Affix Patient Label Here

Masonic Cancer Center, University of Minnesota

CONSENT TO PARTICIPATE IN RESEARCH
Randomized Study of Single Course of Intraperitoneal (IP) ALT-803 Followed by Subcutaneous (SQ) Maintenance ALT-803 Versus Subcutaneous (SQ) Maintenance ALT-803 Only after 1st Line Chemotherapy for Advanced Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

Principal Investigator: Melissa A. Geller, MD
Department of Obstetrics, Gynecology and Women's Health (OBGYN)

Researcher Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Supported By: The study drug, ALT-803, is being provided without cost by NantCell Inc for the purposes of this study. Nant also is covering some of the costs of research related tests and procedures. Minnesota Ovarian Cancer Alliance (MOCA) is providing funding to conduct this research.

What is research:

Doctors and researchers are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to answer one or more questions about a new treatment approach to learn if it is safe and effective. Researchers learn things by following the same treatment plan with a number of participants. You, as an individual, may or may not be helped by volunteering for a research study; however your participation helps answer the research question(s). Often one or more of the drugs offered on a research study are only available on a research study.
- The goal of routine (standard) treatment is to help you get better or to improve your quality of life using drugs and other methods that have been proven (often through previous research studies). Standard treatments are available from any cancer doctor.

If your doctor is also responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research study. However; you have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

Why you are being asked to take part in this research study:

You are invited to take part in this research study because you were recently diagnosed with ovarian, fallopian tube or primary peritoneal cancer which was treated with surgery and post-surgery chemotherapy.

What you should know about a research study:

- The research study will be explained to you.
- You will receive a copy of this consent form to review.
- You can ask all the questions you want before you decide.
- It is up to you whether or not you take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.

Why this research is being done:

There is no standard maintenance therapy after surgery and chemotherapy in gynecological cancers other than watching and waiting. Unfortunately, approximately half of all women have their cancer regrow after the best effort to fully treat it at diagnosis. Once the cancer recurs, the goal is to keep it under control by giving additional chemotherapy and/or other treatments.

This study offers an alternative to observation through the use of a new immune system stimulating drug called ALT-803.

The long term goal of this research is to take advantage of a person's own immune system by "jumpstarting" it with an immune stimulatory drug, such as ALT-803, to suppress cancer growth. ALT-803 is currently being tested in a number of clinical (research) trials, including at the University of Minnesota. These studies all give ALT-803 as an under the skin injection (subcutaneous); however, with gynecologic cancers, treatment is often

given into the peritoneal space (into the "belly"). This is how some of the post-surgery chemotherapy was given.

This study is the first to give ALT-803 directly into the peritoneal space. The primary aim of this study is to determine if this type of administration is better than injecting the drug under the skin. This will be done by randomly assigning half of the patients to receive the 1st 4 weekly ALT-803 doses into the peritoneal space (IP for short). The other half of the patients will receive the 1st 4 weekly doses ALT-803 as an under the skin injection (subcutaneous or SC for short). After the 1st 4 doses of ALT-803, all patients receive it SC.

ALT-803 is an investigational drug that is not approved by the Food and Drug Administration (FDA); however this study is being conducted with the FDA's permission.

Duration of study treatment:
You may receive up to 4 courses of ALT-803 over approximately 8 months (4 weekly treatments followed by 4 weeks of no treatment = 1 course). A final treatment visit occurs 4 weeks after your last dose of ALT-803.

After your final treatment visit, direct participation in this study ends; however, your medical record will be review or your local doctor contacted for the results of routine cancer reassessment for up to 2 years from the 1st dose of ALT-803.

What you need to do to participate:
If you are interested in taking part in this study, your intraperitoneal (IP) catheter must stay in place after you complete your post-surgery chemotherapy. You must begin on this study within 3 months after your last dose of chemotherapy, but you must wait a minimum of 3 weeks to allow your blood counts to recovery.

