered standard of care and would be done even if you were not participating in this study.
- You will have ECGs done on days 1, 8, and 15 of the first two cycles.
- You will have blood draws for standard lab testing for safety at each cycle. For the first two cycles, these will be drawn every two weeks. After that, they will be drawn only on the first day of the cycle.

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- If clinically indicated, HIV and Hepatitis testing may be performed for participants with a known history of infection. If you do not want to be tested you may choose not to participate in this research study.
- On the first day of each cycle, you will have a review of dosing diary for ribociclib taken at home and will be asked to return the empty ribociclib containers or any unused supplies.

You will also have a tissue biopsy of at least one tumor collected about half way through the second cycle (about day 15). If you have any questions, ask your study team for more information about these samples.

End of Treatment

When the decision to discontinue treatment is made you will have the following procedures completed:

- You will have a physical exam and measure of your vital signs, including weight. You will also be asked about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects.
- Evaluation of your ability to perform everyday activities (performance status).
- You will have your blood drawn taken for standard lab testing for safety.
- You will have a CT scan. This is considered standard of care and would be done even if you were not participating in this study.
- You will have an ECG.
- If you choose to participate you may also have an additional biopsy of your tumor to help us evaluate the effects of the drug on the tumor. This biopsy is optional and not required for participation in the study. All optional testing is related to this research study. Please **initial** and **date** the appropriate box below to let us know if you would like to participate:

End of Treatment Biopsy:

initial_____ /date_____I **do** want to participate in the optional end of treatment biopsy.

initial_____ /date_____I **do not** want to participate in the optional end of treatment biopsy.

Safety Visit

About 30 days after your last dose of study therapy you will have a safety follow-up to check on any side effects you may have.

Follow-up

Once you complete your end of treatment visit, you will continue to be followed every 3 months for up to 24 months. If you stop coming in to see your doctor for any reason, phone calls and/or medical chart reviews will occur to continue to check on your health. The follow up will consist of reviewing your regularly scheduled visits to see how your cancer is doing and if there have been any long term effects from the study treatments. All testing and treatment during follow-up will be determined by you and your doctor.

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What are the Uses for my Samples Collected during the Study

Your participation in genetic testing is a mandatory part of this study. It will be performed in order to learn more about factors which may predict response to the study treatments.

Segments of the DNA called genes are responsible for passing particular traits such as eye color from parents to children.

We may perform a whole genome or whole exome analysis on your blood sample. In whole genome or whole exome analysis, all or most of your genes are studied and used by researchers to find causes of diseases, such as cancer. It is also possible that this type of testing will discover a gene that you do not know about that may indicate you or a relative is at risk for a genetic disorder in the future.

You will not receive any of your genetic information that comes from the testing in this study, nor will it become a part of your medical record. The results will be kept on password-protected computers and results will be accessible only to the investigator and other authorized people.

Optional Future Use of Samples

If you agree to participate the study team would like to save (bank) any leftover tissue and blood samples from the study testing for future cancer research that is not specifically related to this study. The tissue bank will be managed at the University of Utah and will be kept by them. Participation in the specimen banking is completely optional. If you choose not to participate in the banking part of the study, your decision will not exclude you from the main study.

The study team at the University of Utah will be able to link your personal information to your samples. You do not have the option to have your samples de-identified. If this is not acceptable to you, you should not participate in the optional specimen banking portion of the study.

At any time, you may ask that your samples not be used for future research and that they be destroyed by contacting the study doctor and/or study team. If you ask for this, study tests will be done but samples will not be used for future research testing. However, any information collected from your samples before your request to destroy them will be kept by HCI.

If you decide to stop taking part in the study, but do not request that your samples be destroyed, HCI and its authorized representatives may continue to use your samples for future research and genetic testing.

Because the results from future research will not directly affect your health care, we will not share the results from future studies with you or your doctors.

