UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
INFORMED CONSENT FORM

Sponsor / Study Title:	**Janssen Research & Development, LLC / "A Phase 3b, Open-label, Multicenter Study to Evaluate Transmural Healing and Disease Modifying Effect of Guselkumab in Crohn's Disease Patients Transmural Healing and Disease Modifying Effect of Guselkumab in Crohn's Disease Patients"**
Protocol Number:	**CNTO1959CRD3008**
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Why have I been given this document?
To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

You are invited to be in a research study, if you are eligible, sponsored by Janssen Research & Development LLC, a pharmaceutical company. Here are a few things to know:

- Taking part in a research study is voluntary and is not part of your regular health care.
- Take your time to read this Informed Consent form (ICF) carefully to understand the study, why it is being done and what it involves.
- Discuss taking part with your doctors, medical professionals, family, and friends.
- Ask questions and request any additional information from the clinical staff at the study site.
- You are free to decide to join this study or not and if you agree now, you can change your mind any time. Whether or not you take part is up to you. Whatever choice you make, you will not lose access to the medical care you already receive, gain any penalty, or give up any of your existing rights or benefits.

Thank you for taking the time to consider joining this study

The sponsor may share sensitive Company information with you to help you decide about joining this study. We kindly ask you to consider this when discussing details about the study with people other than your healthcare provider(s), family, and friends or when using social media.

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.

STUDY OVERVIEW AND GENERAL INFORMATION

The purpose of this study is to evaluate how the study drug could help heal the gut wall and influence the course of the disease to help researchers understand more about the possible effectiveness and safety of study drug in patients with active Crohn's disease.

All reference to the words "**study drug**" means guselkumab.

All reference to "**clinical staff**" includes the study doctor(s) and other study staff specifically involved in the study (for example, nurses, scientists, healthcare professionals).

"**Study Site'** can refer to an institution or hospital depending on where the study is being conducted.

You can ask the clinical staff to forward any questions, concerns, or complaints you may have to the Institutional Review Board (IRB), the sponsor, or the sponsor's authorized representatives. The IRB is an independent committee who review research studies to protect the rights and welfare of research participants.

About 5 people will take part in this study at UCSF. About 112 will take part in this study at all research sites. You will be in the study for about 104 Weeks and you will need to visit the study site approximately 28 times, this number may also vary depending on the study treatment group you are assigned and whether you will use the option of self-administration of the study drug at home at certain timepoints.

This is a Phase 3b, multicenter, open-label study to evaluate transmural healing and the disease modifying effect of guselkumab in participants aged 18 years or older, with active Crohn's disease. Eligible participants must be diagnosed with luminal Crohn's disease (confirmed by radiography, histology, and/or endoscopy) for a minimum of 3 months, have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or Advanced therapy (for example, biologic or jak inhibitor), or have medical contraindications to such therapies.

Participants with active moderate-to-severe Crohn's disease will be enrolled in this study. Research has shown that certain diseases, treatments, and medications affect people differently depending on their age, sex assigned at birth, gender identity, sexual orientation, race, ethnicity, access, and genetic background. You may be asked questions which may help ensure various groups are included in the study. Your information will be included in your study record but does not change the care and treatments you receive during the study or in the future. To make sure clinical trials are available to everyone, you may be asked about where you live and how easy it is to come to the study site. This ensures people are made aware of available trials and how to access them.

WHAT HAPPENS DURING THE STUDY?

If you are eligible and agree, you will sign this informed consent form when you have read and understood the study requirements. **You should come to all your study visit appointments. Please also tell the clinical staff about any health problems or concerns you have during the study, including side effects.**

The table below describes the procedures you can expect during this research study. Not all procedures will be done at every visit. The clinical staff will discuss this with you in more detail.

Examinations, Test and Procedures	**What is it?**	**When is it done?**
Informed Consent	The study doctor/study staff will talk to you about the study, and you will decide if you want to join.	Screening phase
Review of eligibility	The study doctor/study staff will check if you are eligible for the study.	Screening phase
Review of medical history and demographics	You will discuss your current and past health with the study doctor/study staff. Your medical history (including disease diagnosis), any allergies, previous treatments, and all medications, including prescriptions, over-the-counter medicines as well as vitamins you have been taking.	Screening phase
Review of medications	You will talk with the study doctor/study staff about any medicines you take.	Screening phase, Initial phase, Maintenance phase, Follow-up visit, Study intervention discontinuation visit
Review of side effects	At each visit, the study doctor/study staff will ask about any side-effects. Side effects are any unexpected or unwanted reactions that may happen from taking a study drug (during study	Screening visit, Initial phase, Maintenance phase, Follow-up visit,

