CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor/Study Title:	**Eli Lilly and Company / "A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study Comparing the Efficacy and Safety of Tirzepatide versus Placebo in Patients with Nonalcoholic Steatohepatitis (NASH)"**
Protocol Number:	**I8F-MC-GPHR**
Principal Investigator: (Study Doctor)	**Anuj Bhargava, M.D.**
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Introduction

You are being asked to voluntarily be in a medical research study of a study drug known as tirzepatide. Eli Lilly and Company and its representatives ("sponsor"), are sponsoring this study and are paying the study doctor and/or study site for their work in this study.

The purpose of this form is to help you decide if you want to be in this study.

Please read this form carefully. It may contain words that you do not understand. Please ask the study doctor or study nurse to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this form to think about or discuss with family or friends before making your decision. If you sign and date this form, you are giving your permission (or consent) to be a part of this study. You can agree to take part in this study and change your mind later.

If any important new information is found during this study that may affect your wanting to continue to be part of this study, you will be told about it right away.

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.

Confidentiality of Trial Information

The information in this informed consent document is intended to help you determine whether participating in this study is right for you.

You may wish to discuss this information with others for the purposes of helping you decide whether to participate in the study or as needed for medical treatment. You are asked to treat this information as confidential and to inform any others with whom you share this information that it is confidential. During the course of this study, you and/or a family member or caregiver of yours may learn, or have access to, proprietary information of the Sponsor, including study drug product information. Proprietary information should be maintained as confidential. Please ask your study doctor for more specifics if you have a question about the nature of any particular information.

Why is this study being done?

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

- Whether tirzepatide can help study participants with nonalcoholic steatohepatitis (NASH).

"Investigational" means that the study drug being tested has not been approved for routine clinical use or for the use described in this study by the United States Food and Drug Administration (FDA). The FDA is allowing the use of this study drug for research.

How many people will take part in the study?

Approximately 196 study participants will be taking part in this study.

What will happen during the study?

You will be asked to:

- Sign and date this consent form;
- Give your health history. The study staff will review your medical history and test results to see if you can be part of this study.
- Tell the study staff if you take any over-the-counter or prescription drugs, vitamins, or herbs.

The study staff will discuss what is required for you to be part of this study.

You can take part in this study if:

- You were diagnosed with NASH by liver biopsy.
- You are 18 to 80 years of age.
- You have BMI greater than or equal to 27 kg/m^2 and less than or equal to 50 kg/m2 and a stable body weight for at least 3 months.

You cannot take part in this study if:

- You drink more than 14 units (1 unit = 12 oz of beer, 5 oz of wine or 1.5 oz of distilled spirits) a week of alcohol if you are female or more than 21 units a week if you are male.
- You have other types of liver disease, which the study doctor will discuss with you.
- You are unable or unwilling to undergo a liver biopsy.

- You have used illegal substances within the last year.
- You have used marijuana or cannabidiol (CBD) oil within the last 3 months and are unwilling to stop use during the study.
- You use insulin or have certain complications from diabetes, which the study doctor will discuss with you.
- You have had surgery for obesity within the last 5 years or plan for surgery during the study.
- You have other medical conditions, which the study doctor will discuss with you.
- You currently use certain type of medications which the study doctor will discuss with you.