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Please **initial** and **date** the corresponding line below to let us know if you would like to participate:

initial_____ /date_____I **do** want to participate in the optional specimen banking.

initial_____ /date_____I **do not** want to participate in the optional specimen banking

RISKS

You may have side effects from the drugs or procedures used in this study. Side effects can vary from mild to very serious and may vary from person to person. Everyone taking part in the study will be watched carefully for any side effects. However, the study doctor and other doctors do not know all of the side effects that could occur. Your study doctors may give you medications to help lessen side effects, and you may need to temporarily or permanently stop treatment. Many side effects go away soon after you stop what is causing them. In some cases, side effects can be serious and may be long lasting problems or may never go away. There also is a rare risk of death. You should talk to your study doctor about any side effects you have while taking part in the study.

Ribociclib

Ribociclib may cause one or more of the side effects listed below. This information is based on data from cancer patients treated with ribociclib. In addition, there may be side effects that are not yet known that may occur. You should tell your doctor or nurse right away about any possible side effects that you experience.

VERY COMMON

In 100 people receiving ribociclib, as many as 10 and up to 100 may have:

- Possible effects on the blood:
  - Neutropenia (low levels of infection fighting cells)
  - Decrease in white blood cells
  - Decrease in red blood cells, causing anemia
  - Decrease phosphorus levels in the blood
  - Decreased sugar levels in the blood
  - Decreased protein levels in the blood
  - Decreased potassium levels in the blood
- Possible gastrointestinal effects:
  - Nausea
  - Fatigue
  - Diarrhea
  - Vomiting

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- Constipation
- Decrease in appetite
- Swelling with or without open sores in the mouth and on the lips
- Stomach pain

- Possible effects on the skin:
  - Hair loss or thinning
  - Rash
  - Itching
- Possible effects on the heart and blood vessels:
  - Swelling in the legs
- Possible effects on the liver:
  - Liver test abnormalities
- Possible effects on the immune system:
  - Increased risk of infection
- Possible effects on muscles and skeleton:
  - Joint pain
  - Back pain
  - Feeling of weakness or decreased muscle strength
- Possible effects on the nervous system
  - Headache
  - Tiredness
  - Trouble sleeping
  - Dizziness
- Possible effects on the kidneys:
  - Urinary tract infections
  - Decreased kidney function
- Possible effects on the lungs:
  - Cough
  - Shortness of breath
- Other
  - Fever

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COMMON

In 100 people receiving ribociclib, as many as 1 and up to 10 may have:

- Possible effects on the blood:
  - Low levels of platelets, the blood clotting cells
  - Fever when the immune system is low, which can indicate infection
  - Decrease in red blood cells requiring a transfusion (replacement of red blood cells from a donor)
  - Low calcium levels
- Possible effects on the heart and blood vessels:
  - Abnormal electrical activity in the heart called QT prolongation
  - Fainting
- Possible effects on the skin:
  - Vitiligo (a condition in which patches of skin lose their color)
  - Dry skin
  - Skin redness
- Possible effects on the gastrointestinal system:
  - Heartburn
  - Taste changes
  - Dry mouth
  - Mouth pain
- Possible effects on the liver:
  - Increase in bilirubin in the blood
- Possible effects on the muscles and skeleton:
  - Leg and arm pain
- Possible effects on the eyes:
  - Dry eyes
  - Increased tearing

Side effects that occurred in less than 1% of patients but were considered medically important or severe or life-threatening and rarely fatal are listed below. These events occurred in studies of ribociclib given alone. If you are at the clinical site and notice any signs or symptoms of the side effects listed below, check with the staff in the clinic immediately; if you are no longer at the clinical site, call your doctor or go immediately to the nearest hospital.

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RARE

In 100 people receiving ribociclib, less than 1 may have:

- Inflammation in the lungs
- Lung infection
- Lung scarring
- Severe shortness of breath requiring a ventilator
- Severe infections
- Sudden cardiac death

Belinostat

Belinostat may cause one or more of the side effects listed below. This information is based on data from cancer patients treated with belinostat. In addition, there may be side effects that are not yet known that may occur. You should tell your doctor or nurse right away about any possible side effects that you experience.

