Informed Consent Form Main

AND

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Eli Lilly and Company / "A Randomized, Multicenter, Double-Blind, Placebo-Controlled Development Program to Evaluate the Efficacy and Safety of LY4268989 (MORF-057) for the Treatment of Adults with Moderately to Severely Active Ulcerative Colitis (EMERALD-3)"**
Protocol Number:	**J6E-MC-KWAM**
Principal Investigator: (Study Doctor)	**Harold Preiksaitis, MD**
Telephone:	**509-474-1107** **509-496-2782 (24 Hour)**
Address:	**Principle Research Solutions** **907 S Perry St** **Spokane, WA 99202**

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

Welcome

The purpose of this document is to help you learn more about this study so you can decide if it is right for you.

Joining this study is voluntary. You can choose not to participate, leave the study, or stop taking the study drug at any time. This will not change your regular medical care or take away any of your normal benefits.

Participating in this study may not benefit you.

Please take all the time you need to review this document. The study staff will review it with you and help answer any questions you may have now and during the study.

Who is responsible for this study?

Eli Lilly and Company is the sponsor of this study and pays for the study costs. An Institutional Review Board/Independent ethics committees and any required regulatory agencies have also reviewed it. The study doctor and institution/clinic are independent from the sponsor and are not acting as the sponsor's agent.

What is the purpose of this study?

The purpose of this study is to learn more about LY4268989 (also called MORF-057), a possible new treatment for moderately to severely active ulcerative colitis. LY4268989 is not approved by the U.S. Food and Drug Administration (FDA) for the treatment of any disease and its use in this study is therefore considered experimental.

About 1431 people will be in this study.

This study aims to learn:

- Whether LY4268989 can help people with moderately to severely active ulcerative colitis achieve remission and improve symptoms.
- Whether LY4268989 works better than a placebo (a placebo is an inactive or "pretend" study drug) for the treatment of moderately to severely active ulcerative colitis.
- What are the possible side effects.

What are your other options?

There are other ways to manage your moderately to severely active ulcerative colitis.

These options might include:

- Different medicines to treat moderately to severely active ulcerative colitis, which may include:
  - mesalamines,
  - conventional medicines such as corticosteroids, azathioprine or 6-mercaptopurine,
  - advanced medicines that work in a special way such as anti-TNF drugs, integrin inhibitors, IL-12/23 and IL-23 inhibitors, JAK inhibitors, and S1P receptor modulators.
- Non-medicine treatments for moderately to severely active ulcerative colitis.
- Choosing not to have any treatment.

The study doctor can review your treatment options, how your condition is usually treated outside the study, and explain the possible benefits and risks.

How long will this study take?

This study will take about 114 weeks to complete.

What will happen if you join the study?

During the study, some activities may take place at the study doctor's office, at your home, or in other places. This depends on the study and local rules.

The study doctor will explain the study to you. They will tell you:

- which treatments you can still use,
- how the study works and what you will need to do,
- any anticipated potential benefits you may receive during this study, and
- answers to any questions you have.

The study is done in periods. The activities might change a little in each period. These changes are explained in the sections below.

You will use a device (e.g., tablet or phone) to do some study activities. The device will be your own device, or one provided to you by the sponsor.

Screening Period and Washout Period

Screening Period

The first part of this study is the Screening Period. It lasts up to 42 days depending on your personal health care situation. This period will help figure out whether you can continue to the next part of the study.

During this time, you will have some tests and activities, including:

- Medical and family history, including over-the-counter or prescription medicines, vaccines, vitamins, herbal supplements you take and substance use
- Ulcerative colitis specific medical history
- Vital signs like blood pressure, temperature, respiratory (breathing) rate and pulse rate
- Height, weight, and physical examinations. Pelvic, rectal, and breast examinations may be performed, based on your symptoms
- Blood draws and urine collection for laboratory tests
- Stool tests and sample collections
- Chest X-Ray
- Electrocardiograms (ECGs)
- Colonoscopy or sigmoidoscopy with biopsies
- Questionnaires related to the study
- You will be educated on how to take part in the study and follow instructions
- You may need to adjust your current medications during the washout period

Washout Period

The washout period is the time when you are not getting your regular treatment for your moderately to severely active ulcerative colitis before you begin taking study drug. The purpose of the washout period is to eliminate certain medicines from your body. During this time:

- Your study doctor may tell you to change your usual medicines or take new ones for moderately to severely active ulcerative colitis.
- You may be asked not to eat before certain study visits. The study doctor will tell you how long to avoid eating before the visit.
- You need to contact your study doctor or study staff before starting or changing any medicines or procedures (such as physical therapy).