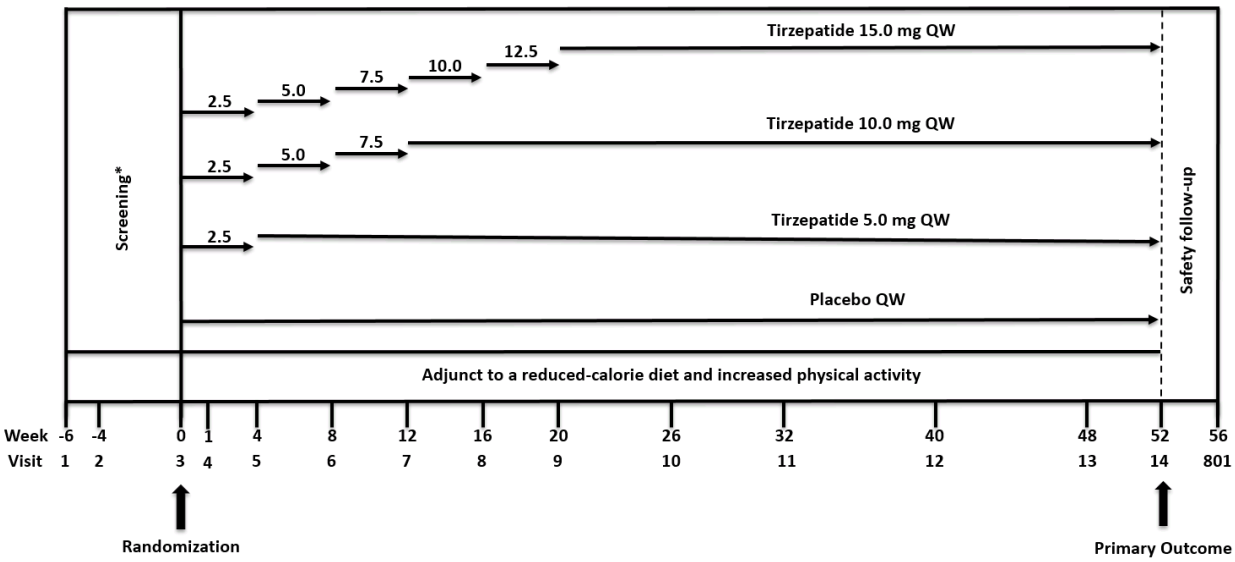
You may need to have some exams or tests done to find out if you are a candidate to begin the study drug. Some of these tests may be done even if you do not join the study as part of your normal care.

Neither you nor the study doctor will know what study drug you are taking. However, your study doctor may find out which study drug you are on if needed for your care. If this happens, your participation in the study will end. The study doctor may not be able to tell you which study drug you are on until everyone finishes the study (which may be years in some cases). Whether you receive tirzepatide (5 mg, 10 mg, or 15 mg) or placebo will be determined by chance. A placebo is a solution that looks like the study drug but has no medicine. The chance that you will get any one of the study treatments is 1 in 4. The study drug is given as an injection under your skin that is called subcutaneous injection (SC).

Participants will be assigned to 1 of the following study treatment groups randomly (like flipping a coin):

- Tirzepatide 15 mg SC every week
- Tirzepatide 10 mg SC every week
- Tirzepatide 5 mg SC every week
- Placebo SC every week

Study Diagram



Abbreviation: QW = once weekly.

*Screening may take longer or shorter than 6 weeks

You will:

- Use the study drug only as instructed by the study staff;
- Return any unused study drug and containers at the end of this study, or as instructed by the study staff.

It is important that you are completely truthful with the study staff about your health history. It may be harmful to you or to other people who may take the study drug if you are not truthful with the study staff. You should not take part in this study if you do not meet all requirements.

If you choose to be in this study, your part in the study is expected to last up to 68 weeks (screening should be less than 12 weeks, study treatment is 52 weeks, and follow-up is about 4 weeks).

If you develop antibodies to tirzepatide, you may be asked to occasionally return to the study site for up to 1 year for additional blood samples after the study ends.

Please review the table below. This will give you information about what will happen at each specific visit and how often the procedures will happen.