Very Common

Out of 100 people who receive belinostat, 10 or more people may have the following:

- Possible effects on the blood
  - Low counts of red blood cells, causing anemia
  - Low platelet counts
  - Increase in a blood protein called lactate dehydrogenase (LDH)
  - Decrease in potassium in the blood
- Possible effects on the gastrointestinal system
  - Nausea
  - Vomiting
  - Constipation
  - Diarrhea
  - Decreased appetite
  - Abdominal pain
- Possible effects on the heart and blood vessels:
  - Swelling in the legs
  - Abnormal electrical activity in the heart called QT prolongation
- Possible effects on the nervous system
  - Headache
  - Fatigue
  - Chills
- Possible effects on the skin
  - Rash
  - Itching
- Possible effects on the lungs:
  - Cough
  - Shortness of breath

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- Other possible effects:
    - Fever
    - Pain at the injection site

Common

Out of 100 people who receive belinostat, at least 1 but less than 10 people may have the following:

- Possible effects on the blood
    - Neutropenia (low levels of infection fighting cells)
    - Decrease in white blood cells
    - Fever when the immune system is low, which can indicate infection
    - Decrease in platelets, the blood clotting cells
    - High blood sugar
    - Low blood calcium levels
    - Low blood potassium levels
    - Low blood magnesium levels
    - Low blood sodium levels
- Possible effects on the heart
    - Palpitations
- Possible effects on the eye
    - Blurry vision
- Possible effects on the gastrointestinal track
    - Abdominal distension
    - Abdominal pain
    - Dry mouth
    - Heartburn
    - Flatulence
    - Mouth sores
    - Liver test abnormalities
- Possible general effects
    - Chills
    - Flat mood
    - Injection site pain
    - Injection site inflammation
    - Swelling
    - Fever
    - Allergic reactions
    - Trouble sleeping
    - Possible infections
    - Yeast infections
    - Possible effects on the limbs
    - Joint pain
    - Muscle pain

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- Possible effects on nerves
    - Dizziness
    - Headaches
    - Numbness
    - Tingling
    - Abnormal sensations
- Possible effects on the skin
    - Dry skin
    - Sweating
    - Itching
    - Rash
- Possible effects on blood vessels
    - Hot flushes
    - Low blood pressure
    - High blood pressure
    - Inflammed blood vessel

Side effects that occurred in less than 1% of patients but were considered medically important or severe or life-threatening and rarely fatal are listed below. These events occurred in studies of belinostat given alone. If you are at the clinical site and notice any signs or symptoms of the side effects listed below, check with the staff in the clinic immediately; if you are no longer at the clinical site, call your doctor or go immediately to the nearest hospital.

Rare
Out of 100 people who receive belinostat, less than 1 person may have the following:

- Abnormal liver tests
- Fever with a low immune system, which may indicate infection
- Liver failure
- Severe infection
- Tumor lysis syndrome
- Cardiac arrest

There may be additional unforeseen risks associated with the use of ribociclib in combination belinostat treatment. You should tell your study doctor or study staff immediately about any side effects that you have or about any change in how you feel while on this study.
Both ribociclib and belinostat may increase your risk for low platelets in the blood and neutropenia (low immune cells). Giving both of these treatments together may increase the occurrence of those risks.

Risks of blood draws or IV
Risks associated with drawing blood or putting a needle in your vein might include pain from the puncture, bruising, bleeding, infection, or fainting. Every effort will be made to minimize discomfort.

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Biopsies

Risks associated with biopsies may include pain, bleeding, which could be mild or severe, infection, puncture of an organ, or reaction to anesthetic.

Loss of Confidentiality

Although all reasonable and appropriate steps will be taken to maintain the confidentiality of your identifiable health information, there is always a possibility that your identifiable health information will be disclosed accidentally. Personal, private information about you will be protected against disclosure to other family members but you should be aware that accidental disclosure of genetic information can have implications for a relative. Results could affect relationships with family, friends or acquaintances and also may affect employment and/or insurance.

Other Risks and Inconveniences including Genetic Risks

There are also non-physical risks associated with taking part in this study, such as the risks associated with a breach of privacy or confidentiality. For example, if your identity as a participant in genetic research or your identifiable genetic or health information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers or insurance providers. The risks of such improper disclosure are very small because Huntsman Cancer Institute has adopted strict privacy and confidentiality procedures for this research.