Routine tests and evaluations are done to determine if you qualify for the study. This is called a screening period. Screening for the study must occur within the 4 weeks before the 1st dose of ALT-803. If you are eligible and agree to take part in the study, you will be randomized (assigned by a computer) to receive the 1st 4 weekly doses of ALT-803 as an under the skin injection (SC) in your abdomen or infused into your peritoneal space (IP). Regardless of which way the ALT-803 is given, all participants will have peritoneal fluid collected prior to each ALT-803 dose and 1 week after the 4th dose. The IP catheter is removed after the 5th collection.

More detailed information about the study procedures can be found under **"What is involved in this study**".

Is there any way that being in this study could be bad for you:
No further treatment with frequent follow-up visits after the initial surgery and chemotherapy is the current standard of care.

If you decide to participate in this study, you will need to have an IP catheter in place for longer than you would if you did not take part in this study. There is always a risk of localized infection or irritation at the site of insertion. ALT-803 given as a SC (under the skin) injection in the abdomen usually causes a localized skin that may be large and last for a week or more. This may be uncomfortable, itchy and even painful. ALT-803 also may cause flu-like symptoms (fever, chills, and nausea). Collecting fluid from peritoneal space and infusing ALT-803 into the peritoneal space (IP) may cause pain and cramping which may continue for several hours afterwards. Medication may be used to prevent or lessen the expected side effects.

More detailed information about the risks of this study can be found under ***"*Risks of being in this study*".***

Will being in this study help you:
It is hoped that giving ALT-803 after standard surgery and chemotherapy will delay or prevent the cancer's re-growth (recurrence). The usual follow-up schedule is once every 3 months and you will continue to follow this whether or not you are on the study. After you complete the planned study therapy

More detailed information about the benefits of this study can be found under **"Benefits of taking part in this research".**

Alternatives to being in this research:
You do not have to be in this study. The usual plan after initial surgery and chemotherapy when there is no evidence of cancer is regular follow-up visits to monitor your disease status. There may be other investigational studies available elsewhere. Your study doctor can answer any questions you may have about the risks and benefits of different options.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be enrolled in this study:
Up to 28 women will be enrolled on this study.

***What* is involved in this study:**
The first step is to determine if you qualify (are eligible) for this study and if you are healthy enough to undergo the planned treatment. If after learning about the study and reading through this consent form, you are interested in the study, you will be asked to sign this form. By signing this form, you are giving permission to undergo routine tests and procedures to see if you qualify for the study treatment. This is known as study screening.

The following routine tests or procedures will be done during the screening period. These tests and procedures are part of your regular cancer care and may be done even if you do not join the study. The following routine tests and evaluations will be done to determine if you are eligible for this study.

- Medical history, physical exam and review of current medications
- Routine blood tests (requiring approximately 4-5 teaspoons of blood) including white blood count, platelets, and blood chemistries to check liver and kidney function
- CA-125 blood level (requiring less than 1 teaspoon of blood) as a baseline measure
- CT scan of your chest, abdomen and pelvis to assess your disease status, if not done in the previous 30 days before study enrollment
- Electrocardiogram (ECG or EKG, a tracing of the electrical activity of the heart)
- Additional tests, X-rays or scans may be done if indicated by your medical history

In addition, to be eligible for this study you must have a sample of tumor from a previous biopsy or your surgery available for research related testing.

Randomization (Treatment Assignment)

If you are eligible and agree to take part in the study, you will be randomized to one of the following treatment plans:

- Intraperitoneal (IP) administration of your 1st four weekly doses of ALT-803 followed by 12 additional doses of ALT-803 by under the skin (SC) injection **OR**
- All 16 doses of ALT-803 given by under the skin (SC) injection

Randomization is assignment by chance to a treatment to make each treatment group similar. It is done by a computer, but in this study with only two treatment possibilities, randomization is like flipping a coin. Neither you nor your doctor can choose which treatment plan you will receive.

Regardless of which treatment plan you are assigned, your intraperitoneal catheter will remain in place until 1 week after your last dose of ALT-803 of the 1st treatment course as explained in the next paragraph.

