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

Study Title:	**A Phase Ib Adaptive Study Dasatinib for the Prevention of Oxaliplatin-Induced Neuropathy in Patients with Metastatic Gastrointestinal Cancer Receiving FOLFOX Chemotherapy with or without Bevacizumab.**
Principal Investigator:	**Anne Noonan, MBBChBAO, MSc**
Sponsor:	**The Ohio State University** **Pelotonia OSUCCC Intramural Research Program**

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

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

You are being asked to take part in this study because you have been diagnosed with colorectal cancer, or any other kind of Gastrointestinal cancer for which FOLFOX chemotherapy is an option. Nerve damage, also known as neuropathy causing numbness, tingling, and pain, is one of the most common side effects of oxaliplatin chemotherapy, and can sometimes be permanent. It also limits the amount of oxaliplatin a patient can receive, even if the drug is effective against their cancer. You may or may not have experienced any

nerve damage as a result of previous chemotherapy or other disease, but the researchers think you may be a good candidate for this study.

A drug called dasatinib may prevent or reduce a patient's nerve damage by blocking the organic cation transporter 2 (OCT2), which is the way oxaliplatin is carried into the nerve cells. Dasatinib is a pill that is currently approved for treating certain blood cancers, but not for use in preventing nerve damage.

This study is being done to assess if dasatinib is safe to give with certain chemotherapy drugs (5FU, oxaliplatin, leucovorin and bevacizumab)and to assess if it can potentially reduce the development of damage to nerves.

Approximately 10 people will take part in this clinical trial at OSU. You will remain on the study for 2 months, although you may receive the chemotherapy drugs for longer if your doctor thinks the chemotherapy is effective against your cancer. You will undergo several medical procedures during this study, including: blood draws, physical exams, pregnancy tests, and taking the study medication.

Common side effects of Dasatinib include: swelling, rash, body fluid retention, stomach pain, diarrhea, nausea, vomiting, fever, pain, headache, shortness of breath, and tiredness.

However, since you will be receiving Dasatinib only 4 times instead of daily, your risk of developing side effects may be lower.

Blood draw risks include: pain, swelling, bruising, and tissue discoloration or scarring around the vein used to draw the blood sample.

You may or may not benefit directly from participating in the study. It is the researchers' hope that information gained in this clinical study will help reduce the risk of nerve damage for future cancer patients.

You do not have to take part in this clinical trial, and may still receive cancer care at The Ohio State University without taking part.

1. Why is this study being done?

You are being asked to take part in this study because you have been diagnosed with colorectal cancer, or any other kind of Gastrointestinal cancer for which FOLFOX chemotherapy is an option. Neurotoxicity (damage to nerves) from oxaliplatin usually causes peripheral sensory neuropathy, which can cause tingling, pain, and numbness, mainly of the fingers and the feet. It is one of the most common side effects of oxaliplatin chemotherapy.

The neuropathy may or may not continue after oxaliplatin chemotherapy is completed. It is sometimes permanent, and can lead to functional impairments, such as difficulty doing buttons, difficulty picking things up, and difficulty walking. The nerve damage can often limit the amount of oxaliplatin chemotherapy that can be given to a patient, resulting in the drug being stopped even when it is effective against the cancer. Oxaliplatin is thought to cause nerve damage by damaging a part of the nerves called the dorsal root ganglion located in the spine.

Research performed at The Ohio State University has shown that a drug called dasatinib may prevent or reduce a patient's nerve damage by blocking the organic cation transporter 2 (OCT2), which is the way oxaliplatin is carried into the nerve cells. Dasatinib is a pill that is currently approved for treating certain blood cancers, but not for use in preventing nerve damage. In two previous clinical trials, dasatinib was given daily alongside chemotherapy drugs to patients with advanced colorectal cancer, and it was found to be safe and well tolerated.

This study is being done to assess if two doses of dasatinib, given 24 hours before and also 30 minutes before oxaliplatin, is safe to give with the chemotherapy drugs oxaliplatin, 5FU, leucovorin, and bevacizumab, and can potentially reduce the development of damage to nerves.

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

Up to 10 participants will take part in this study at the Ohio State University.

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

If you agree to take part in this study, you will first be asked to sign this consent form. Your medical records will be reviewed for eligibility. If you meet the eligibility criteria needed to participate in the study, you will then be enrolled.