Examinations, Test and Procedures	What is it?	When is it done?
	treatment phase) or having a procedure (during entire study, from screening visit to follow-up).	Study intervention discontinuation visit
12-lead ECG (Electrocardiogram)	Sticky patches that are connected to a machine that shows the electrical activity of your heart, are placed on your chest.	Screening phase
Stool samples collection	Stool samples will be collected to test for bacteria that live and reside within the intestinal tract (enteric pathogens) or fecal calprotectin to assess inflammation.	Screening phase for enteric pathogens; Screening visit, Initial phase, Maintenance phase (Week 12, 16, 32, 48, 64, 80, 96) and Study intervention discontinuation visit for fecal calprotectin
Chest radiograph and/or Chest Computed Tomography (CT) Scan	An X-ray (picture) of your chest may be taken to make sure that you do not have signs of tuberculosis (TB) or other problems. TB is a bacterial disease that usually affects the lungs. You will not need to have a chest x-ray if you had one within the last 12 weeks before the first administration of study drug. Chest radiograph will be the first choice. If further clarification is required based on the findings of chest radiograph, supplementary imaging by means of thoracic CT may be performed. If a thoracic CT has been performed for any other reason in the previous 3 months, then an additional CT scan/Chest-X-ray will not be required.	Screening phase
Serum hcG pregnancy test	Your blood serum will be used to check for pregnancy, if you are a female who could get pregnant	Screening phase
Vitals	The study doctor/study staff will take your temperature, pulse/heart rate, respiratory rate and blood pressure	Screening phase, Initial phase, Maintenance phase, Follow-up visit,

Examinations, Test and Procedures	What is it?	When is it done?
		Study intervention discontinuation visit Vitals are not mandatory for at-home administration visits; however, they may be conducted where determined necessary by the study doctor.
Physical examination	The study doctor/study staff will check your body for general health, including weight measurement	Screening phase, Week 48, Week 96, Follow-up visit.
Weight measurement	Your weight will be measured by a scale	Screening phase, Initial phase, Maintenance phase (Week 12, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96), Study intervention discontinuation visit
Blood draw/tests	The study doctor/study staff will draw blood from a vein in your arm. The total blood volume to be collected from each participant will be approximately 90 mL (6 tbsp) during the study. Repeat or unscheduled samples may be taken for safety reasons or for technical issues with the samples. Your blood will be used to check your eligibility to join the study and for ongoing participation: • Your general health • Hepatitis B virus, Hepatitis C virus, Human Immunodeficiency Virus (HIV) test. The results of these tests will be kept confidential.	Screening phase, Initial phase, Maintenance phase (Week 12, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96), Study intervention discontinuation visit

Examinations, Test and Procedures	What is it?	When is it done?
	• Blood count • Blood chemistry (including tests for kidney and liver function) • Signs of tuberculosis and inflammation • How your body handles the study drug The study doctor/study staff will discuss in the event of positive test results with you for HBV, HCV, or HIV infection. Positive results for Hepatitis or HIV will be reported to health authorities as per the local requirements.	
Tuberculosis evaluation/other infection assessment (signs and symptoms)	You will be tested for TB (tuberculosis). This is a special blood test used to check for TB (called QuantiFERON-TB or other allowed test). The study doctor may be required by law to report the result of this test to the local health authority.	Initial phase, Maintenance phase, Study intervention discontinuation visit
Urine pregnancy test	Your urine will be used to check for pregnancy, if you are a female who could get pregnant	Initial phase, Maintenance phase, Study intervention discontinuation visit, Urine pregnancy tests are not mandatory for at-home administration visits; however, they may be conducted where determined necessary by the study doctor.
MRE (Magnetic resonance enterography)	An MR enterography procedure uses magnetic resonance imaging (MRI) technology to obtain detailed images of the small bowel. MR enterography, also called Magnetic resonance enterography (MRE), is a complementary advanced, accurate and noninvasive diagnostic imaging test to evaluate a broad range of disorders including Crohn's Disease.	Screening phase (from -8 to -4 weeks), Maintenance phase (Week 16, Week 48, Week 96), Study intervention discontinuation visit