Study Schedule

Visit	1	2[a]	3	4	5	6	7	8	9	10	11	12	13	14	801	ET
Week of Study Treatment	–6	–4	0	1	4	8	12	16	20	26	32	40	48	52	56	
Fasting Visit	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Informed consent	X															
Study doctor will ask how you are feeling and what medications you are taking	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Medical history including alcohol and tobacco use	X															
Receive blood glucose meter/supplies, counseling			X													
Receive coaching about diet and physical activity			X		X	X	X			X		X				
Receive and review study diary			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Get injection training			X	X												
Receive study drug and injection supplies			X	X	X	X	X	X	X	X	X	X	X			
Return study drug supplies					X	X	X	X	X	X	X	X	X	X		X
Vital signs (BP, pulse rate, and temperature) weight, and waist circumference *height measured	X*		X		X	X	X	X	X	X	X	X	X	X*	X	X*
Physical exam [b]	X															
Eye exam[c]	X															
Provide blood sample (approximate volume in mL)	39		84	5	21	8	80	8	54	80		31	10	80	36	56
Provide urine sample	X		X				X			X				X	X	X
Pregnancy test[d]	X		X		X	X	X	X	X	X	X	X	X	X	X	X
ECGs	X		X							X				X	X	X
Liver biopsy		X												X[e]		X
Transient Elastography (Fibroscan)[f]	X		X							X				X		X
MRI[f]			X							X				X		X
Fill out questionnaires	X		X										X	X		X

Abbreviations: BP = blood pressure; ECG = electrocardiogram; ET = early termination; MRI = magnetic resonance imaging; T2DM = type 2 diabetes mellitus.

a Participants with acceptable previous liver biopsy do not need to attend Visit 2.

b Additional physical examinations may be performed throughout the study if determined necessary.
c An eye examination will be performed between Visit 1 and Visit 2 by an eye care professional (ophthalmologist or optometrist) for T2DM participants who have not had an eye examination in the last 12 months
d Serum pregnancy test will be performed at Visit 1 for women of child-bearing potential. A urine pregnancy test will be given to all women of child-bearing potential at Visit 3 to confirm lack of pregnancy. Additional urine pregnancy tests will be given to women of child-bearing potential at all other visits beginning at Visit 5. Other pregnancy tests may be performed at the study doctor's discretion if pregnancy is suspected during the study.
e End of study treatment liver biopsy may be collected between Weeks 49 and 53.
f Transient Elastography imaging should be collected after at least a 3-hour fast. MRI should be collected after at least a 6-hour fast. Drinking a small amount of water is acceptable for Transient Elastography and MRI.

Other Information

Meals/Diet – Study participants will fast (no food or drink except for water) for at least 8 hours overnight prior to each outpatient visit where fasting samples are drawn. Study participants will fast for at least 8 hours prior to weight measurements.

Alcohol – Alcohol will not be permitted 8 hours prior to the study site visits, until the study participant has been discharged from the clinical research site.

Blood Donation – Study participants should not donate blood or blood products during the study and for 8 weeks following the study.

Study Drug – During the study, you will be trained on how to inject study drug and should be willing to self-inject or have assistance of the trained person who will inject the study drug

Paper Study Diary – you will use a paper study diary as instructed by the study staff. You will use the diary to record your weekly study drug dose injections. If you have Type 2 Diabetes you will also record blood glucose values and low blood glucose information. You will bring the paper study diary to every study office visit.

At 3 office visits during the study you will be asked to return to the clinic for the blood draws within 1 to 24 hours or 24 to 96 hours after the study drug dose injection at the office visit to find out how much study drug is in your blood. The study staff will instruct you at which time point the blood draws should be taken.

Are samples being collected?

Please review the information below. This explains what samples are being collected, how they will be used, and how long they will be stored. Additional samples may be required to repeat a test if needed. The samples and any data generated from the sample can only be linked back to the study participant by the study doctor or study site personnel.

General Information Regarding Sample Collection

Various blood, urine, and liver tissue samples will be collected from you during this study. The specific procedures for collecting these samples and the risks associated with collection are explained in the procedure table and risks section in this document. Your samples will be identified by your study participant number, and not by your name.

The analysis of your sample(s) may contribute to the creation of new laboratory tests, new medicines, or other items that may be commercially valuable to the sponsor. The sponsor has no plans to provide you, either now or in the future, any compensation, royalty, or any other financial benefit that might result from any product, procedure, or other item that may be developed from studying your sample(s) or any information or data that is derived from such research.