There may be FDA-approved treatments for your cancer that are available as an alternative to this trial. For example, for women with recurrent ovarian cancer that has returned 6-12 months after the last chemotherapy, chemotherapy containing carboplatin or cisplatin may improve survival compared to other treatments. You should talk to your oncologist about how effective standard therapies could be for you.

REPRODUCTIVE RISKS

It is possible that if these treatments are given to a pregnant woman it will harm the unborn child. Women of childbearing potential must have a negative pregnancy test before beginning treatment. Pregnant women must not take part in this study, nor should women who plan to become pregnant during the study. Women should not breastfeed a baby while on the study and for at least 6 months after you have stopped taking the study drugs. Women of childbearing potential must use an effective contraceptive while on the study and for 6 months after the last dose of study medication.

Examples of medically acceptable birth control include medically prescribed IUDs, a contraceptive rod implanted into the skin and double barrier methods, e.g., condom in combination with spermicide or oral birth control pills and a condom. Check with your study doctor about what kind of birth control methods to use. Some methods might not be approved for use in this study.

If you become pregnant while taking part in the study, you must immediately tell your research doctor. If you become pregnant, you will be withdrawn from the study and we will follow the outcome of your pregnancy.

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Male Reproductive Risks
Because the study drugs may affect an unborn baby, you should not father a baby while taking part in this study. You and your sexual partner should use an effective method of birth control as described above, while taking these investigational treatments. You should continue using birth control for 3 months after receiving the last dose of study medication. If you think that you have fathered a baby while receiving treatments in this study, you should inform your doctor immediately.

UNFORESEEABLE RISKS
In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS
It is hoped that the patients in this trial will benefit from this treatment, however we cannot guarantee or promise that you will receive any benefits from this research. The study treatments may or may not help treat your cancer. It is possible that you will receive no direct health benefit from being in this study.

It is hoped that the information learned from this study may help future patients with cancer. This research may give rise to new or improved drug treatments.

ALTERNATIVE PROCEDURES
You do not have to be in this study to get help for your cancer. You may choose not to take part in this study and discuss other treatment options, and their related benefits and risks, with your study doctor.

Some other things you might do are:
- Use Standard of Care treatment only.
- Use other investigational treatments.
- Get supportive care.
- Choose to have no further treatment.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, you can contact Dr. Werner at 801-585-0255. If you think you may have been injured from being in this study, please call Dr. Werner at 801-585-0255. Dr. Werner is available Monday-Friday from 8:00am-5:00pm. The University Hospital Operator can be reached at this number: 801-581-2121 available 24-hours a day. Please ask for the hematologist/oncologist on call.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

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RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. You may decide not to take part or you may leave the study at any time. Refusal to take part or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled.

Tell the study doctor if you are thinking about stopping or decide to stop, as it may be necessary to do certain tests in order to ensure your safety. If you choose not to return for an assessment, we may ask for medical records from your current general practitioner in order to continue to monitor your health.

If you decide not to continue in the study at any time, your study doctor will arrange for you to receive alternative treatment and any necessary assessments or procedures according to standard of care.

RIGHT OF INVESTIGATOR TO WITHDRAW

Your study doctor may decide to take you off this study at any time without your consent for any of the following reasons:

- if your disease becomes worse,
- if he or she believes it is in your best interest,
- if you do not follow the study rules,
- if you miss study visits and/or procedures,
- if you have serious side effects
- or if you become pregnant.

There is also the possibility that the investigator, may close the study before your participation is complete and without prior warning. If any of these events were to happen, your study doctor would assist with arrangements for your continued care as appropriate.

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COSTS AND COMPENSATION TO PARTICIPANTS

Some of the procedures and treatments you'll have while you are on the study are considered "standard of care" for your type of illness. Even though you will be a part of the study, these types of procedures and treatments will be billed to you and/or your insurance company just like regular medical care. Some procedures you'll have while you are on the study are considered "study related" and are not billed to you and your insurance company. You should ask your study coordinator and treating physician for details about the specific procedures for which you or your insurance company will be financially responsible.