Examinations, Test and Procedures	What is it?	When is it done?
IUS (Intestinal ultrasound)	An Intestinal Ultrasound (IUS) is a non-invasive, quick and accurate technique. No radiation is used in this procedure. An ultrasound scanning device consists of computer and a transducer that is used to scan the body. A transducer is a small hand-held device about the size of a bar of soap that is attached to the scanner by a cord. A lubricating gel is spread on the skin over the area being examined, and then the transducer is pressed firmly against the skin to obtain images.	Initial phase, Maintenance phase (Week 16, Week 48, Week 96), Study intervention discontinuation visit
Endoscopy	A procedure where the inside of your body is examined using a long thin flexible tube which relays images to a television screen. The tube is inserted through a natural opening such as through your bottom. The colonoscopy procedure will be video recorded to see whether you have ulcers and inflammation from your Crohn's disease.	Initial phase (Week 0), Maintenance phase (Week 48, Week 96), Study intervention discontinuation visit
Colombia-Suicide Severity Rating Scale (C-SSRS)	This questionnaire will allow to assess suicidal ideation and evaluate whether you are eligible for the study. This will also be checked throughout the whole study duration at each visit.	Screening phase, Initial phase, Maintenance phase, (Week 16, 32, 48, 64, 80, 96), Study intervention discontinuation visit
Fistula assessment	Fistula status will be assessed by direct physical examination. Physician will inspect the anus and surrounding skin for tenderness and visible signs of a fistula. The opening of a fistula is usually a red and inflamed spot that may ooze pus. Sometimes gentle pressure on the skin around the tract is needed to express a purulent or bloody discharge.	Screening phase, Week 0, Maintenance phase (Week 12, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96), Study intervention discontinuation visit
Electronic diary to collect data for Crohn's Disease Activity Index (CDAI) evaluation	You will be given a diary and an explanation of how to use it. This will be through an electronic device, like a Smart Phone. You will enter information into the diary once a day. You will enter details about pain,	Screening phase, Initial phase, Maintenance phase, Study intervention discontinuation visit

Examinations, Test and Procedures	What is it?	When is it done?
	frequency of stools, intake of anti-diarrheal medication and your general well-being. You must bring the diary with you to each visit.	
Participant Interviews and Questionnaires	At specified study visits, you will be asked questions by study staff, and you will be asked to complete several questionnaires, about your general health, how you are feeling, your pain level, the symptoms of Crohn's Disease, the impact of your disease on productivity at work, utilization of medical resources and your daily activity, fatigue, suicidal ideation, and sexual functioning. Completion of the questionnaire regarding sexual functioning is optional.	Screening phase, Initial phase, Maintenance phase, Study intervention discontinuation visit
Study drug administration	You will receive guselkumab 200 mg intravenous (IV, into the vein) at Weeks 0, 4 and 8 (Initial Phase). At Week 12, you will be assigned to low-dose group (guselkumab 100 mg SC Q8W) or high-dose group (guselkumab 200 mg SC Q8W). You will be alternately assigned at study level. If you are assigned to low-dose group, you will switch to guselkumab 100 mg SC Q8W at Week 16 through to Week 96 (Maintenance phase). After Week 24, your dose may be escalated to 200mg SC Q4W based on your disease condition. If you are assigned to high-dose group, you will switch to guselkumab 200 mg SC Q4W at Week 12 through to Week 96 (Maintenance phase) After Week 16 (starting at the Week 20 visit), participants (or caregivers) who are able and who have been appropriately trained in the administration of study drug may administer study drug at home at certain timepoints.	Initial phase, Maintenance phase
Study drug diary for at home administration (AHA Diary) - for 200mg group only	Participants opting for at-home administrations at certain visits will be trained in the use of the pre-filled syringe (PFS) assembled with the YpsoMate Autoinjector (PFS-Y) Autoinjector device at the Week 16 study site visit (or any further visit as appropriate) prior to using an	Maintenance Phase (Week 20, Week 28, Week 36, Week 44, Week 52, Week 60, Week 68, Week 76, Week 84, Week 92)

Examinations, Test and Procedures	What is it?	When is it done?
	option of self-administration. Study drug diary for at home administration (AHA Diary) will need to be completed by participant prior to and after each self-administration at home.	
Injection-site reactions	Infusion site and injection sites will be evaluated for reactions	Initial phase, Maintenance phase

WHAT IS THE STUDY DRUG?

The sponsor provides the study drug, called "guselkumab". This will be Intravenous infusion during Initial Phase (Week 0 – Week 8) and Subcutaneous administration during Maintenance Phase (Week 12 – Week 96), and the last injection may be in Week 88 or Week 92. This study treatment is only for your use and must not be shared.

Guselkumab has been approved by in the United States of America (USA), the European Union (EU), Canada and several other countries for the treatment of adults with moderate to severe plaque psoriasis and active psoriatic arthritis. It is sold as TREMFYA. The use of guselkumab in this study is investigational. An investigational use is one that is not approved by the United States Food and Drug Administration (FDA).

Guselkumab is also being studied to treat several other illnesses such as pediatric psoriasis and inflammatory bowel disease.

What study treatment will I receive?

All participants in this study will receive guselkumab.
Both you and the clinical staff will know the study treatment you are receiving. This is an open-label study.

If you miss a dose, please let the clinical staff know.

How do I use the study drug?

- **Intravenous (IV) infusion:** The study drug is put into a vein in your arm through a small tube attached to a needle by a member of the study staff. At week 0, week 4 and week 8 all participants will receive one IV infusion of guselkumab. The infusion will take 1-2 hours.