Samples for Study Qualification and Health Monitoring

Blood and urine samples will be collected to determine if you meet the requirements to participate in this study.

Additional blood and urine samples will be collected throughout the study to monitor your health and your response to study drug.

Blood samples will be tested for hepatitis B and C which are serious and contagious diseases. If your test results are positive, your study doctor or study staff will contact you.

Blood samples will be tested for HIV, the virus that causes AIDS. If your test results are positive, your study doctor or study staff will contact you and may give you information on counseling services.

The results of hepatitis B and C and HIV testing will be kept confidential and disclosed only as required by law.

All samples collected for study qualification and health monitoring will be destroyed within 60 days of confirmation of the test results, unless laws, regulations, or international laboratory certification standards require a longer retention period. This confirmation will either occur immediately after initial testing, or may require that samples be held to be retested at a defined later point in time.

Samples for Measuring Study Drug Levels
Blood samples will be collected to measure the amount of study drug that is in your body and how your body breaks it down. The samples will be stored for a maximum of 1 year after this study is finished.

Samples for Genetic Research
Blood will be collected to study your DNA. Your samples will be identified by your study participant number, and not by your name. DNA is genetic material that is found in all the cells of your body. DNA contains instructions that your body reads to understand how it should be built and work. Some of these instructions tell your body how to react to medicines. For this reason, looking at DNA can sometimes help explain why people with a disease respond differently to the same medicine. For example, some people taking this study drug may respond well. Others may have little or no response, or have side effects.

Researchers may study your DNA to learn how the study drug works for you. Information about your DNA may be used to create or improve tests to measure these genetic factors. Researchers may also study your DNA to better understand the disease for which this study drug is developed. The samples and any data generated from the sample can only be linked back to the study participant by the study doctor or study site personnel.

The DNA sample may be stored for up to 15 years after this study is finished.

Samples for Biomarker Research
Sometimes scientists measure substances in the body to diagnose, evaluate, or monitor a person's medical condition or disease. For example, cholesterol levels in the blood can be used to monitor a person's risk for heart disease. In this example, cholesterol is a biomarker.

Blood will be collected to identify or better understand biomarkers.

Researchers may use biomarkers to learn more about NASH or how study participants respond to study drug or other medicines that you are taking during this study. Your sample(s) may also be used to create or improve tests to help identify study participants in the future who may respond to this study drug. The samples and any data generated from the sample can only be linked back to the study participant by the study doctor or study site personnel.

The sample(s) may be stored for up to 15 years after this study is finished.

Samples for Antibody Research
Blood sample(s) will be collected to determine if your body produces antibodies against the study drug. Antibodies may affect how a drug works in your body if you take it in the future. The sample(s) may be stored for up to 15 years after this study is finished. The samples and any data generated from the sample can only be linked back to the study participant by the study doctor or study site personnel.

Liver Tissue Samples
Substances in your liver tissue may help us understand how you respond to study treatment or your prognosis.

Liver tissue will be collected to understand the study drug's effect on your disease. Researchers will study your tissue to learn how the study drug works for you. A liver biopsy will be performed before you receive study drug and at the end of study treatment period or at time of study discontinuation if you have received study treatment for at least 9 months (36 weeks).

If any liver tissue was obtained from your original diagnosis, it will not be returned to your study doctor. Slides containing sections of liver tissue will be stored for up to 15 years after this study is finished. The samples and any data generated from the sample can only be linked back to the study participant by the study doctor or study site personnel.

What will happen when I am finished with the study?

The study doctor or one of the study doctor's staff members may try to reach you after you have stopped study treatment if you have developed anti-drug antibodies. They will ask you to come back to the clinical research site to provide additional blood samples. The blood samples will be used to see how quickly the anti-study drug antibodies leave your body.

What side effects or risks can I expect from being in the study?

There may be risks to you if you are in this study.