What will happen during this study:

Treatment Course 1:

Intraperitoneal Washings (All Patients – Research Related)

Prior to administration of each ALT-803 dose and 1 week after the last dose, saline (approximately 8 ounces or 1 cup) will be infused through the intraperitoneal catheter. You will then be asked to change position to distribute the saline, after which the fluid will be drawn out through the IP catheter. This procedure is called intraperitoneal (IP) washing. Your IP catheter will be removed after the final washing (1 week after the last dose of ALT-803).

IP Administration Arm:

If you are assigned to the IP arm, for the 1st treatment course only, ALT-803 (approximately 2 ounces or ¼ cup) is administered intraperitoneally once a week after the IP washing procedure for 4 weeks (4 doses total) followed by 4 weeks of no treatment. To distribute the ALT-803 throughout the abdominal cavity, you will be asked to change positions every 15 minutes for a total of 2 hours.

SC Administration Arm:

If you are assigned to the SC arm, ALT-803 is administered as an under the skin injection (SC) once a week after the IP washing procedure for 4 weeks (4 dose total) followed by

4 weeks of no treatment. You will be required to stay for 2 hours after the 1st injection to be sure there are no unacceptable side effects. If the 1st injection goes well, the stay time will be reduced to 30 minutes.

Treatment Courses 2, 3, and 4 (All patients):
Treatment courses 2, 3, and 4 are identical for all patients. ALT-803 is administered by a SC injection once a week for 4 weeks followed by 4 weeks of no treatment. This 8 week period equals 1 treatment course.

ALT-803 Daily Side Effect Record:
After each ALT-803 treatment, you will be asked to complete a daily side effect log. You are asked to record your temperature each morning and to record side effects possibly associated with ALT-803. The completed log must be returned at the time of your next appointment.

Evaluations, Tests and Procedures While on Treatment

- Before each planned ALT-803 dose (once a week for 4 weeks in a row):

  You will have a brief assessment and routine blood work including white blood count, platelet and blood chemistries requiring approximately 4 teaspoons of blood. Your side effects since the last dose of ALT-803 will be reviewed.

  If you are having ongoing side effects or other health issues (such as a fever which may be a sign of an infection), the ALT-803 dose may be skipped for that week. Any skipped dose will not be made up.

- Extra visits doing the 1st Treatment Course only:
  - At the end of the 1st week of the 1st ALT-803 dose, you will have a brief assessment and blood work requiring slightly more than 1 teaspoon of blood.
  - 1 week after the last dose of the 1st ALT-803 treatment course only, you will have a brief assessment and routine blood work requiring approximately 4 tablespoons of blood. At this appointment your IP catheter will be removed.

- End of Treatment Visit 4 weeks after the last ALT-803 dose:
  You will have a final study treatment visit with a brief assessment and routine blood work. This visit ends your direct participation in this study unless you have

ongoing side effects. In this case you will be continued to be followed as medically appropriate until they resolve or stabilize.

Disease Re-Assessment and Follow-Up:
Imaging studies and a CA-125 blood level will be done every 3 months as part of routine follow-up. For this study, your medical record will be reviewed for up to 2 years for these results. After 2 years, your medical record may be reviewed as part of our required follow-up to the Food and Drug Administration (FDA).

Research Related Sample Collection and Testing:
As this is a clinical research study, research related testing will be done on blood, peritoneal fluids, and tumor samples.

Additional blood will be collected for research related studies. The amount of blood collected for research each time point will be up to 60 ml (slightly more than 4 tablespoons). Blood will be collected before each dose of ALT-803, once (3 to 5 days) after your 1st treatment and at your final treatment visit. The blood collections will be at the same time as your routine blood tests for your care whenever possible.

Research samples may be sent to an outside laboratory for testing that cannot be performed at the University of Minnesota. No identifying information will be provided on these samples.

Approximately 1 teaspoon of blood will be collected before you before the start of each treatment cycle, and approximately 4 weeks after your 1st and last doses of ALT-803. These samples will be sent to Nant to test for an unwanted immune response that reduces or neutralizes the therapeutic effect of ALT-803. This testing is called immunogenicity testing and is required by the FDA. The results will not affect the planned treatment.