Because you may not be getting your regular treatment for moderately to severely active ulcerative colitis, your disease could come back or may get worse.

During this time, you can expect about 1 blood draw, about 1 ECG, and 1 colonoscopy or sigmoidoscopy but you might need to have more.

Study Treatment Period

This period of the program lasts for about 104 weeks and includes 3 parts: induction study (10 weeks), maintenance study (42 weeks), and long term extension study (52 weeks). This is when you get either LY4268989 or placebo to compare how well they work. We refer to these all together as "study drug."

In general, neither you nor your study doctor will know which study drug you are getting. The drug that you get in the study is chosen by chance, similar to flipping a coin. This is called randomization.

In certain situations, for example if your disease does not improve enough, you may receive an "open label" LY4268989 treatment. This means that both you and your study doctor will know which LY4268989 dose you are receiving.

Induction Study: Initial Study Treatment Allocation

During the induction, you will receive your first dose of study drug. It will be either LY4268989 or placebo. You will have:

- 1 in 3 chance of receiving LY4268989 400 mg twice daily,
- 1 in 3 chance of receiving LY4268989 200 mg twice daily, and
- 1 in 3 chance of receiving placebo.

The induction study is expected to last for 10 weeks, although it may end sooner if you leave the study early. Once you complete the induction study, you will enter the maintenance study.

Maintenance Study: Continued Study Treatment

During maintenance, your study treatment can be adjusted based on whether you have shown sufficient improvement or not. More precisely:

- if your disease improves enough while on LY4268989 during induction you may receive LY4268989 200 mg twice daily or placebo. This is chosen by chance. You will have:
  - 1 in 3 chance of receiving placebo, and
  - 2 in 3 chance of receiving LY4268989 200 mg twice daily.
- if your disease improves enough while on placebo during induction, you will continue receiving placebo.
- if your disease does not improve enough while on LY4268989 or placebo during induction, you will receive LY4268989 400 mg twice daily for 10 weeks, and may receive LY4268989 200 mg twice daily for the following 32 weeks. This study treatment will be open-label, which means that both you and your study doctor will know that you are receiving LY4268989.
- if your disease improves enough while on LY4268989 or placebo at first but worsens later, you'll enter the next period called long-term extension study and receive open-label LY4268989 200 mg twice daily. Your study doctor may adjust your other ulcerative colitis medications if necessary.

The maintenance study treatment is expected to last for 42 weeks, although it may end sooner if you leave the study early or lose response. Once you complete the maintenance study or lose response during this study, you may enter long-term extension study.

Long-Term Extension Study: Extended Study Treatment

During the long-term extension you will receive open-label LY4268989 200 mg twice daily for 52 weeks, unless you leave the study early.

Interim Analysis: Possible Adjustments

Once a certain number of participants have enrolled in the study, an analysis known as the Interim Analysis will be conducted. Based on this analysis, the study treatments and your chances of receiving them may change.

The following changes could happen:

- Induction study changes
  One of the LY4268989 doses may be removed. If that happens before you are enrolled, your chances will be:
  - 1 in 3 chance of receiving placebo
  - 2 in 3 chance of receiving LY4268989 at 200 mg or 400 mg twice daily
- Maintenance study changes
  A 100 mg twice daily dose may be added. If that happens and your disease improves enough at end of the induction study, your chances will be:
  - 1 in 5 chance of receiving placebo
  - 2 in 5 chance of receiving LY4268989 at 200 mg twice daily

  - 2 in 5 chance of receiving LY4268989 at 100 mg twice daily
- Long-Term Extension study changes
  If the 100 mg twice daily dose is added during maintenance:
  - Participants who were receiving LY4268989 during maintenance will continue on the same dose in the long-term extension.
  - Participants who were receiving placebo during maintenance will switch to LY4268989 at 200 mg twice daily in the long-term extension.