As of 15 June 2018, 338 adults with type 2 diabetes (T2DM) and 67 healthy adults have taken tirzepatide in completed studies. Many of these participants were considered overweight or obese. Lilly has reviewed safety information from these studies.

The following table lists the risks and discomforts associated with tirzepatide for participants with T2DM.

Table 1: Risks and Discomforts Associated with Tirzepatide

Very Common (10 or more out of 100 participants)	Feeling sick to the stomach Loose or frequent stools Throwing up, vomiting Loss of appetite	
Common (1 or more out of 100 participants)	Headache Dizziness Indigestion Heartburn Feeling tired, fatigue Hard or infrequent stools	Passing gas Bloating Belching Stomach pain or discomfort Weight loss Low blood sugar
Uncommon (1 or more out of 1000 participants)	Feeling full quickly when eating	

Cases of pancreatitis have been reported in participants with T2DM who have taken tirzepatide and other glucagon-like peptide-1 receptor (GLP-1) medicines. Pancreatitis is an inflammation of the pancreas, a gland in your abdomen that helps with digestion. Pancreatitis is usually associated with stomach pain, which may be severe. Although pancreatitis usually improves without long-term effects, it may be severe and could lead to hospitalization or even death.

If you develop abdominal pain that is not normal for you, or if you develop severe nausea with or without vomiting, you should call your study doctor immediately for evaluation and proper care. If you have pancreatitis symptoms or if routine laboratory tests suggest a need for evaluation, you may be asked to return to the study site for further evaluations, which may include additional blood tests, X-rays, or other abdominal pictures.

Symptoms of nausea, vomiting, and diarrhea may lead to loss of fluids (dehydration). The loss of fluids could worsen kidney function, which includes kidney failure, and requires immediate evaluation by the study doctor for appropriate care.

Tirzepatide is not recommended for participants with severe stomach problems, such as slowed emptying of the stomach (gastroparesis) or problems with digesting food.

Increases in resting heart rate (HR) above the normal range (more than 100 beats per minute) have been seen in both healthy subjects and participants with T2DM taking tirzepatide. Increased HR can have no symptoms or symptoms such as pounding heart, irregular or "skipped" heartbeat that you can feel, chest pain, or other more severe symptoms. Your HR, blood pressure, and electrical recordings of the heart (electrocardiograms) will be checked regularly.

If you take tirzepatide with or without other medicines used to treat T2DM, your blood sugar could become too low (hypoglycemia). While taking tirzepatide, you may be more likely to have low blood sugar if you are also taking an insulin secretagogue (sulfonylurea).

It is important to follow the study doctor's recommendations for monitoring your blood sugar level during your participation in this study. You should tell the study doctor if you experience any symptoms of low blood sugar, such as sweating, hunger, shakiness, or confusion.

Cases of severe and potentially life-threatening allergic reactions have occurred rarely in participants taking other GLP-1 medicines and may be a potential side effect with tirzepatide. Tirzepatide should not be given to participants who have had a serious allergic reaction to tirzepatide or any of its ingredients.

Your body's disease protection system (immune system) may react to tirzepatide by making antibodies. Your study doctor will take blood samples during the study to check for antibodies to tirzepatide.

Very rarely, cases of medullary thyroid cancer were reported with other GLP-1 medicines. If you or anybody from your family (genetic relatives only) have had this type of cancer or another disease called multiple endocrine neoplasia syndrome type 2, please tell your study doctor because you should not receive tirzepatide. If you are participating in a long-term study with tirzepatide, your calcitonin levels will be measured.

Additionally, it is possible that you could have other unknown side effects while taking tirzepatide.

You should not take tirzepatide if you are pregnant or may become pregnant. Female rats that were given tirzepatide had irregular menstrual cycles and body weight loss or decreased body weight gain or both. Pregnant rats and rabbits that were given tirzepatide and lost too much body weight had offspring that were smaller than normal. Some of these offspring had malformations (organ development abnormalities). Because tirzepatide has only been tested in pregnant animals, humans who take tirzepatide while pregnant may experience other unknown side effects.