Cells will be collected from your abdomen through the IP catheter by peritoneal washing as described in the procedures section above. The samples will be collected on all patients before each of the four ALT-803 doses given during the 1st treatment cycle and 1 week after the last dose of the 1st treatment course. After the last sample is collected, the IP catheter will be removed.

Research samples (blood and/or IP washings up to the time the IP catheter is taken out) may be collected up to 3 additional times at other times if it is thought the samples would

contribute to the understanding of this treatment. For example, if you had a strong reaction to the treatment, blood may be collected to compare with pre-treatment samples.

In addition to the research samples described above, a small sample of blood (1/2 teaspoon) and part of the tumor preserved from your original surgery will be sent to NantOmics, an outside lab, for gene sequencing through the QUILT (Quantum Immuno-oncology Lifelong Trial) Programs. The QUILT program is a worldwide master plan to centralize information related to cancer immunotherapy with the goal to better understand genetic changes in tumors leading to better treatments and earlier prediction of disease response. This study is one of the few studies at the University of Minnesota to be selected for sample testing.

Neither you nor your insurance company/health plan will be charged for costs related to drawing, processing, storage or testing of the research related blood, intraperitoneal cells or tumor. The results of this genetic analysis will not be shared with you, alter your therapy or be placed in your medical record.

Leaving this research:
You can leave the research at any time if you change your mind about taking part in the study. Leaving will not be held against you.

If you decide to leave the research, contact the investigator or study staff. A member of the study team may ask you some questions about being in the study. If you decide to leave the study let your study doctor know so you can receive the proper supportive care. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Meaning, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected information about you may not be removed from the study database. You will be asked whether the investigator can collect information from your routine medical care, such as your medical records. If you agree, this information will be handled the same as the information obtained for the research study.

Risks of being in this study:
While on treatment, you will have side effects from the ALT-803. You are at risk of having all, some, or none of these side effects and the side effects may vary in severity. The

severity may be mild, moderate or severe, including death. Any symptoms or conditions that you have before you start study treatment may get worse. Also, there is always the chance of a side effect that is not yet known.

You may be given medications to prevent or lessen the side effects. In addition, the dose of ALT-803 may be reduced or treatment delayed if side effects are severe. Many side effects are reversible and go away shortly after the treatment is stopped, but in some cases side effects can be serious, long-lasting, or even fatal.

ALT-803

The most common side effects seen in studies with subcutaneous (under the skin) injections of ALT-803 have been change in blood pressure (increase or decrease), fever, fatigue, injection site reaction with an associated skin rash, which at times has been widespread. These localized skins reactions are common (occurring in more than 50% of patients).

You will receive medications to reduce the risk and/or severity of expected side effect. The skin rash may be treated with steroid cream if it causes discomfort.

ALT-803 has never been given intraperitoneally (IP); however, one ongoing study for bladder cancer gives the ALT-803 directly into the bladder and minimal side effects have been seen. At this institution, the most common side effects from doing IP washings and administering study drugs has been abdominal pain and cramping. If pain occurs during the IP washing, the collection will be stopped. Pain medication will be given to help control the pain if it occurs in this study.

The drug ALT-803 can cause many side effects which may be similar to the side effects of interleukin-2 (IL-2), which has been used for more than 20 years.

Risks of ALT-803		
Most likely (greater than 10% - 1 in 10 patients)	**Less likely (3% to 10% - 1 in 30 to 1 in 10 patients)**	**Rarely (< 3% - 1 in 30 patients)**
• pain and redness at the injection site • weight gain with swelling of hands and feet due to fluid retention • feeling tired or short of breath due to a low red blood count (anemia) which	• heart problems - causing low blood pressure, dizziness, chest pain or changes in heart rhythm (heart beat) • changes in liver and kidney	• allergic reaction • temporary thinning of hair • buildup of fluids in the abdominal space