During study treatment period time you will take study drug by mouth for up to 104 weeks by mouth. You will also have some tests and activities, including:

- Vital signs like blood pressure, temperature, respiratory rate and pulse rate
- Weight, and physical examination
- Blood draws and urine collection for laboratory tests, including biomarker analysis
- Stool tests and sample collections
- Electrocardiograms (ECGs)
- Questionnaires related to the study
- Other diagnostic tests like colonoscopies or sigmoidoscopies
- You will be educated on how to take part in the study and follow instructions
- You may be asked to fast for some study visits

During this time, you can expect about 31 blood draws, about 3 ECGs, and about 3 colonoscopies or sigmoidoscopies but you might need to have more. Ask the study doctor if you want to know more.

Follow-Up Period

After you finish the study treatment period and stop getting the study drug or you decide to stop study drug, the study doctor will keep checking on your health. This time is called the Follow-up Period, and it lasts for about 4 weeks.

During this time:

- You will no longer receive study drug
- You will have some tests/activities including:
  - Vital signs like blood pressure, temperature, respiratory rate, and pulse rate
  - Weight, and brief physical examination
  - Blood draws for laboratory tests and urine collection
  - Questionnaires related to the study

You can expect about 1 blood draws, but you might need to have more. Ask the study doctor if you want to know more.

Could there be risks for you?

Participating in this study has potential known and unknown risks. The study doctor will speak to you about all the potential risks to you. Below are the known risks for you to consider if you participate in this study.

Risks for drugs in the study

Below are the known risks for the study drug being tested. You may experience some, all, or none of the side effects listed below.

LY4268989

210 people have taken LY4268989 in clinical trials. Of these

- 171 were adults without the disease being studied, and
- 39 were adults with ulcerative colitis.

In an ongoing study, 280 people with ulcerative colitis are taking either LY4268989 or placebo (a pill that does not contain the active drug).

Risks for All Studies

In clinical studies involving adults without the diseases being studied, who received LY4268989 with or without other drugs, no serious or severe side effects were reported.

Of the 39 people who had received LY4268989 for ulcerative colitis in the completed study, no serious or life-threatening side effects were reported. Of the 39 people who had received LY4268989 for ulcerative colitis in the completed study, 2 or more people experienced the following side effects:

- 11 people experienced worsening of ulcerative colitis.
- 4 people each experienced
    - a lower than normal number of red blood cells, and
    - infection of the upper part of the airways.
- 2 people each experienced
    - acne,
    - abnormal connection between the intestine and skin near the anus, and
    - inflammation of the nose and throat.

Of the 280 people with ulcerative colitis in the ongoing study, 5 or more people experienced the following side effects when taking either LY4268989 or placebo (a pill that does not contain the active-drug):

- 13 people experienced headache,
- 11 people experienced lower than normal number of red blood cells,
- 10 people experienced inflammation of the nose and throat,
- 7 people experienced worsening of ulcerative colitis,
- 6 people experienced infection of the upper part of the airways, and

- 5 people experienced fever.

In the ongoing study in people with ulcerative colitis, 5 people had the side effects below, which were serious or life-threatening when taking LY4268989 or placebo (a pill that does not contain active drug). The study doctor did not think these side effects were related to the study drug.

- 2 people experienced worsening of ulcerative colitis, and
- 1 person each experienced
    - rise in the levels of liver enzyme,
    - slipped disc, and
    - collapsed lung.