Subcutaneous (SC) Injections: The study drug is put just under your skin with a needle by a member of the study staff. Participants will be alternately assigned at the study level to 2 dose groups, low and high dose.

Participants assigned to low-dose group will receive 100mg SC injections of guselkumab every 8 weeks (Q8W) from week 16 until week 88. 100 mg SC Guselkumab will be provided in a single-use pre-filled syringe (PFS) assembled with the UltraSafe PlusTM Passive Needle

Guard (PFS-U).

Participants assigned to high-dose group will receive 200mg SC injections of guselkumab every 4 weeks (Q4W) from week 12 until week 92. 200 mg SC Guselkumab will be provided in a single-use pre-filled syringe (PFS) assembled with the YpsoMate Autoinjector (PFS-Y).

After Week 16 (starting at the Week 20 visit), participants (or caregivers) who are able and who have been appropriately trained in the administration of study drug may administer study drug at home at certain visits (Week 20, Week 28, Week 36, Week 44, Week 52, Week 60, Week 68, Week 76, Week 84, Week 92). Study staff will instruct participants on how to transport, store, and administer study drug for at-home use.

SAFE STORAGE OF STUDY DRUG

The study drug packaging is not child-resistant; keep the study treatment out of reach of children, as it may cause them harm. If you feel you cannot do this, you should not take part in the study.

Follow the instructions from clinical staff about the use and storage of the study drug (**which is only for your use and must not be shared)**. Return unused/empty packages at each visit.

WHAT ARE THE POSSIBLE RISKS AND SIDE EFFECTS OF THE STUDY?

There may be risks to using guselkumab that we do not know about. The clinical staff will tell you if new, significant information is discovered about guselkumab, risks or its side effects so you can decide whether you want to continue in the study.

If you have any side effects or problems during your participation in this study, you should let your study doctor know right away. This section describes how frequently side effects occurred in participants who were treated with guselkumab. In this section, the following terms are used:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000

Very Common:

- Infections of the nose, sinuses, airways or throat

Common:

- Increased level of liver enzymes in the blood (transaminases)
- Headache
- Joint pain
- Diarrhea
- Rash

Uncommon:

- Herpes simplex infections, which may appear as blisters or sores on the lips (cold sores) or genitals (genital herpes)
- Fungal skin infections (for example athlete's foot)
- Gastroenteritis (an infection of the stomach and/or intestine)
- Decreased number of a type of white blood cell (neutrophils), which may increase your risk of infection
- Hives
- Injection site reactions (redness, pain, bruising, swelling, itching, hardness, skin irritation, bleeding and/or rash at the place where the injection is given)

Rare:

- Allergic reactions
- Serious allergic reactions (including anaphylaxis), which may appear as hives, swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, low blood pressure or lightheadedness

Infections

Guselkumab is a drug that may change how your body fights infections. Serious infections requiring hospitalization have been seen in guselkumab studies. Life threatening infections may occur. It is unknown if guselkumab may stop you from developing a fever if you do have an infection, and therefore hide that you have one. Tell your study doctor if you have a new infection, if an infection keeps coming back, or if you have any signs of infection, such as fever, chills or cough.

Participants who receive guselkumab may also be at a greater risk for certain serious infections such as tuberculosis. Tell your study doctor if you have ever had tuberculosis or if you have come in contact with someone who has tuberculosis. Tell your study doctor if you develop symptoms such as night sweats, weight loss, and/or coughing up blood.

Cancer

It is unknown whether taking guselkumab increases your risk for developing cancer. Some drugs that suppress the immune system are associated with an increased risk of cancer. Because guselkumab may suppress your immune system, it is possible that it may increase your risk of developing cancer.

Allergic Reactions

Guselkumab may cause an allergic reaction in some people. Serious allergic reactions, including a type of reaction called anaphylaxis, have been reported with guselkumab and can be life threatening. Symptoms of an allergic reaction may include:

- Hives
- Rash

- Nausea
- Flushing (redness)
- Lightheadedness
- Shortness of breath
- Wheezing
- Swollen face, lips, mouth, tongue or throat
- Difficulty swallowing or breathing
- Low blood pressure
- Anaphylaxis (life threatening allergic reaction)

Another type of allergic reaction (called serum sickness-like reaction) has occurred in some participants 1 to 14 days after receiving similar medications. The symptoms of this type of allergic reaction may include fever, rash, muscle aches and joint pain.

Tell your study doctor or get medical help right away if you have symptoms of an allergic reaction so that appropriate treatment can be administered. If you experience a serious allergic reaction to guselkumab, you will not receive any more study treatments.

Antibodies to Guselkumab
Sometimes the body can make special antibodies that may increase the risk of an allergic reaction to either guselkumab or other antibody medicines. If you have an allergic reaction during this study, you may not be able to have these types of medications in the future. You should tell your doctors that you have been treated with human antibodies in this study.