Risks of ALT-803		
Most likely (greater than 10% - 1 in 10 patients)	**Less likely (3% to 10% - 1 in 30 to 1 in 10 patients)**	**Rarely (< 3% - 1 in 30 patients)**
could cause you to faint • increase or decrease in blood pressure, which could cause you to faint • flu-like symptoms such as fever, chills, shaking, headache, stiffness, aching muscles and joints • increased risk of infection due to a low white blood count • increased risk of bruising and bleeding due to a low platelet count • skin rash • weakness, headache, dizziness • vomiting, nausea, loss of appetite • reduced levels of electrolytes as detected by routine blood tests	function as detected on routine blood tests • cough and shortness of breath • mouth sores • confusion, sleepiness and depression especially in older persons or persons with a history of depression	which may cause belly swelling (ascites)

Risks of the Keeping an Intraperitoneal (IP) Catheter in Place After Chemotherapy
The primary risk associated with an IP catheter is localized skin infection although this risk is rare approximately 1 in 1,000 patients requiring antibiotic treatment. An even rarer, and possibly life-threatening complication, is infection within the abdomen and/or blood. You will have frequent assessments (including blood work) while the IP catheter is in place, and if infection occurs, it will be treated appropriately based on the infection source.

Very rarely, the catheter becomes plugged and is not usable.

If complications arise with the catheter and it needs to be removed before the last IP washing, you will be permitted to continue on the study, but without further IP washings. If you are assigned IP administration you will switch to SC administration.

General Risks of Intraperitoneal Infusions and Washings

- abdominal discomfort due to the infusion of fluids into the abdominal area
- fever
- infection within the abdomen

Risks of Drawing Blood

Risks of having blood drawn for routine blood tests and research purposes include:

- pain at the site of the needle stick
- tenderness and/or bruising at the site of blood collection
- dizziness or light-headedness
- very rarely, infection at the site of the needle stick

Risks of a chest, abdomen, pelvis CT scan or PET/CT:

You will be required to have another scan to enroll in this study if it has been more than 30 days since your last scan. This would be an extra scan, and for this reason, its cost will be paid for research funds.

You will be exposed to ionizing radiation during the scanning to evaluate your disease status. The scientific unit of measurement for radiation dose is the millisievert (mSv). The average amount of radiation received from natural sources of radiation by a Minnesota resident in one year (3 mSv). Each CT scan of the chest, abdomen and pelvis would expose you to 17 mSv radiation. This is equal to approximately 6 years of background radiation. If you have a PET/CT each exposure is 25 mSv and equal to approximately 8 years of background radiation. Exposure to radiation may increase your risk of developing a 2nd cancer.

Your disease re-assessment study may be done with contrast (a chemical substance to allow a better view of what is being scanned). You may develop a skin rash or itchiness if you're allergic to the contrast. A life-threatening allergic reaction can also happen, but this is rare. Tell your doctor about any sensitivities to medications, or any kidney problems you have. IV contrast can increase the risk of kidney failure if you're dehydrated or have a pre-existing kidney problem.

Costs:

ALT-803 will be provided free of cost by Nant who has acquired the company (Altor BioScience Corporation) that originally developed the drug. Research related testing on blood and intraperitoneal fluid samples will be paid for by research funds. If you are required to have a repeat disease assessment (CT scan of chest, abdomen and pelvis) to confirm eligibility to this study, this cost will be paid for by the study.

You and/or your insurance company will be responsible for the remaining costs related to this treatment including but not limited to, clinic visits, routine lab work, and any medications given to prevent or treat side effects. You will be responsible for any costs your insurance does not cover, such as deductibles and co-payments. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Research Related Injury:

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Benefits of taking part in this research:

There may be no benefits to you from your taking part in this research. It is not known if giving ALT-803 will delay or prevent disease recurrence as compared to no treatment (standard of care). It is not known if giving ALT-803 by IP infusion is better than by SC injection. Determining if IP administration is better than SC injection is the primary goal of this study In gynecologic cancers, drugs are given by IP infusion as this method delivers the treatment directly to the cancer cells.

Duration of Study Participation:

You may receive up to 4 courses of ALT-803 over approximately 8 months; however, study treatment may be ended early with or without your consent for any of the following situations:

- If your cancer worsens (progresses).
- If your overall medical condition changes significantly at any time during treatment.
- If you have ALT-803 side effects that the study doctor considers unacceptable despite adjusting the schedule or dose.
- If you are unable to receive at least 1 dose of ALT-803 during the 1st treatment course.
- If you refuse to have tests needed to determine whether the study treatment is safe and effective.
- If you require treatment with drugs that are not allowed on this study.