Other Safety Information

Some people who have taken other medicines that work like LY4268989 have reported the side effects as follows:

- Infections: Increased risk of some infections or worsening of infections.
- Progressive multifocal leukoencephalopathy (PML) is a rare infection of the brain that is caused by the John Cunningham virus. PML can occur in people who have a lower ability to fight infections because of a weak immune system. No cases of PML have been reported in participants receiving LY4268989. There has been 1 case of PML reported in a patient treated with a medicine called vedolizumab similar to LY4268989. However, that patient had multiple other disease conditions, including human immunodeficiency virus infection, that increased their chance of getting PML.
- Liver problems: rise in liver enzymes in the blood which may be a sign of liver problems.
- Serious allergic reactions including potentially life-threatening reactions. If you develop symptoms of an allergic reaction while taking the study drug you should seek immediate medical attention.
- Increased risk of cancer because of the way LY4268989 affects the immune system.

When certain medications are taken together with LY4268989, the levels of LY4268989 or the other medication in your blood can change. It is very important that you tell your study doctor if you are taking other medications, dietary supplements, natural remedies, or vitamins.

Animal Safety Data

LY4268989 has been given to animals. The information from animal studies may be useful to you in considering whether to participate in the study because similar effects could be observed in people. Important effects seen in animals are

- Effect on the liver
    - When LY4268989 was given to animals at doses higher than what human participants take, it caused an increase in liver enzyme levels.
    - When animals were given higher dose of LY4268989 than what humans would take, some of the animals developed stones in their gallbladder.

- Effect on gut
    - When animals were given LY4268989 at higher doses than what humans take, it caused some stomach changes that could lead to stomach discomfort.
- Effect on pregnancy
    - When pregnant animals received LY4268989 early in their pregnancy at lower doses than what humans use, a risk of their babies dying was identified. The risk was greater among the animals who did not eat well and lost weight. It is important to follow instructions for using contraceptives.
- Effect on general well-being
    - Additionally, when animals were given LY4268989 at doses higher than what humans take, they ate less, felt less hungry, and lost weight.

Important Signs and Symptoms for All Studies

Call the Study Doctor Right Away if you Have…	**Because it may indicate…**
For All Participants	
headaches, memory loss, changes in mental status, speech and vision difficulties, loss of strength, limb weakness, seizures, partial paralysis, or loss of coordination.	that you are developing a brain infection due to a weakened immune system.
fever, chills, muscle aches, cough, shortness of breath, runny nose, sore throat, red or painful skin or sores on the body, tiredness, or pain during urination.	that you are developing an infection
itching, swelling of the lips, tongue, throat, or face; rash, itchy skin called hives, shortness of breath or trouble breathing; wheezing; dizziness; feeling hot; or palpitations (feeling like your heart is racing).	that you are developing a serious allergic reaction. In this case, you should seek emergency medical help immediately.
feeling tired, loss of appetite, pain on the right side of the stomach, dark urine, or yellowing of the skin and eyes	that you are developing liver problems

During the study, you may also take certain medications such as corticosteroids, 5-ASAs, azathioprine, 6-mercaptopurine, and antidiarrheals. Ask your study doctor about any risks that may be associated with the use of these medications.

Risks for study activities

There might be some risks with the activities in this study. Most of the activities are regular medical procedures, and the risks are the same whether they are done in the study or outside of it.

The study staff can answer any questions you have about what will happen in the study and the risks for you.

The following are risks associated with the activities in this study.

Blood Tests	You might feel a quick pinch when the needle goes in, and sometimes a bruise might form. After the procedure, you might feel dizzy or faint.
X-Ray (Standard)	A small amount of radiation is used that is generally considered safe for most people.
ECG	You might feel a bit of discomfort when the devices are placed on or removed from your skin. You might have mild skin irritation after the test.
Tuberculosis test	Depending on the type of tuberculosis test used, you might experience skin irritation at the injection site. There is a small chance you might have an allergic reaction to the substance used in the test. The study doctor may be required by law to report the result of this test to the local health authority.
HIV, Hepatitis B or C	The study doctor may be required by law to report the results of these tests to the local health authority.
Sedation or General Anesthesia	You may need sedation or general anesthesia in order to have a colonoscopy or sigmoidoscopy. You might feel groggy, dizzy, or have trouble breathing when you wake up. You also might feel nauseous or throw up after the procedure. There is a small chance that you might have an allergic reaction to the anesthesia.
Colonoscopy or sigmoidoscopy with biopsy	You might experience the following: • **Discomfort**: You might feel cramping or bloating during or after the procedure. • **Bleeding**: There's a small chance of bleeding, especially if the doctor removes something or takes a sample. • **Infection**: There's a very small chance of getting an infection where the colonoscope was inserted. • **Tear**: Very rarely, the colonoscope could make a tear in the colon, which might need surgery to fix.
Questionnaires	Some people may find that doing questionnaires is upsetting or embarrassing.