Injection Site Reactions
Injection site reactions have been observed in participants receiving guselkumab and similar medications. The signs and symptoms seen at injection sites may include:

- Redness
- Swelling
- Pain
- Bruising
- Itching
- Skin irritation
- A burning sensation
- Bleeding
- Hardness
- Rash

Vaccinations
Vaccines are made to help protect people from certain illnesses. Ask your study doctor about all vaccines you are thinking about getting. It is not known if guselkumab may interfere with your body's response to a vaccine.

Some vaccines are made from live bacteria or live viruses. You cannot receive live vaccines during the study. Some kinds of live vaccines may not be given to you for 12 weeks after your last dose of study drug. You could get sick from live vaccines while on guselkumab. If you do get a live vaccination during this study, you must tell your study doctor immediately.

Liver Injury
Severe liver injury (very high liver enzymes) resulting in hospitalization has been reported in participants treated with guselkumab through the vein (IV) in clinical studies.

Tell your study doctor if you have:

- Skin and eyes turning yellow (jaundice)
- Fever
- Dark, brown-colored urine
- Pain on the right side of your stomach area

Other Therapies
Tell your study doctor if you are receiving medicines that weaken the immune system while you are enrolled in this study. For example, oral corticosteroids, azathioprine, 6-MP, or methotrexate. It is unknown if taking these medicines with guselkumab increases your risk of diseases related to a weakened immune system.

There may be risks associated with the procedures described under "What Happens During the Study". Please discuss with the clinical staff if you have any concerns. For example, you may get a bruise or irritation from a blood draw or feel faint.

Side effects from tests and study drug administration

- **Blood Draw:** Taking blood may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases, infections may occur.
- **ECG:** There is generally no risk with having an ECG. The sticky patches may pull your skin or cause redness or itching.
- **MRE:** There are no known risks or side effects from an MRI. The magnets used in an MRI can cause problems with pacemakers or cause implanted metal screws or pins to shift in the body. You cannot have an MRI-scan if you have certain type of metal implant. If you are claustrophobic or have a hard time in enclosed spaces, you may feel uncomfortable while in the MRI machine. Contrast dye will be used during the MRI. The most common side effects of contrast dye include injection site pain, nausea, itching, rash, headaches and dizziness. There is a risk of reaction to the contrast dye in people with known reaction to medications, contrast dye, iodine, or shellfish; in that case you should notify the radiologist or technologist. If you know you are allergic to contrast dye, you should not participate in this study.
- **X-Ray:** The amount of radiation in the X-ray is small. The exposure from 1 standard chest X-ray is 0.1mSV, comparable to 10 days of exposure to natural background radiation. This is painless and there is no significant risk from this amount of radiation.

- **CT-scan** (only in exceptional cases a CT-scan will be needed during this study)**:** CT-scans do create low levels of radiation, which has a small potential to cause cancer and other defects. The exposure from 1 chest CT scan is 6.1 mSv, comparable to 2 years of exposure to natural background radiation.
- **IV Infusion:** Placing the needle in your vein may produce pain, skin discoloration or bruising, bleeding, swelling, blocking of the blood vessel by clot formation in the vein, dizziness, or rarely, fainting, infection, accidental puncture of an artery or local nerve damage. The IV catheter may be flushed with a sterile solution to keep the needle from clogging.
- **SC Injection:** The injection is given under the skin with a small needle. You may have mild pain, bleeding and a change in skin color or bruising, and/or an infection where you were injected.
- **Endoscopy:** Risks include bleeding and colonic perforation. These risks are well-recognized but are rare.
- **Preventative Medicine for TB Infection:** Medicines used to prevent tuberculosis infection may have side effects. Side effects may include nausea, vomiting, abdominal pain, hepatitis and possibly other events. Your study doctor will provide you with more information on tuberculosis preventative treatment if you require this treatment to participate in the study.

Other procedures like physical examinations, breathing rate, pulse, blood pressure and body temperature measurements, as well as weight and height measurement are generally of no risk to you.

Other risks
Any surgical treatment, including drainage of abscess, curettage, seton placement or seton removal, has potential risks. In case you need a surgical treatment while you are taking part in this study, the study doctor/study staff will inform you in advance about the potential risks of the treatment.

There may be risks to using guselkumab that we don't know yet. As stated above, the study doctor/study staff will tell you in a timely manner if new information is discovered about the study drug or its side effects that could make you change your mind about being in the study. The time it takes to recover from the effects of the study drug may be 12 weeks, but this cannot be guaranteed.

Possible risk associated with Crohn's disease: Suicide risk
If you are having suicidal thoughts or feel in crisis, call the study doctor at the telephone number listed on the first page of this form. 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. You can also present to a healthcare provider, your local emergency room, or call 9-1-1 to be connected to local emergency services.

As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the study doctor, sponsor, study site, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

WHAT ARE THE BENEFITS OF JOINING THE STUDY?

Taking part in this study may improve your Crohn's Disease but this is not guaranteed to happen. During the study, your condition may stay the same or get worse and you may experience side effects. Your participation may help future patients as researchers understand more about the possible effectiveness and safety of guselkumab in Crohn's Disease.

WHAT ELSE DO I NEED TO KNOW?

What other treatments are there outside this study?

Instead of taking part in this study, you may choose to take other available treatments, such as antibiotics, corticosteroids, immunosuppressants, biologic (infliximab), Alofisel (darvadstrocel) or surgery, managed under the care of your regular doctor. There may also be other clinical studies available. The clinical staff will explain to you the benefits and risks of these other treatments or studies (if available) and discuss which would be best for you.

Birth control and pregnancy during the study

The effect of guselkumab on human sperm or unborn babies is not known.

Pregnant women and women who are breastfeeding cannot participate in this study. Female participants must have a urine test when beginning this study that shows they are not pregnant.

It is very important that women taking part in this study do not become pregnant and agree to use highly effective birth control methods while taking part in this study, and for 150 days after last dose of study drug. Women taking part in this study must also not donate ova during the study or for 12 weeks after last dose of study drug. It is very important that men taking part in this study do not get a woman pregnant while taking part in this study and for 90 days after last dose of study drug, or donate sperm while taking part in this study or for 12 weeks after last dose of study drug.

Your study doctor will discuss effective birth control methods with you.

Please ensure you follow these instructions or if you are unable to, discuss with the clinical staff. Please inform your clinical staff if you change your birth control methods during the study.

If you become pregnant during the study, you must tell clinical staff immediately. They will advise you about continuing the study treatment, medical care, and collecting information about the pregnancy and the baby. By signing this consent, you agree to share relevant medical information about your pregnancy. You are free to change your mind at any time.

If your partner becomes pregnant by you during the study, they will be asked to sign a separate consent to collect information about the pregnancy and the health of the baby. This is optional for your pregnant partner, and they can change their mind at any time. When you sign this main consent as the study participant, you agree to this information being collected.

Will I be paid?

You will be paid $52.00 per study visit. You will be paid following each completed visit. If you do not complete the study, you will be paid for each study visit that you have completed.

Who pays for the study tests and procedures?

No. There is no cost to you or your insurer if you take part in this study. However, you may need to pay for items such as parking and transportation.

You or your insurer will be billed for the costs of any usual medical care you receive outside of this study. You will also be responsible for any deductibles or co-payments for these usual medical care costs.

Can I change my mind about participating?

You can change your mind at any time for any reason, but we encourage you to talk to the clinical staff before making this decision. You may be asked to confirm your decision in writing, but this is not mandatory. Please refer to the “Withdrawal of Consent” section.

Can I be removed from the study?

Yes, but this will be fully discussed with you, along with alternative treatments or research options. Reasons can include:

- It is in your best medical interest to stop.
- You do not follow clinical staff instructions.
- The study is cancelled or stops accepting new participants, before you enroll.
- You no longer meet the eligibility requirements.
- You become pregnant or plan to become pregnant within the study period.

Can I take the study drug after the study is over?

After you complete the study, you will no longer receive guselkumab. The clinical staff will discuss all your future treatment options with you. In the countries/territories where continued access to the study drug is required per local regulations, the sponsor will provide continued access to participants who have completed the study and are benefiting from the study drug, as determined by the clinical staff.

TREATMENT AND COMPENSATION FOR INJURY

If you get hurt because of this study, the University of California will give you medical treatment that you need. The University or the study sponsor might pay for the medical costs instead. But usually, they don't pay for other things besides medical care if you get hurt. If the sponsor pays for these costs they will need to know some information. This can include your name, birthdate, and Medicare Health Insurance Claim Number or Social Security Number. This information will be used to check to see if you receive Medicare. If you receive Medicare, the sponsor will notify Medicare about the payment.. The sponsor will not use this information for any other purpose. If you want to know more, call the office of the University of California Institutional Review Board at 415- 476-1814.

WILL MY MEDICAL INFORMATION BE KEPT CONFIDENTIAL?

If you take part in this study, there may be some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records may be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. People involved with your future care and insurance may become aware that you participated in this study. They may see information added to your medical record. Study tests and information obtained from you will be part of your research records. This information may be added to your medical record. Your personal information may be given out if required by law. Information from this study may be published or presented at scientific meetings. If it is, your name and other personal information will not be used.

By California law, some medical test results must be shared with the county public health department. This is done so health experts can keep track of these diseases. The report we share with the health department will include information like your full name and social security number. The researchers can tell you what kinds of tests in this study will be shared.

Positive HIV test results will be shared with the county public health department. This applies even if it is not a new HIV diagnosis. When someone tests positive for HIV, we share this information with the San Francisco Department of Public Health:

- CD4+ count (or T-cell count)
- Viral load
- Viral genotype

If you do not live in San Francisco County, this information may also be shared with your home county health department.

- Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:
- Representatives of the Sponsor Janssen Research & Development, LLC
- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)
- Representatives of the Office of Human Research Protections (OHRP)
- Advarra IRB

Clinical staff and the sponsor will look after your personal data (information collected from you and collected during this study) as required by Health Insurance Portability and Accountability Act (HIPAA). The "Privacy Appendix" in this document describes your rights about the use and protection of your personal data.

INFORMATION ON STUDY SAMPLES

Clinical staff will collect biological samples from you for the purpose of the study and provide them to the sponsor or an authorized representative, as described in this consent form. Clinical staff will tell you if there are any changes to testing on your samples during the study.

How are my samples kept private?

To protect your privacy, clinical staff will label your samples and any test results with the study number and your coded participant number. No direct personal identifiers are used and only the clinical staff will be able to match the sample to your name.

How long will my samples be stored?

Your samples will be discarded after study completion.

Your imaging data (MRE, endoscopy, IUS) will be stored for up to 15 years and may be used for potential future research.

Will genetic testing be done on my samples?

No genetic research will be done on your samples.

USE OF STUDY RECORD AND SAMPLES

This section describes how your Study Record and samples may be used, shared and the measures in place to protect participant privacy.

Coded Data and Samples

The sponsor and other authorized parties may use and share your coded Study Record and samples (without personal identifiers) for study and compatible research purposes, to advance clinical science and medical knowledge, as described below:

- To evaluate and understand guselkumab and Crohn's disease and associated health problems.
- To support the development and approval of guselkumab and diagnostic tests for Crohn's disease
- To apply learnings from past studies to new ones or improve scientific analysis methods
- To ensure the sponsor complies with decisions and/or approvals from the Regulatory authorities for study drug availability and reimbursement (where applicable)
- To meet legal and regulatory obligations, in relation to clinical studies and product safety requirements
- To publish the results of the research described above in scientific journals or use them for educational purposes

Anonymous Data and Samples

The sponsor may generate anonymous data or samples for the purposes of scientific research. Research using anonymous data or samples may have a scientific purpose beyond the compatible research described above. To generate anonymous data or samples, your coded participant number and other information that could indirectly identify you, such as your exact dates of study treatment, will be removed from your data and samples. The sponsor may share anonymous data or samples with others for scientific research purposes, as allowed by applicable laws.

For any scientific research that might be conducted that is not part of the study, you will not receive details nor results of the research and that research is not expected to provide any financial or direct benefit to you.

Additional Future Research

Image data (including MRE, IUS and endoscopy data) collected in this study may be stored for up to 15 years (or according to local regulations) for additional research. The data will only be used to understand guselkumab, to understand Crohn's disease, to understand differential intervention responders, and to develop tests/assays related to guselkumab and Crohn's disease. The research may begin at any time during the study or during the post-study storage period.

Stored images will be coded throughout the storage and analysis process and will not be labeled with personal identifiers.

Optional Real-World Data Collection

With your consent, limited personal data from your medical records (for example, name and birth date) may be shared with and used by Sponsor or its service providers to generate a unique string of letters and characters called a "*token*" that can be used to combine your Study Record with de-identified data sets about you from third parties. We refer to this combined data as "Tokenized Data." Tokenized Data is considered "de-identified" because we have removed information that can be used to identify you. By combining and de-identifying data from your Study Record together with, for example, clinical and claims data from third parties, this process may enable novel insights and provide opportunities to study and understand guselkumab and Crohn's disease.

Five (5) years after the study ends (or upon withdrawal of your consent), the Sponsor will stop combining new data from third-party sources with your Tokenized Data, but the existing Tokenized Data may continue to be used for research and other purposes described in this consent form. These records will be accessed from up to 5 years before you started your participation in the study, and for up to 5 years after the study ends. To withdraw your consent to creation of Tokenized Data, please notify your Study Doctor.

By checking the box below I agree to the use of personal data from my medical records to create Tokenized Data, including for example, Tokenized Data that combines my Study Record with de-identified clinical and claims data from third parties to better understand the study drug and your disease, as described in the section "Tokenized Data." I understand that I do not have to agree to this use of my personal data in order to participate in the Study and that I may change my mind about allowing the creation of Tokenized Data at any time.

WITHDRAWAL OF CONSENT

You may withdraw your consent at any time; please refer to the table below for withdrawal options.