Procedure Risks

Subcutaneous Injection

For most people, needle punctures for SC shots do not cause any serious problems. Sometimes they may cause bleeding or bruising where the shot is given. Sometimes people complain of discomfort, infections, and/or pain at the site of the shot. Infection may happen with SC shots because the needle breaks the skin. Then germs can get into the skin underneath. Shots may cause abscesses or skin and soft tissue infections. Additionally, if a blood vessel is hit by the needle, the risk of infection will be even greater if germs are taken into the blood system.

Blood Tests

For most people, needle punctures for blood draws do not cause any bad problems. However, sometimes they may cause bleeding, bruising, discomfort, infections, and/or pain where you had the blood drawn. You may also feel dizzy.

Electrocardiograms (ECGs)
There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.

Glucose Monitoring for Participants with Type 2 Diabetes
Blood sugar testing requires pricking your finger and testing a drop of blood. This does not usually cause serious problems, but it can cause some discomfort.

Liver Biopsy
For most people the removal of a piece of liver does not cause any serious problems. The removal of liver tissue for a biopsy may cause the following:

- Bleeding
- Bruising
- Discomfort
- Infection and/or pain at the place of the biopsy
- Depending on the site of the tissue, a biopsy can cause damage to an organ.

Magnetic Resonance Imaging (MRI) Scans
MRI scans do not usually have bad effects unless you have metal in your body. Do not take part in this test if you have any pieces of metal in your body because of earlier injury or surgery. Some older tattoo ink may contain metal, so you should also tell the study doctor or MRI staff if you have any tattoos.

People who do not like to be in small spaces (claustrophobia) might feel confined by an MRI. You may be bothered by the noise the scanner makes. You will be given ear plugs or headphones to reduce the noise of the scanner.

Transient Elastography (FibroScan)

A FibroScan is an ultrasound of your liver to measure how elastic or stiff it is. There are no risks involved. It is painless and not invasive (meaning it's not carried out inside your body and does not break the skin).

Risks of Eye Exams for Participants with Type 2 Diabetes
There is no pain associated with eye and vision testing performed in this study. Occasional mild discomfort can be experienced, mostly related to bright light exposure. When you are given eye drops to dilate your pupils, you will experience difficulty focusing on close objects, sensitivity to bright light, and blurred vision that can interfere with activities such as driving, working, and reading, for a limited period of time after the exam.

Discomfort with questionnaires
Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

Please talk to the study doctor or study staff about any questions or concerns that you may have about the procedures required for this study.

What are the Reproductive Risks?

If you are female, you should not become pregnant or breastfeed a child while in this study. Naturally, the best way to not become pregnant is not to have vaginal sex (intercourse). If you are sexually active, you must use birth control. You should talk with your study doctor about the types of birth control that are best for you and your partner. Tell your study doctor right away if you become pregnant or think you are pregnant.

If you are male, you should not father a baby while in this study. You should not have vaginal sex (intercourse) without using effective birth control. Talk to your study doctor about the types of birth control that might be best for you and your partner. Tell the study doctor right away if your partner becomes pregnant or thinks she may be pregnant. Also, you should not donate semen/sperm while in this study and for 4 months after the last dose of study drug.

Taking part in this study can result in risks to an unborn child or breastfeeding child. You must continue to use birth control for 1 month after the last dose of the study drug for female participants and for 4 months after the last dose of the study drug for male participants.

If you or your female partner becomes pregnant while you are participating in this study, tell your study doctor or study staff immediately. The study doctor may ask to collect medical information about your or your partner's pregnancy until the end of your or your partner's pregnancy, whether or not the pregnancy goes to term, including after delivery.

There may also be unknown risks to your embryo, fetus, or nursing child.

Other Risks

In addition to the side effects already described, tirzepatide and the study procedures may have other unknown risks.