	You must tell your study doctor right away if you have any thoughts about hurting yourself. If you are having suicidal thoughts or feel you are in a crisis, call 9-1-1 to be connected to local emergency services. You can also present to your local emergency room, or a healthcare provider. You can also call or text the National Suicide & Crisis Lifeline at 9-8-8 or 1-800-273-TALK (8255). The Lifeline numbers are answered 24 hours a day every day of the year by a skilled, trained counselor. If you have had suicidal thoughts, have been in a crisis, have called 9-1-1, or presented to the emergency room or a health care provider, please call the study doctor at the telephone number listed on the first page of this form.
MRI (Magnetic Resonance Imaging)	If your doctor thinks you have potential for PML, you may need an MRI scan. You may feel cramped or nervous inside the machine due to the noise and narrowness of the machine. There is a small chance you might have an allergic reaction to the dye used in the test. If you have certain metal implants or devices in your body, the MRI might not be safe, or it could affect the images.

Risks Related to Using Your Personal Mobile Device

If you use your personal mobile device for this study, there may be certain privacy and security risks.

- If your device is lost, stolen, or used by others without permission, they might see your study data.
- You will need to install a mobile application for the study on your device. This application might use the mobile battery and data. This can lead to extra data charges from your service provider.

You will need to follow these steps:

- create a password or code to access the application,
- create a strong password to protect your device, and
- enable automatic locking for added security.

If your device is lost or stolen, report it to the study team right away.

Lifestyle changes you may need to make

Being in a study:

- may require you to make lifestyle and medication changes,
- could expose you to unknown risks, and
- could expose an unborn baby you are carrying or a baby you are breastfeeding to unknown risks

Below are the lifestyle changes that you may need to make if you participate in this study. Your study doctor will explain the lifestyle and medication changes you need to follow based on your situation.

Pregnancy and Contraception

It is important to understand the contraceptive restrictions for this study. If you can get pregnant, the following guidance applies:

- Birth control should be used during the study and for 7 days after you have completed receiving the last dose of study drug.
- Tell your study doctor right away if you or your sexual partner(s) become pregnant or if you plan to breastfeed. The study doctor will ask to collect information about the pregnancy and health of the child for about 6 to 8 weeks beyond the estimated delivery date.
- The study doctor will talk with you about whether you may need to use birth control, and which type you will need to use during the study. Oral contraceptives are not allowed.

Below are things to think about for your other medicines and possible lifestyle changes:

Medication and Vitamins

- You might not be able to take some of your usual medicines or supplements. You may also need to change some parts of your daily routine.
- You might need to take new medications to manage side effects or as part of the study. These new medications could have risks and might interact with the study drug.
- If you decide to take any new medicines or supplements while in the study, talk to your study doctor first.

Meals and Diet

- You may need to avoid food and drinks (except water) for 12 hours before certain visits. The study doctor will remind you if this is the case.
- You may need to take the study drug with a meal or a certain amount of time before or after a meal.
- You should avoid eating Seville oranges, grapefruit, or star fruit or any products containing these fruits while taking the study drug.

Other Lifestyle Restrictions

- You should not donate blood and blood products during the study and sperm during the study and for 7 days after your last dose of study drug.

Could something change while you are in the study?

You may be taken out of the study for different reasons. For example, if you have a bad reaction, become pregnant, find out which study treatment you are getting before the study ends, or do not follow the study rules. You could also be taken out of the study if the sponsor or study doctor finds new safety concerns, stops working on the study drug, or closes the study site.