Some of the exams, tests, and procedures outlined in the study calendar may be completed via Telehealth visit (phone, video call, or email) if the investigator deems it appropriate. Ask your physician if you have questions about Teleheath or Telehealth visits.

Study visits:

Within 28 days of signing this informed consent form:

- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination
- ECOG Performance Status (a measure of how well you are feeling)
- You will complete a CIPN20 Questionnaire (to assess the level of nerve damage you have)
- Your Vitals, Height, and Weight will be recorded.
- Blood will be collected for standard of care medical testing
- Pregnancy Test (may be a blood or urine test)
- You will have a CT scan or MRI scan to assess your cancer

Your doctor will prescribe FOLFOX (5FU, leucovorin and oxaliplatin) with or without bevacizumab chemotherapy, which is a standard, effective chemotherapy regimen for patients with advanced colorectal cancer.

On Cycle 1, Day 1, you will:

- Receive chemotherapy treatment with FOLOFX +/- bevacizumab
- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination
- ECOG Performance Status (a measure of how well you are feeling)
- Have a urine test
- Have an ECG taken
- Have your blood drawn

Some of these procedures may not be done on this date if you have had them done recently. Your study doctor will determine this and let you know which procedures you will need to complete.

On Cycle 1 Day 14, you will:

- Receive dasatinib
- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination
- ECOG Performance Status (a measure of how well you are feeling)
- Have a urine test
- Have your blood drawn

On Cycle 1, Day 15 you will:

- Receive chemotherapy treatment with FOLOFX +/- bevacizumab
- Receive dasatinib
- Your health information will be recorded
- Have your blood drawn

On Cycle 1, Day 28, you will:

- Receive dasatinib
- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination
- ECOG Performance Status (a measure of how well you are feeling)
- Have a urine test
- Have your blood drawn
- Have an ECG taken
- Be asked to complete a CIPN20 Questionnaire (to assess the level of nerve damage you have)

On Cycle 2, Day 1:

- Receive chemotherapy treatment with FOLOFX +/-bevacizumab
- Receive dasatinib
- Your vitals will be recorded
- Have a urine test
- Have your blood drawn

On cycle 2, Day 15, you will:

- Receive chemotherapy treatment with FOLOFX +/-bevacizumab
- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination
- ECOG Performance Status (a measure of how well you are feeling)
- Have your blood drawn
- Have an ECG taken
- Be asked to complete a CIPN20 Questionnaire (to assess the level of nerve damage you have)

End of Study Visit:

- Receive chemotherapy treatment with FOLOFX +/-bevacizumab
- Your health information will be recorded
- Your current medications will be recorded
- You will complete a physical examination
- ECOG Performance Status (a measure of how well you are feeling)
- Have your blood drawn
- Be asked to complete a CIPN20 Questionnaire (to assess the level of nerve damage you have)

Blood Draws

The first time you receive FOLFOX and bevacizumab, you will not receive dasatinib, but you will come to the clinical trials unit for blood tests to help us determine the levels of oxaliplatin in your blood. These blood tests will be drawn according to the following schedule on cycle 1 day 1:

- Pre-dose (within 15 min of starting oxlaliplatin)
- 1 hour ± 5 mins after the start of the oxaliplatin infusion
- Immediately prior to end of infusion of oxaliplatin (within 5 min)
- 0.5 hour after end of infusion (±5 min)
- 1 hour after end of infusion (±5 min)
- 2 hours after end of infusion (±5 min)
- 4 hours after end of infusion (±5 min)

As part of the study, you will receive 4 doses of dasatinib – one dose on cycle 1 day 14, which is 24 hours before your second dose of oxaliplatin. You will receive a second dose 30 minutes before the oxaliplatin on cycle 1 day 15. You will come to the clinical trials unit for blood tests on cycle 1 day 14 as well, and the blood tests will be drawn according to the following schedule:

- Pre-dose (within 15 min prior to taking the dasatinib pill)
- 0.5 hour after taking the pill (±5 min)
- 1.5 hour after taking the pill (±5 min)
- 2.5 hours after taking the pill (±5 min)
- 3 hours after taking the pill (±5 min)
- 4.5 hours after taking the pill (±10 min)
- 6.5 hour after taking the pill (±10 min)