At any time during this study, you may experience a return or worsening of your disease, if you receive placebo (a liquid that has a similar appearance to the study drug but has no medicine) as your study drug.

There may be unknown risks of possible harmful interaction with other medication you may be taking.

You should not give the study drug to other people and should keep it out of the reach of small children.

Are there benefits to taking part in the study?

You may or may not receive any benefit from being in this study. If you take part in this study, other people with NASH may be helped.

Information obtained from this study will also benefit the sponsor of the study and may benefit study participants in the future. You may receive information from physical examinations, laboratory tests, or other testing that is done in this study but these tests may not have any impact on your health.

What other choices do I have if I do not take part in this study?

You do not have to take part in this study to be treated for your condition; however there is no drug treatment for your condition. The only treatment available is to lose weight. You can discuss the risks and benefits of these other choices with your study doctor.

What happens if I want to stop the study?

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at any time. You may do so without a penalty or loss of benefits to which you are otherwise entitled.

Your participation also may be stopped by the study doctor or sponsor for any reason without your consent. If this happens, it might be due to a bad reaction you have to tirzepatide or new information about tirzepatide safety or effectiveness.

If you stop being part of this study, the study doctor or one of the study staff members will talk to you about any medical issues regarding the stopping of your participation.

What are the costs of taking part in this study?

Study drug and study procedures will be provided at no cost to you.

You will be provided a fixed amount for inconvenience of $75 per study visit for Visits 1, 3 through 13, and 801; $600 per study visit at Visits 2 and 14 or Early Termination.

You will also be provided a fixed amount for caregiver inconvenience of $200 per study visit at Visits 2 and 14 or Early Termination.

You and your caregiver may be paid an inconvenience fee of $75 if an eye exam is performed between visits 1 and 2.

You or your caregiver will be provided a fixed amount of $0.24/mile starting at mile 1 per study visit when public transportation is not being paid. This amount applies to all visits conducted in according with the protocol.

You may be reimbursed actual expenses for all study visits completed on the following items indicated below:

- Public transportation (taxis, bus, train, subway). Applicable to visits where mileage is NOT being paid. There is a $50 maximum limit for public transportation round trip per visit. You will be reimbursed the actual amount up to the maximum amount. Car rental is not included in this coverage. Receipts are required.

- Parking fees and tolls, if applicable. There is a $50 maximum limit per visit. You will be reimbursed the actual amount up to the maximum amount. Parking fees will not be reimbursed if the cost is covered by the site. Receipts are required if applicable/available.

- Meal reimbursement will be provided for you at up to $25/meal with receipts as follows:
    - One meal at all visits,

  - One additional meal at Visits 2, and 14 or Early Termination if you are traveling greater than 90 miles round trip, and
  - Up to 3 meals per day at Visits 3, 10, and 14 or Early Termination if you are traveling greater than 90 miles round trip for your MRI/CT1.

- Meal reimbursement for 2 meals may be reimbursed up to $25/meal with receipts for your caregiver at Visits 2, and 14 or Early Termination if you are traveling greater than 90 miles round trip.

- Hotel stay reimbursement may be provided as follows:
  - One shared stay for you and your caregiver at Visits 2, and 14 or Early Termination if traveling greater than 90 miles round trip.
  - One stay at Visits 3, 10, and 14 or Early Termination if you are traveling greater than 90 miles round trip for your MRI/CT1.
- You will be reimbursed the actual amount up to the maximum amount $200. Reimbursement may not cover the entire hotel rate. Receipts are required.

Note: The IRS requires that compensation (not documented by receipts or other tracking methods) greater than or equal to $600 be reported to the IRS as required by law. Refer to http://www.irs.gov/pub/irs-pdf/i1099msc.pdf.

You will be paid following each completed visit. You will not be paid for telephone visits.

If you do not finish the study, you will be reimbursed for the part of the study that you did complete. However, your expenses could be more than the amount you are reimbursed.

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

If you are injured, please seek medical help. If you follow the directions of the study doctor and study staff, the sponsor will pay the medical expenses for the treatment of a physical injury because of a properly given drug or procedures. The study sponsor has no plan to pay for injuries caused by the negligence of the study doctor or study staff.

You retain the right to seek compensation for injury even if you sign and date this form, accept medical care, or accept payment for medical expenses and you retain the right to seek compensation for injury related to the negligence of those involved in the research.

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. 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.

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, please contact the Investigator 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 subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00038256.

Will my medical information be kept private?

The study doctor and staff will handle your personal health information in a confidential manner except when sharing the information is required by law or as described in this informed consent. Personal health information includes both your study data and your original medical records. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed.

By signing the consent document for this study, you give permission ("authorization") for the uses and disclosures of your personal health information in the following ways.

- Your original medical records (which may contain your full name or other information that may directly identify you) may be shared with or viewed by to ensure the quality of the study conduct and study data:
    - The sponsor of the study and its representatives "sponsor",
    - the regulatory authorities in this country and in other countries, and
    - the ethical review board overseeing this study.
- Your study data (information collected for the study which only identifies you by a code and not your full name or other information that may directly identify you) may be shared with or viewed by:
    - the sponsor and their business partners (including those in other countries),

- When the sponsor shares any data outside of this country, the sponsor will respect the terms of this data privacy statement even if other countries may have privacy laws that do not provide the same protections
- The sponsor will only share your study data with their business partners, only if they need the information as a part of this work with the sponsor. The business partners must sign a contract that requires it to protect your study data in the same way as the sponsor.

  - the regulatory authorities in this country and in other countries,
  - the ethical review board overseeing this study, and
  - the doctors at other institutions participating in the study.

- The sponsor will use the study data:
  - to support the study purposes described in the consent document,
  - to determine how safe or effective any of the drugs or treatments included in the study,
  - to better understand the disease(s) included in the study, or
  - to improve the design of future studies.
- Study data that does not directly identify you may be published.

Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed by your study doctor to these other parties.

You have the right to see and copy your personal health information related to the research study. However, you may not be able to review some of the study data until after the study has been completed to ensure the scientific integrity of the study.

Your authorization for the uses and disclosures of your personal health information does not have an expiration date unless required by state law. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign this authorization document.

You may cancel your authorization for the uses and disclosures of your personal health information at any time by providing written notice to the study doctor. If you cancel your authorization:

- The study doctor and staff will only use or disclose some of your personal health information if it is needed to confirm the accuracy of the study data.
- The sponsor will still use study data that was collected before you cancelled your authorization.
- You will no longer be able to participate in the study.

_____	_____
Print Study Participant Name	Study Participant Signature
_____	
Date (Study Participant must personally date)	
_____	
Name of individual conducting authorization discussion (print or type)	
_____	_____
Signature of individual conducting authorization discussion	Date (individual conducting authorization discussion must personally date)

Study Participant Information and Consent Form Signature Page

To become a part of this study, and to authorize use and disclosure of your personal health information, you must sign and date this page.

Only sign and date this consent after:

- You have read all of the information in this Study Participant Information and Consent Form, and you have had time to think about it.
- All of your questions have been answered to your satisfaction.

You voluntarily agree to be part of this research study, and to do the following:

- To follow the study procedures,
- To provide necessary information to the study doctor, nurses, or other staff members, as requested, and
- Allow the study doctor and the sponsor to use and disclose your personal health information as described in this document

You may freely choose to stop being a part of this study at any time. You will receive a copy of this signed and dated Study Participant Information and Consent Form to keep.

FOR STUDY PARTICIPANT TO COMPLETE

Signature of Study Participant	Date (Study Participant must personally date)
Study Participant 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 procedures) to the study participant before the study participant voluntarily agreed to participate.

Name of Individual Conducting Informed Consent Discussion (print or type)

Signature of Individual Conducting Informed Consent Discussion

Date (Individual Conducting Informed Consent Discussion must personally date