If new information is learned that may change your mind about staying in the study, the study doctor will tell you promptly.

If you are

- taken out of the study,
- choose not to continue the study,
- choose to stop taking the study drug, but stay in the study,

the study doctor will discuss what this means for you.

Are there benefits to taking part in the study?

You may or may not receive any benefit from being in this study. Information obtained from this study will also benefit the sponsor of the study and may benefit study participants in the future.

How will your samples be used?

Samples from your body will be collected. Please see the table below for more information about how your samples will be used and who will have access to them.

Type	**Purpose**	**Length of time stored**	**Who may use it or see your data**	**Notes**
Blood, stool, and urine	To confirm that you can be in the study and monitor your health.	Until tests are done and confirmed	Only researchers in this study	You may be tested for hepatitis, HIV, tuberculosis, pregnancy, or other diseases. If tests say you have one of these conditions researchers will contact you. Certain positive results may be reported to public health officials based on local law.
Blood	To see how fast your body breaks down the study drug.	Up to 1 year after all participants have finished the study	Only researchers in this study	

Type	Purpose	Length of time stored	Who may use it or see your data	Notes
Blood, stool, and tissue	To learn more about moderately to severely active ulcerative colitis or how people respond to the study drug.	Up to 15 years after all participants have finished the study	Study researchers and others*	Biomarkers are substances in the body that can tell researchers about a condition. For example, cholesterol in the blood can be a biomarker for heart disease.
Blood	To learn more about moderate to severely active ulcerative colitis and how the study drug works for you or to help find out why people react to drugs differently.	Up to 15 years after all participants have finished the study	Study researchers and others*	DNA tells your body how cells should be built and work. Some of these instructions tell your body how to react to drugs.

*"Others" refers to a business partner who will be required to sign a written agreement to protect your samples and uses the samples as agreed to in this consent form.

All samples will ultimately be destroyed based on laboratory procedures, laws, regulations, or international laboratory standards.

Will you have costs or be reimbursed for joining the study?

You will receive the study drug, study treatments, and procedures that are directly related to the study at no cost. Depending on how your healthcare is paid for, you may have some personal expenses. The study staff can explain further.

Using the mobile app may use data from your mobile data plan. You are responsible for any data charges from your mobile provider. To reduce data costs, use secure Wi-Fi whenever possible. For support with the mobile app, please contact your study team.

If you spend money to be a part of this study, you will be reimbursed for certain costs, such as meals, transportation and hotel stays. You will only be given money back for expenses associated with study activities completed. In addition, you may receive money for your time and effort for participating in the study. You will be provided a fixed amount per study visit. The study staff will provide information and review more details about how reimbursement will be provided. You will receive a compensation information sheet.

Your samples may help with the development of other items, such as products or procedures, that may be worth money to the sponsor. You will not receive any rewards or benefit from this.

What happens if you are harmed during the study?

If you get hurt while you are in the study, here is what you should do:

- Get appropriate medical help.
- Tell your doctor and nurse that you are part of a clinical study.
- If you get hurt but it is not an emergency, call the study doctor as soon as you can.

If you are physically hurt, the sponsor of the study might pay for some medical bills. This could include:

- The cost to find out what your physical injury is if it seems to be related to the study drug, or a procedure required by the study.
- The cost for treatments you need for your physical injury, if your physical injury is directly caused by the study drug or a procedure required by the study.

The sponsor will decide if they will pay these costs based on a few things, such as:

- If your study doctor and study site followed the study instructions.
- If your health private insurance already pays for these costs.

Paying for your medical bills does not mean the sponsor is admitting the study drug or study procedure caused your injury.

To decide if your costs will be covered, you may need to give more paperwork, like your medical records and insurance information. To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Finally, being in this study and signing its forms does not take away any legal rights you have. You can still take legal action if you think you were injured because of the study.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00092452.

How can you learn more about this study?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The general requirements to join the study and countries participating can be found on this website.