On cycle 1 day 15, you will receive dasatinib 30 minutes prior to the oxaliplatin. You will have blood tests drawn according to the following schedule:

- Pre-dose of dasatinib (within 15 min prior to taking the dasatinib pill)
- Prior to starting oxaliplatin infusion (within 5 min)
- 1 hour after the start of the oxaliplatin infusion (±5 min)
- Immediately prior to end of infusion of oxaliplatin (within 5 min)
- 0.5hour after end of oxaliplatin infusion (±5 min)
- 1 hours after end of oxaliplatin infusion (±5 min)

- 2 hours after end of oxaliplatin infusion (±5 min)
- 4 hours after end of oxaliplatin infusion (±10 min)

On cycle 1 day 28, you will be seen in clinic and will receive dasatinib 24 hours before your oxaliplatin and 30 minutes prior to oxaliplatin on cycle 2 day 1. You will not need to have research bloods on these days.

We will also ask you to complete a research questionnaire, the CIPN 20 Questionnaire, to assess the level of neuropathy that you have, if any.

STUDY CALENDAR

	Screening visit	**C1D1**	**C1D14**	**C1D15**	**C1D28**	**C2D1**	**C2D15**	**End of study visit C3D1**
Scheduling Window (Days):	Day -28 to day -1							
Informed Consent	X							
Inclusion/Exclusion Criteria	X							
Demographics and Medical History	X							
Prior and Concomitant Medication Review	X							
Dasatinib			X	X	X	X		
mFOLFOX6 + bevacizumab		X		X		X	X	X
Full Physical Examination	X	X	X		X		X	X
Vital Signs and Weight	X	X	X	X	X	X	X	X
ECOG Performance Status	X	X	X		X		X	X
Pregnancy Test – Urine or Serum β-HCG	X							
Blood tests	X	X	X	X	X		X	X
Urine test		X	X		X			
ECG and QTc measurement	X	X			X		X	
CIPN20 Questionnaire	X		X		X		X	X

4. How long will I be in the study?

You will be on the study for approximately 2 months, but your FOLFOX and bevacizumab chemotherapy will continue as long as your doctor thinks it is working. You will have scans done at certain time points determined by your doctor to check if your cancer is responding to chemotherapy. The dasatinib pills will only be given on the following dates:

- Cycle 1 day 14
- Cycle 1 day 15
- Cycle 1 day 28
- Cycle 2 day 1

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.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the Sponsor or any of the regulatory bodies overseeing the study such as the IRB

By signing this consent form, you give your permission for your information to be used and shared for the purposes of this study at any time in the future. This means your authorization for release of your health information has no expiration date.

You may cancel your authorization at any time. You do this by sending written notice to the study doctor:

Anne M. Noonan, MB/BCh
1800 Cannon Dr.
13th Floor, Lincoln Tower
Columbus, Ohio 43210
United States

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

Side effects of Dasatinib:

In patients taking dasatinib **every day**, the following side effects were seen:

COMMON

- Swelling (3% to 22%)
- Rash (14% to 68%)
- Body fluid retention (21% to 48%)
- Abdominal pain (11% to 78%)
- Diarrhea (18% to 84%)
- Nausea (8% to 84%)
- Vomiting (5% to 83%)
- Febrile neutropenia (fever with low white blood cell counts)
- Pain in muscles and bones (8% to 83%)
- Headache (14% to 77%)
- Shortness of breath (3% to 35%)
- Tiredness (9% to 59%)
- Fever (6% to 85%)

SERIOUS

- Heart failure or problems with the pumping of the heart (2% to 4%)
- Fluid around the heart (3% to 4%)
- Abnormalities with the electricity of the heart (prolonged QT interval) (1%)
- Bleeding from the gut (2% to 9%)
- Anemia (low hemoglobin)(13% to 74%)
- Febrile neutropenia (fever with low white blood cell counts)(4% to 86%
- Bleeding (8% to 26%)
- Low neutrophil counts (neutrophils are a type of white blood cell) (29% to 79%)
- Low platelet counts (22% to 85%)
- Fluid in the abdomen (less than 1%)
- Inflammation of the liver
- Infections
- Bleeding in the brain (Up to 3%)
- Fluid in the sac around the lungs (20% to 28%)
- Pneumonia (lung infection) (1% to 28%)
- Fluid in the lung tissue (1% to 4%)
- Pulmonary hypertension (high blood pressure in the lungs) (2% to 5%)
- Severe infection (sepsis)

In addition, there is a slight chance that the addition of dasatinib could decrease the effectiveness of the FOLFOX6 +/- bevacizumab. This effect of dasatinib on FOLFOX6 +/- bevacizumab will be carefully monitored. If dasatinib should decrease neuropathy, it might lead to additional doses of FOLFOX6 +/- bevacizumab with a potential for better effectiveness.

Since you will only receive 4 doses in total of dasatinib, it is very likely that your risk of these side effects will be much lower.

Possible Side Effects of FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin):

COMMON, SOME MAY BE SERIOUS
In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), more than 20 and up to 100 may have:

- Hair loss
- Redness, pain or peeling of palms and soles (Hand Foot Syndrome)
- Rash, increased risk of sunburn, itching
- Diarrhea, nausea, vomiting, constipation, loss of appetite
- Difficulty swallowing
- Sores in mouth
- Heartburn
- Infection, especially when white blood cell count is low
- Anemia which may require a blood transfusion
- Bruising, bleeding
- Headache
- Tiredness
- Numbness, tingling or pain, "pins and needles" of the hands, feet, arms and legs
- Tingling or a loss of feeling in your hands, feet, nose (also known as neuropathy), or tightness in throat or jaw, or difficulty swallowing or breathing which may be made worse by exposure to cold
- Cough
- Fever, pain

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), from 4 to 20 may have:

- Chest pain
- Abnormal heartbeat which may cause fainting
- Swelling and redness at the site of the medication injection
- Hives
- Skin changes
- Weight gain, weight loss, belly pain
- Internal bleeding which may cause black tarry stool, blood in vomit or urine, or coughing up blood
- Changes in taste
- Blood clot which may cause swelling, pain, shortness of breath
- Bleeding from multiple sites including vaginal bleeding, bleeding of the testis, or bleeding of the brain
- Liver damage which may cause yellowing of eyes and skin
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Change in voice
- Confusion, dizziness
- Muscle weakness
- Inability to move shoulder or turn head
- Blurred vision, watering eyes
- Discomfort from light
- Abnormal body movement including the eye and eyelid
- Difficulty walking, using your hands, opening mouth, talking, with balance and hearing, smelling, eating, sleeping, emptying the bladder
- Hearing loss
- Swelling of the body which may cause shortness of breath
- Kidney damage which may require dialysis
- Scarring of the lungs
- Blockage of the airway which may cause shortness of breath, cough, wheezing
- Dehydration

RARE, AND SERIOUS
In 100 people receiving FOLFOX (Leucovorin, 5-Fluorouracil, Oxaliplatin), 3 or fewer may have:

- Damage to the heart which may cause shortness of breath
- A new cancer resulting from treatment of a prior cancer
- Redness, pain, peeling or blistering of the skin (Stevens-Johnson Syndrome)

Additional precautions during oxaliplatin treatment (FOLFOX): Avoid cold drinks, use of ice, and cover exposed skin prior to exposure to cold temperature or cold objects. Protect from direct sun exposure. Do not drive or use machines.

Possible Side Effects of Bevacizumab
COMMON, SOME MAY BE SERIOUS
In 100 people receiving bevacizumab, more than 20 and up to 100 may have:

- High blood pressure which may cause headaches, dizziness, blurred vision

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving bevacizumab (rhuMAb VEGF), from 4 to 20 may have:

- Anemia which may require blood transfusion
- Low white cell count that may increase the risk of infection
- Infection, including collection of pus in the belly or rectum
- Abnormal heartbeat which may cause palpitations or fainting
- Pain in the belly, rectum, chest, joints, muscles, or tumor
- Low appetite, constipation, diarrhea, heartburn, nausea, vomiting, or dehydration
- Internal bleeding which may cause black tarry stool, blood in vomit, coughing up blood, or blood in urine
- Bleeding from other sites, including the vagina or nose
- Blockage of internal organs which may cause vomiting or inability to pass stool
- Sores in the mouth
- Allergic reaction during or after infusion of bevacizumab which may cause fever, chills, rash, itching, hives, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Delay in healing of wounds or spontaneous opening of wounds
- Weight loss, tiredness, or dizziness
- Muscle weakness
- Damage to the jawbone which may cause loss of teeth
- Headache
- Numbness, tingling or pain in the fingers or toes
- Hoarseness, stuffy nose, or cough
- Dry skin
- Swelling and redness of the skin
- Blood clot in limbs or lungs which may cause swelling, pain, shortness of breath
- Leakage of protein in the urine, which can rarely lead to damage to the kidney

RARE, AND SERIOUS
In 100 people receiving bevacizumab (rhuMAb VEGF), 3 or fewer may have:

- Clots in the arteries, causing stroke (which may cause paralysis or weakness) or heart attack (which may cause chest pain or shortness of breath). This risk is significantly increased in patients who are elderly or with history of diabetes
- Heart failure which may cause shortness of breath, swelling of ankles, and tiredness
- Bowel perforation (a tear in the bowel) that can cause pain or bleeding and require surgery to repair
- A tear or hole (fistula) in internal organs such as the nose, throat, lungs, esophagus, rectum, or vagina. These conditions may cause serious infections or bleeding and require surgery to repair
- Sores in the throat
- Flesh-eating bacteria syndrome, an infection in the deep layers of skin
- Damage to organs (bone, lungs, others) which may cause loss of motion
- Bleeding in the tumor, brain, belly or lungs which may cause confusion, blood in stool or coughing up blood
- Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)
- Kidney damage which may require dialysis
- Redness, pain or peeling of palms and soles

Additional information on possible side effects for bevacizumab:

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- Risk in pre-menopausal women: more likely to develop menopause when taking bevacizumab.

Blood Draw Risks:

You may experience side effects of having your blood drawn. These include pain, swelling, bruising, tissue discoloration or scarring around the vein that is used to draw the blood sample. There is a possibility that some of these tissue changes and scarring could become permanent. There may be the risk of infection at the site where the needle is inserted into the vein. There is also the possibility that you may faint during or shortly after the needle is inserted. If you feel dizzy, you should tell someone and lie down to avoid falling and hurting yourself. These are the same risks that are associated with any blood drawing from your vein. All blood draws will be timed to routine blood work that you would normally get for your chemotherapy visits.

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

You may or may not benefit directly from participating in the study. It is possible that the dasatinib pill will reduce your chances of developing nerve damage (numbness, tingling, pain, difficulty using your fingers or feet) while you are receiving oxaliplatin chemotherapy**.** It is the researchers' hope that information gained in this clinical study will help reduce the risk of nerve damage for future cancer patients.

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

You make take part in another clinical trial, if one is available, opt to receive Standard of Care treatment for your cancer, opt to receive no treatment, or opt to receive palliative care/comfort care.

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

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

The study drug, dasatinib, will be provided to you at no cost during this study. You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of this research study and are outside the standard of care [what is normally done] for your condition.

You and/or your insurance company **will** be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research study. You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner. You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage. You will be responsible for any charges not reimbursed by your insurance company.

Some insurance companies will not pay for routine costs for people taking part in research studies. Before deciding to be in this research study, you should check with your insurance company to find out what they will pay for.

The study doctor will explain to you which procedures, tests, and doctor visits are considered standard of care, including any the FOLFOX chemotherapy regimen, general lab tests needed for monitoring FOLFOX and bevacizumab, and the CT scans required by this study.

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

You will not be paid for taking part in this study. However, you may receive a parking voucher for the days you have to stay in the CTU.

Your blood tests (biospecimens) taken for research purposes during this study will not be sold or used to make new products or technologies.

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

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

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

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

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

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

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

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

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

No.

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.

There is the rare risk of loss of confidentiality with your biospecimens. However, all efforts will be made to ensure they remain confidential and de-identified.

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:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
- Records about any study drug you received

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

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: the sponsor of the study, The Ohio State University Pelotonia OSUCCC Intramural Research Program, your usual health care providers

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 study doctor:

Anne M. Noonan, MBBChBAO
1800 Cannon Dr.
13th Floor, Lincoln Tower
Columbus, Ohio 43210
United States

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. Anne Noonan 614-385-2039 (office) 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 Wexner Medical Center
Suite E2140, 600 Ackerman Road,
Columbus, OH 43202
Telephone: (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. Anne Noonan 614-385-2039 (office) 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)**
	AM/PM
Relationship to the participant	**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