You may be eligible for assistance with costs associated with travel for purposes of research participation. Please speak with your study coordinator or physician for details. If eligible, you may be asked to provide receipts in order to receive reimbursement. It will be necessary for us to collect your Social Security Number for your reimbursement. You will need to provide this information on a Federal W-9 Form that is filed with our accounts payable department. No other information (e.g. the name of this study) will be provided to that office. This amount will not be reported to the Internal Revenue Service (IRS).

Tissue or blood samples obtained from you in this research may help in the development of a commercial product by the study sponsor or its research partners. There are no plans to provide financial compensation to you should this occur.

Ribociclib will be provided to you free of charge by Novartis for this study.

Belinostat will be provided to you free of charge by Acrotech Biopharma for this study.

NEW INFORMATION

You will be given any new information about the study drugs that may affect your willingness to start or continue in the study as it becomes available. You will not receive any results from the genetic testing performed in this study. The results will also not be included as part of your medical records.

During the study, we may learn something about your health that could help you and your doctors make decisions about your healthcare. If this happens, we will tell you about these results. We will contact you and make arrangements to discuss this with you.

NUMBER OF PARTICIPANTS

We expect to enroll up to 34 participants at the Huntsman Cancer Institute of the University of Utah and one additional site.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address telephone number, and email address

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- Related medical information about you like family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results
- All tests and procedures that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information and HIV test results will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by 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.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Members of the research team and the University of Utah Health Sciences Center;
  - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
  - Novartis, as a provider of ribociclib, and their affiliates
  - Acrotech Biopharma, as a provider of belinostat, and their affiliates.
  - Government agencies responsible to confirm research accuracy such as the United States Food and Drug Administration (FDA), and the National Cancer Institute (NCI) which is a part of the National Institute of Health (NIH)
  - Governmental agencies in other countries where the study drug may be considered for approval.

- If we share your identifying information with groups outside of the University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- In the United States, the Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination in health coverage and employment based on genetic information. GINA, together with the Health Insurance Portability and Accountability Act (HIPAA), generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. Utah State Law also offers protection against discrimination in health coverage and employment. The Affordable Care Act (ACA) prohibits discrimination in

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health insurance based on pre-existing conditions. This law provides substantial protection for individuals with genetic conditions or who are at risk of future health conditions based on genetic test results.

- All positive contagious diseases, such as HIV, hepatitis B, and hepatitis C tests must be reported to the Utah State Health Department. The State and Local Health Departments have established procedures for contacting individuals who have had contact with persons testing positive for communicable diseases. Your partner(s) will be notified. If your test is positive, you will not be eligible for this study. The follow-up to a positive test will be done according to standard procedures. The results will be securely stored in a locked filed cabinet, accessible only to the investigator and other authorized people.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

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CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____ _____
Participant's Signature Date Time

_____
Name of Person Obtaining Authorization and Consent

_____ _____ _____
Signature of Person Obtaining Authorization and Consent Date Time

LANGUAGE INTERPRETER STATEMENT (if applicable):

I confirm that I was present as an interpreter for the duration of the consent process for this research study. I confirm that I am qualified and have the necessary skills to provide interpretation between the participant's language and English. By signing this form, I confirm that I provided a full and complete interpretation of the exchange between the researcher obtaining consent and the participant, to the best of my ability.

_____ _____ _____
Name of Interpreter Signature of Interpreter Date

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Information requested for federal grant reporting purposes *(optional)*

Sex/Gender

- ❑ **Male**
- ❑ **Female**

Ethnicity

Do you consider yourself to be Hispanic or Latino? (see definition below)

Hispanic or Latino. A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race.

Select one:

- ❑ **Hispanic or Latino**
- ❑ **Not Hispanic or Latino**

Race

What race do you consider yourself to be? SELECT ONE OR MORE OF THE FOLLOWING:

- ❑ **American Indian or Alaska Native.** A person having origins in any of the original peoples of North America (including, Central or South America) who maintains cultural identification through tribal affiliation or community recognition.
- ❑ **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- ❑ **Black or African American.** A person having origins in any of the black racial groups of Africa.
- ❑ **Native Hawaiian or other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- ❑ **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
- ❑ **Unknown.**

❑ **Check here if you do not wish to provide some or all of the above information.**

Initial and Date

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