Information can also be found at http://euclinicaltrials.eu/search-for-clinical-trials/ with study number 2025-524404-29-00.

When the study is over, a summary of the results will be made available. The study doctor can provide more details about when and where you can access the results.

The study doctor can share which study drug you were given.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

How is your privacy protected?

Will my medical information be kept private?

The study doctor and study staff will handle your personal information in a confidential manner. Personal information includes both your study data and your original medical records.

By signing the consent document for this study, you give permission ("authorization") for the uses and disclosures of your personal information that are

described in this document including sharing your personal information with the study doctor and study staff for study-related purposes.

Why is your personal information collected and how is it used?

Your personal information is information that identifies you or could reasonably be used to identify you. There are different types of personal information that can be collected as part of your participation in the study. If you do not provide your consent, it will not affect your current or future medical treatment, payment for your treatment, enrollment in, or eligibility for benefits to which you are otherwise entitled.

Categories of personal information that are collected include:

- Basic personal details such as name, signature, birth date, and sex at birth.
- Health information such as medical history, prescriptions, health status, and test results
- Behavioral information such as smoking, alcohol consumption,
- Protected characteristics such as racial and ethnic origin
- Biomaterial information such as blood, tissue, stool, and urine samples
- Personal contact information such as address, phone, and email address
- Mobile device information and data entered into the study application
- Financial information for study participant reimbursement

Your personal information will be used and shared for the purposes of conducting and overseeing this study as described in this document. Some of the uses include determining if you are eligible for this study, understanding your medical history, assessing your health, and providing medical treatment during the study. Your health records may be accessed and reviewed by the sponsor, IRB/ethics review boards, and global regulatory authorities (such as the FDA) to assure the quality of the study and study data, or for other uses authorized by law. Additionally, the study doctor and study staff will collect personal information about you from your existing health records or directly from you and store it in a study-specific database only and provide access authorized individuals for study-related purposes. While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed.

If you are not able to attend a planned study visit or stay in contact with the study team, the study doctor or study staff may try to reach you through your family members, provided contacts, your family doctor, or hospitals or clinics that treat you.

They may also search public records, such as national registries or databases. This is to check on your health status to ensure your safety, maintain the scientific integrity of the study, and meet regulatory obligations. They will not contact you or your family if you say you do not want to be contacted further.

If you lose contact with the study team, they may give your name and last known contact information to a participant locator service to try to find your current information, if allowed by local laws and regulations. The participant locator service will not contact you directly, and any new information they find will be shared only with the study team.

How is your personal information protected?

The study doctor and study staff will share information with the sponsor and representatives working on behalf of the sponsor; however, they will assign a code number to represent your personal information to protect your identity.

How is your coded personal information used and shared?

Eli Lilly and Company complies with the European Union (EU)-U.S. Data Privacy Framework ("DPF"), the United Kingdom (UK) Extension to the EU-U.S. DPF, and the Swiss-U.S. DPF, as set forth by the U.S. Department of Commerce for transfers of personal data from the European Economic Area (EEA), UK and Switzerland, respectively. Our Data Privacy Framework Statement can be found here https://www.lillyhub.com/legal/lilly/dpf.html.

The sponsor, its affiliates, and business partners may use this coded data in the following ways:

- As part of this study;
- To meet global regulations and approvals;
- For legal purposes (for example, litigation);
- To publish its findings in study reports or scientific presentations;
- For further medical research projects or development of medical products/devices/diagnostic tests, the specific details of which may not be fully known at present;
- For further examination of the safety or efficacy and/or identification of new medical uses of any medical products/devices/diagnostic tests or treatment included in the study;
- For further examination of the disease(s) or condition(s) that are the subject of the study to identify new learnings;
- To analyze how the sponsor can improve its clinical research processes;

- To develop artificial intelligence and/or machine learning tools that can help us learn more about the disease or condition being studied; and
- To analyze the study data using artificial intelligence and/or machine learning tools.