- If other causes prevent you from continuing in this study.
- If the company (Nant) decides to end the study.

Disease and survival status information as available in your medical record or other sources will be collected for up to 2 years from the 1st dose of ALT-803.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Confidentiality and Privacy:
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy.

Organizations that may inspect and copy your information including those that have responsibilities for monitoring or ensuring compliance include:

- Research personnel from the Masonic Cancer Center at the University of Minnesota and/or their designee,
- The Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution,
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA), the U.S. Department of Health & Human Services (DHHS), and the Office for Human Research Protections (OHRP)).

NantBio will receive some study information such as copies of any serious adverse event reports that are sent to the FDA. Anything going to the FDA or Nant will use the unique patient code assigned to you at enrollment. They will also receive interim and final study results/findings, none containing direct patient identifiers.

NantOmics will receive a blood sample and a piece of tumor from your surgery without any direct identifiers. The results will be provided to the University of Minnesota; however they will be retained by NantOmics in their database with no possible way to trace them back to an individual patient.

If you decide to participate in this study, some private health information about you will be stored in a computer database at the Masonic Cancer Center at the University of

Minnesota information will include your name and medical record number, date of birth, diagnosis, race/ethnicity, and information about your participation in this study. The purpose of storing this information is to assist the Cancer Center in creating reports about research and in making sure that research studies are being done correctly. Your information will not be used for any other purpose. There are no plans to erase information from the database. It will be stored indefinitely at the Masonic Cancer Center.

The sponsor/investigator, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access.

The results of this study will be used for teaching, publications, or for presentation at scientific meetings. The results also may be summarized in the background section of future research studies and publications. Results will never include information to allow an individual patient to be identified.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. The web site will include a summary of the results after the study is completed. You may search this web site at any time.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Use of Identifiable Health Information

Your personal health information (PHI) created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Contacts and Questions

Information for contacting the study Principal Investigator and Study Coordinator is provided on the 1st page of this document.

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Feedback

After the study, you may be asked to complete a survey about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey after the study is over, but you would like to share feedback, please contact the study team or the Human Research Protection Program (HRPP). See the "Contacts and Questions" section of this form for study team and HRPP contact information.

Optional Storing Of Leftover Research Samples

There may be some leftover blood and/or IP fluid cells from the samples collected for research purposes. With your permission; we would like to store them for up to 15 years after the study ends for future analysis as new research tests become available. These samples will be the property of and under the control of the Principal Investigator Melissa

Geller, MD. They will not be used for studies other than ones to learn about cancer and the immune system.

The samples will be stored with indirect identifiers. They will be labeled with a unique code number, rather than a name or medical record number, and the samples can only be linked back to the patient using a master list for the study. This master list will be kept in a secured manner and only accessible to persons directly involved with the research. There will be no cost to you for storing and future testing of the leftover samples. You will not be paid for allowing your samples to be used for future research. Because it is not known how soon these samples will be used, you will not be given the results of the tests. Fifteen years after the end of the study any remaining samples will be destroyed. However, if you agree to storage now and later change your mind, you may request to have any remaining identifiable samples destroyed by contacting the study doctor or another member of the study staff.

Consent for Storage of Leftover Research Samples:

☐ YES, I consent (agree) to the storing of any leftover samples for future research

☐ NO, I do not consent (do not agree) and want any leftover samples destroyed once research directly related to this study is completed.

STATEMENT OF CONSENT:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Use the signature block below only if a witness to the consent process is required:

☐ ***CHECK IF NOT APPLICABLE***

WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate
☐ The participant is visually impaired
☐ The participant is non-English speaking (refer to the signature block for non-English speaking)
☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other Please describe:

_____

If the participant is non-English speaking use this signature block:

For the Consent of Non-English Speaking Participants when an Interpreter is Used:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter or Witness:
As someone who understands and can read the language spoken by the subject (English or otherwise), I represent that the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual