Preventing an Incurable Disease: The Prevention of Progression to Pancreatic Cancer Trial (The 3PC Trial)

Informed Consent Document
28 September 2023

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
The Prevention of Progression to Pancreatic Cancer Trial
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CONCISE SUMMARY

An intraductal papillary mucinous neoplasm (IPMN) is a growth in the main pancreatic duct or one of its side branches. IPMN may be precancerous or cancerous. This study will test the drug sulindac to see if it can slow the progression of IPMN cysts of the pancreas. The long-term goal of this study is to reduce the risk of developing pancreatic cancer.

If you agree to take part, you will be randomized to take either sulindac or a placebo for up to 3 years. You will then have routine assessment for IPMN progression every 6 months for up to 3 years. Afterwards, you will be followed for progression through a medical record review.

The major side effect of the study drug is gastrointestinal pain. Sulindac may cause GI bleeding, ulceration, and perforation of the stomach or intestines as well as heart attack and stroke. You will be closely monitored throughout the trial for any complications from study drug. Please speak to the study doctor if you are interested in participating in this study.

You are being asked to take part in this research study because you have an IPMN pancreatic cyst. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Allen's and his research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Peter Allen or one of his colleagues will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to look at the effects of sulindac, a non-steroidal, anti-inflammatory drug (NSAID), on progression of intraductal papillary mucinous neoplasms (IPMN). The long-term goal of this study is to reduce the risk of developing pancreatic cancer.

Sulindac is a non-steroidal, anti-inflammatory drug (NSAID) which is FDA approved for various forms

of arthritis and acute painful shoulder. In this study, the use of sulindac is investigational, which means that it is not FDA approved for use in preventing progression of IPMN.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
About 100 people will take part in this study at Duke, Massachusetts General Hospital, Johns Hopkins Hospital, and Memorial Sloan Kettering Cancer Center. Approximately 50 people will take part at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. If you have provided your email address, a link to the online document (or the document itself) has been sent to you and a copy of the completed document will be emailed to you.

Screening:
Screening will occur over several months. If standard of care tests and procedures have been performed, they may be used as documentation for screening.

Screening includes:

- Pancreas imaging: computed tomography (CT) scan or magnetic resonance imaging (MRI)
- Review of medications
- Review of medical and treatment history
- Physical Exam
- Performance Status (how you are doing)
- Pancreatic cyst fluid collection (if you are having a procedure clinically)
- Archival tissue from your pancreas if you have already had a pancreatic resection
- Blood tests including:
    - Complete blood count (CBC)
    - Comprehensive metabolic panel (CMP)
    - Cancer markers
    - Research blood sample (up to 40ml).

Baseline Visit:
If you are determined to be eligible through screening, you will have the following done either at the same time as screening or another visit. If certain tests have not been performed, we may ask you to come into the clinic and have them done:

- A physical exam and routine labs, if you have not had these done within 30 days.
- Performance Status (how you are doing)
- Randomization to receive Sulindac 200 mg by mouth twice daily, or placebo. A placebo is pill that contains no medicine.

- You will be randomly assigned (like the flip of a coin) to receive either sulindac or placebo. You have a (1) in (2) or 50% chance of receiving study drug.

Study Regimen:

In-person study visits will occur every 6 months and you will be contacted every other month between clinic visits to see how you are doing.

- You will take the study drug/placebo twice a day for 3 years. You will be responsible for completing a pill diary daily, and bringing it to your in-person study visits.
- You will be seen in the outpatient clinic every 6 months for 3 years. Procedures include:
  - Review of any side effects
  - Review of medical and treatment history
  - Physical exam
  - Routine blood tests including those for cancer markers
  - Research blood samples (up to 40ml)
  - Pancreatic imaging annually, (1, 2 and 3 years after randomization) per standard of care.
  - Endoscopic ultrasound (EUS) annually, (6 months, 18 months, and 30 months after randomization) per standard of care.
    - Fine needle aspiration (FNA) annually in conjunction with EUS for collection of cyst fluid per standard of care. If excess cyst fluid is available at the time of the FNA, a sample will be collected for research.
- You will be contacted by telephone to answer questions regarding potential side effects of study drug and overall health.

On-Study Follow-up:

If you end the study drug regimen prior to 3 years, you may be asked to continue in person study visits every 6 months for up to 3 years or until IPMN progression.

- You will be seen in the outpatient clinic every 6 months for 3 years. Procedures include:
  - Review of medical and treatment history
  - Physical exam
  - Routine blood tests including those for cancer markers
  - Research blood samples (up to 40ml)
  - Pancreatic imaging annually, (1, 2 and 3 years after randomization) per standard of care.
  - Endoscopic ultrasound (EUS) annually, (6 months, 18 months, and 30 months after randomization) per standard of care.
    - Fine needle aspiration (FNA) annually in conjunction with EUS for collection of cyst fluid per standard of care. If excess cyst fluid is available at the time of the FNA, a sample will be collected for research.

Long Term Follow-up:
Once you complete the study drug regimen, or opt out of on-study follow up, you will be followed for continued IPMN surveillance after treatment every 6 months through a medical record review until the study closes. Data collected includes: procedure information, disease status, clinical evaluations, details of IPMN progression.

End of Study Regimen Visit(s):
If you experience IPMN progression, develop pancreatic cancer, or have surgery of the pancreas, no further clinical information will be collected and end of study procedures will be performed as it aligns with your clinical care plan.
This visit will occur after 3 years of receiving study drug/placebo or if you stop taking the study drug/placebo prior to 3 years. When possible, study visits will be combined. Procedures will include the following:

- You will be clinically evaluated in the outpatient clinic. Procedures include:
  - Review of any side effects
  - Review of medical and treatment history
  - Physical exam
  - Routine blood tests, including those for cancer markers.
  - Research blood samples (up to 40ml)
  - Pancreatic imaging or endoscopy, with or without, FNA per standard of care.
- If you have an endoscopy or surgery of the pancreas, we will collect cyst fluid during the procedure.

Optional archival tissue:
As part of the specimen collection process, we want to request archival FFPE tissue if you have had, or end up having surgery of the pancreas. This means that tissue available from your clinical diagnosis is available we may request a portion of that for up to 3 years after your participation on the study ends. This will allow researchers to request previously collected tissue for the purposes of research on this study.

_____ Yes, I agree to allow for archival tissue requests from my prior or future pancreas surgery.
(initials)
_____ No, I do not agree to allow for archival tissue request from my prior or future pancreas surgery.
(initials)

Study participation may be extended through long term follow up for five years or until the study closes, whichever occurs later.

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HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for up to 5 years, or until the study closes, whichever occurs later. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Clinically relevant results of this research will be communicated with you if it is determined that the study drug is not effective or is harmful, including if the study closes early.

WHAT ARE THE RISKS OF THE STUDY?
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose. This medicine, like all medicines, can cause side effects. Although not everybody gets them, side effects are more likely in older patients.

Sulindac may cause some, all or none of the side-effects listed below.

More likely ***(3% of people or more experience these events)***
- Gastrointestinal pain
- Dizziness
- Headache
- Skin rash
- Constipation
- Diarrhea
- Dyspepsia (indigestion)
- Nausea

Less Likely ***(less than 3% of people experience these events)***
- Swelling
- Nervousness
- Pruritus (itching)
- Abdominal cramps
- Anorexia
- Flatulence
- Vomiting
- Tinnitus (ringing in ears)

Medicines such as Sulindac may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. This risk may occur early in treatment and may increase with duration of use. Patients on medicine to thin the blood, e.g. warfarin, may need their dose adjusted.

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NSAIDs can also cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious GI events.

If any of the following happen, **stop taking study medication and tell your doctor immediately** or go to your nearest hospital emergency department if you experience:

- severe stomach pain
- blood in your feces (stools/motions)
- black, tarry stools
- vomiting of any blood or dark particles that look like coffee grounds
- an allergic reaction causing difficulty in breathing, tightness of the chest, swelling of the face, throat or tongue, nose bleeds, sore, dry or itchy skin
- a severe skin reactions causing rash, red patches or blistering of the skin, mouth, eyes or genitals
- sensitivity of the skin to sunlight, red spots or rash on the skin or unusual bruising or bleeding of the skin
- skin or the whites of your eyes become yellow
- severe upper stomach pain often with feeling or being sick (signs of inflammation of the pancreas)
- if you have fits (seizures)
- feeling unusually tired and pale, feverish, have a sore throat, suffer from more infections than usual

Stop taking the medicine and tell your doctor if you experience:

- indigestion or heartburn
- pains in your stomach, or other abnormal stomach symptoms.

There have been reports of patients suffering from a mild form of meningitis (causing headache, a stiff neck, fever, confusion, feeling or being sick). This is more likely in patients with a collagen vascular disease, such as lupus.

Other less common side effects are:

- liver problems which may cause dark urine, pale stools
- severe stomach upset (gastritis)
- change in urinary function such as difficulty or pain in passing urine, blood, protein or crystals forming in the urine, change in urine color
- swollen ankles and breathlessness, a racing or irregular heart beat

- vaginal bleeding (in women), swollen breasts (in men)
- vertigo, feeling drowsy or tired, sleeplessness
- tingling or numbness in the arms and legs
- headache, fainting,
- feeling dizzy, nervous, confused, depressed, weak or generally unwell
- hallucinating, ringing in the ears
- aggressive or abnormal behavior, mood changes, sweating
- loss of hearing, hair loss
- bitter or metallic taste in the mouth
- raised blood pressure
- high levels of potassium or glucose in the blood
- rarely, swollen red sore skin (vasculitis)
- changes in your eye sight

Tell your doctor if you suffer from loss of vision or blurred vision. You may need an eye examination.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

Reproductive Risks

For Women: When taken in late pregnancy, sulindac and other NSAIDs are associated with a number of cardiac problems in infants; there may also be an increased risk of miscarriage when taken in early pregnancy, particularly around the time of conception. In addition, the effects of pregnancy on the risk of recurrence or progression of IPMN is not known. Women who are pregnant, planning a pregnancy, or breastfeeding are not allowed to participate in this study.

If you are a woman who could possibly become pregnant (you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a blood or urine pregnancy test will be performed, and it must be negative to continue in the study. In women 40 years old and older, blood pregnancy tests may sometimes give a false positive or "indeterminate" result, and additional testing may be required to confirm your eligibility for the study.

You and your partner must agree to either abstain completely from vaginal intercourse for the duration of the study and for 30 days after your last dose of study drug or use an effective method of contraception for the same length of time. Effective methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal methods (birth control pills, implants, injections, patches, vaginal rings), and (e) If you and your partner are not currently using one of these methods your study doctor will discuss options with you given your medical condition, your personal preferences, and the level of effectiveness required for this study. Because no birth control method is

100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant, even if you have had a recent negative pregnancy test.

If you do become pregnant during the study, your study doctor will stop the study drug, withdraw you from the study, and notify the sponsor. You will be followed for the duration of the pregnancy to better understand the potential effects of the study drug on pregnancy outcomes.

Risks of Drawing Blood

Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Risks from CT Scan

Computed Tomography (CT) is a way to make x-ray images of the inside of the body. The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures that show structures inside your body more clearly than regular x-ray pictures. During the procedure, a technologist will take you into the CT scan room where you will lie down on the patient table (usually on your back) inside of the CT machine. You should get comfortable because it is very important that you not move during certain parts of the test.

CT examinations differ depending on the part of your body being studied. For example, if your abdomen is being studied, a series of pictures will be taken from your lower chest to your lower pelvis. During the study, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. Also, you may receive signals from the technologist or from the machine about your breathing. Before or during the study, you may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs. If you have any discomfort during the test or after the injection, be sure to tell the technologist.

Risks From Imaging Tests That Use Radiation

If you take part in this research, you may have one or more abdominal CT scans, which use radiation. To give you an idea about how much radiation you will get each time a abdominal CT scan is done, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year called the 'natural background'. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. The chart below the amount of time in the natural background that gives an amount of radiation that is about equal to the amount of radiation each time you have the test.

A possible health problem seen with radiation exposure is the development of cancer later in life. This extra cancer risk is higher at younger ages and for girls and women. The extra lifetime risk of dying of a fatal cancer due to the radiation exposure from this research is also shown in the chart. At such low radiation exposures, scientists disagree about the amount of risk. These estimates are very uncertain, and there may be no extra risk at all.

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Test	'Natural Background Time' Equivalent for Each Time This Test is Done	Extra Cancer Risk Each Time This Test is Done
Abdominal CT Scan	3 Years	Very Low

Risks From Imaging Tests That Do Not Use Radiation

You may have an MRI study as part of this research. MRI uses a magnet and radio waves to make diagnostic medical images of the body. There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. However, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body, including medical implants, devices such as pacemakers and internal defibrillators, or certain dyes found in in tattoos. We will also keep the MR room locked so that no one carrying metal objects enters the room while you are in the scanner.

If there is any question about potentially hazardous metal within the body, you will not undergo the MRI. This may exclude you from participation in this research study. The MRI involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the MRI. During the MRI, you can have voice contact and physical contact with someone in attendance if you desire. Let the study doctor know if you have a fear of enclosed spaces.

You may have a number of medical imaging exams that are part of the regular care for your condition, and you would have them whether or not you participate in this research. These studies will not add to the risk of the research. However, if you have concerns about the overall radiation exposure, you should discuss them with your physician.

Risks of Endoscopy

Risks associated with endoscopy include aspiration (choking and/or gagging), sore throat, bleeding, and infection. These risks will be reviewed with your physician at the time of the procedure. Major complications occur in a small number of people who have endoscopy. The endoscope could puncture or pierce the intestines (less than 1 in 1,000 chances). This could require additional treatment or surgery.

Risks of Fine Needle Aspiration

Serious complications after fine needle aspiration are rare. Minor bleeding under the skin at the biopsy site can occur. This can result in a tender, swollen area called a hematoma. Infection at the biopsy site is rare, because sterile techniques and equipment are used for all fine needle aspirations. These risks will be reviewed with your physician at the time of the procedure.

Drug and Food Interactions:
For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

Other: By providing your email address for use in the consent process, you are at risk for a loss of confidentiality because email is not a secure means of communication.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefit to you. If you are randomized to receive Sulindac, this may or may not decrease the risk of radiographic progression of IPMN cysts of the pancreas, potentially reducing your risk of developing pancreatic cancer. If you are randomized to receive placebo, you may not have any benefit for your participation. We hope that in the future the information learned from this study will benefit other people with your condition.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
Instead of being in this study, you have the following alternatives:

- Follow the standard guidelines for care which includes active surveillance using CT and endoscopic ultrasound, with or without a fine needle aspiration (FNA).
- Participate in another clinical trial.

Please talk to your doctor about these and perhaps other options.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of this study, you will be asked to have certain tests and/or procedures performed. Some of these tests and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the research data office at Duke. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

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As part of the study, results of your study-related laboratory tests and procedures may be reported to the NIH. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives of the National Institutes of Health, the Duke University Health System Institutional Review Board, the Duke Cancer Institute, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

Some information collected in research studies is maintained in your medical record. However, for this study, since you and the study team are blinded to your drug assignment, that information will be inaccessible until the end of the study, unless your physician(s) decide that it is necessary for your care.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.
If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with your doctor and study coordinator. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

The grant supporting this study will pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

The study drug/placebo will be provided free of charge to you. At the end of the study, or if you decide to withdraw from the study before it ends, you will be asked to return all unused study drug. Your study doctor may request that you return for a checkup before you stop your study drug/biologic if he/she thinks that stopping it suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a person completes the study.

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WHAT ABOUT COMPENSATION?
You will be not be compensated for your participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Peter Allen at 919[redacted] during regular business hours and at 919[redacted] after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Allen in writing and let him know that you are withdrawing from the study. His mailing address is [redacted]. You may be asked to come in for a final study visit as described in the 'What is Involved in this Study' section of the consent.

In addition, you must return all unused study drug to your doctor or study staff. Your doctor may ask you to return for a checkup before you stop your study drug if he thinks that stopping the drug suddenly may harm you. They may also ask you to complete the tests that would ordinarily occur when a person completes the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, if your study doctor determines that it is no longer in your best interest to continue, or if you are not properly following the study procedures for taking the drug and coming to study visits. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include loss of funding, lack of efficacy (meaning the study drug does not work) or poor enrollment. If this occurs, you will be notified and your study doctor will discuss other options with you.

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Your samples and/or data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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 this website at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Peter Allen at ([redacted] during regular business hours and at 919-[redacted] after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time