The sponsor may share this coded data for the purposes in this document with its affiliates, business partners, regulatory agencies in countries around the world, and IRB/ethics committee(s). Once shared, this data may no longer be protected by applicable laws and may fall under data protection laws in other countries that may be less protective than data protection laws in the country or region in which you are participating in this study, however, the sponsor will continue to protect your coded data and use the data only for the purposes described in this document.

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 the sponsor will 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 the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

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.

How long will your information be stored?

Records containing your personal information will be retained at the study site for a period of up to 30 years after the end of the study. In addition, the sponsor will retain the coded data for up to 5 years after marketing of the study drug has completed.

Some states, such as California, require an expiration date for your authorization to disclose and use your personal information as described in this document. Your

authorization will expire 50 years after you sign this document, unless you revoke it (take it back) sooner.

What are your rights related to your personal information collected, used or shared during the study?

You have the right to see and get a copy of your personal information used in the study. Please note however, that while you are participating in the study, your access to your personal information in the study records may be limited to protect the integrity of the study and results. You have the right to withdraw your consent for the collection, use, and disclosure of your personal information for this study at any time. If you decide to withdraw your consent, you cannot continue to participate in the study. Personal information collected prior to your withdrawal of consent must be maintained in the study records due to regulations. To meet regulations, the sponsor, its affiliates, or its business partners may request information about your health status after you withdraw from the study (for example, tracking for an adverse event).

You may also have other legal rights related to your personal information based on where you participate in the study. You may contact the study staff using the contact information on the first page of this form to understand your rights.

If you are not satisfied with the response or believe the study site or the sponsor is not processing your personal information in accordance with the law, you can file a complaint with the relevant regulatory agency (for example a Data Protection Authority or an Attorney General).

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____	_____
Signature of Study Participant	Date (must be written in by Study Participant)

_____
Study Participant First and Last Name (print or type)

_____
Printed Name of Legally Authorized Representative (if applicable)

_____	_____
Signature of Legally Authorized Representative	Date

_____
Authority of Legally Authorized Representative to act on behalf of Participant

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

Sponsor request for confidentiality

The sponsor wants to keep the information in this document confidential. Please share it only if you need to decide whether to join or stay in the study, if you have questions about your rights, or when getting medical care from healthcare professionals.

Joining the study is your decision

To become part of this study, please sign and date below.

Signing this page means that:

- I understand all of the information I have been given about this study, all my questions have been answered, and I have had enough time to review the information and think about it.
- I understand that I choose to be part of the study and do so voluntarily. It is okay if I decide not to join or change my mind later at any time. To withdraw from the study, I can notify the study staff either verbally or in writing.
- I have given my free and informed consent without being influenced by others to be part of this study
- I agree to use and/or return the study drug only as instructed by my study doctor and study staff.
- I agree to use a mobile device and the required mobile app for this study. The device will be one provided by the sponsor or my personal device. I understand the privacy and security risks of using a device for study purposes, as detailed in this document.
- I give permission and consent to the collection, use, disclosure, and transfer of my personal information as detailed in this document.
  I have been informed that I will receive a copy of the signed and dated Informed Consent Form completed by both parties to keep for myself.

For Study Participant to Complete:

Signature of Study Participant	Date (must be written in by Study Participant)

Study Participant First and Last Name (print or type)

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Legally Authorized Representative Date

_____

Authority of Legally Authorized Representative to act on behalf of Participant

For Impartial Witness to Complete (If Applicable):

I witnessed that the information in the consent and any other written information was accurately explained to, and apparently understood by, the study participant or the legally authorized representative, and that informed consent was freely given by the study participant or the legally authorized representative:

_____ _____

Signature of Impartial Witness Date (must be written in by Impartial Witness)

_____

Impartial Witness First and Last Name (print or type)

For Individual Conducting Informed Consent Discussion To Complete:

I have explained the study (such as the purpose, risks, benefits, and the activities) to the study participant before the study participant voluntarily agreed to participate.

Signature of Person Conducting Informed Consent Discussion	Date (must be written in by Person Conducting Informed Consent Discussion)
Person Conducting Informed Consent Discussion First and Last Name (print or type)	
Role of Person Conducting Informed Consent Discussion	