If you withdraw your consent, data and samples already collected will continue to be shared and used to protect the scientific validity and integrity of the study, in accordance with this ICF.

Withdrawal of:	**What happens to you**
Study drug	If you decide to stop taking guselkumab, clinical staff may continue to monitor your health until the study is officially completed. This information will be added to your study record.
Study drug & Visits	You do not need to attend further study site visits. The clinical staff may continue to monitor your health until the study is officially completed. Please inform the clinical staff if you do not agree to this.
Study Images	You may request destruction of samples linked to you. Results of testing completed before your withdrawal will be added to your study record. It may not be possible to destroy image data if they cannot be linked directly to you.

Withdrawal of:	**What happens to you**
Use of your Study record	If you withdraw your consent to use and share your coded Study Record before the study is over, you cannot continue in the study. After withdrawal, no new information will be collected from you.
Additional Future Research	If you have changed your mind for your consent to use your imaging data, including MRE, IUS and endoscopy data for compatible additional scientific research purposes, you can withdraw your consent. Participants may withdraw their consent for their imaging data to be stored for additional future research, but it may not be possible to destroy data if they cannot be linked directly to you.

If you stop coming to study visits, the clinical staff may try to contact you by standard ways to check your health (including telephone, video call, e-mail, certified mail, contact your other doctors or locally allowed public registries).

WHAT HAPPENS AFTER THE STUDY?

A market research company employed by the sponsor may contact you after you finish the study to discuss your clinical trial experiences. This is very important and could help improve future clinical trials for both participants and clinical staff. Please indicate your choice at the end of this consent to allow your contact details to be provided to a supplier. This feedback is optional; you can agree now but you may decline when contacted later. If you withdraw early, you can change your mind and let the clinical staff know not to share your contacts.

A summary of study results written in plain language may be made available to you sometime after all study participants have completed the study, and this may be accessed through a regional and/or local website or the clinical staff. Please ask the clinical staff if such a summary will be made available to you. By signing this consent, you agree that you may be contacted by clinical staff after you have finished the study to be offered the results summary.

Use and Disclosure of Your Coded Study Record by the Sponsor

This section describes how the sponsor will use and disclose your coded Study Record, along with the records of the other participants, for research purposes.

How will my Study Record be protected?

The clinical staff will copy information from your medical record into your Study Record. The Study Record will be coded by the clinical staff before it is provided to the sponsor for study purposes. That is, your coded Study Record will only be identified by the study number and your coded participant number. Direct personal identifiers such as your name, initials, and date of birth will not be included in your Study Record. The clinical staff can match the Study Record to your name, but this information will be kept confidential and not shared with the sponsor or anyone else, except where required by law or as stated in this consent form.

How will my Study Record be used and shared?
The sponsor and other authorized parties will use and share your coded Study Record for scientific research purposes and compatible research as described and authorized in this consent form. More information was provided in the "Use of Study Records and Samples" section above. Authorized parties may include organizations providing services for the sponsor (such as laboratories), other researchers, collaborators, and companies who may share an interest in the study drug or the disease. The sponsor, other authorized parties, and regulatory authorities may be located outside the United States, where laws may provide different levels of privacy protection.

How will my Study Record be protected if accessed outside the United States?
If your Study Record is transferred to or accessed by someone outside of the United States, such as for review by researchers and regulators, it will be protected by applicable privacy and data protection regulations, and other regulations on clinical research.

How long will my coded Study Record be kept?
The Sponsor may retain your Study Record for as long as required, in accordance with applicable laws.

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: Pro00072790.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, you can also call the office of the University of California Institutional Review Board at 415-476-1814.

YOUR AGREEMENT TO PARTICIPATE

If you agree to all the following statements and choose to join the study, please sign below. You will receive a copy of the signed Informed Consent Form.

- **I have read the entire Consent document. I understand the information provided and voluntarily consent to participate.**
- The clinical staff and I discussed the study and my responsibilities in detail. I understand what is expected of me as a research participant.
- I am satisfied with the answers to all my questions about the study, guselkumab, and possible risks and side effects.
- I agree that clinical staff may inform my other doctors that I am in this study and of any side effects.
- I agree for my doctors, other health professionals, institutions and hospitals, or laboratories to release my disease and treatment information to clinical staff for the purposes of this study.
- I agree to the processing and transfer of my data as described in this consent form.
- I understand my rights and that I can withdraw at any time.
- You will also be given the Experimental Subject's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

YOUR AGREEMENT TO PARTICIPATE

I agree to the use of my personal data as described in the section **"Optional Real-World Data Collection"**

Check Yes or No:

Yes ☐ No ☐

If an electronic device is used for this consent form I understand and agree that:

- A copy of my signed consent form (with my name and signature) will be stored in a database that resides outside of Canada
- My electronic signature has the same effect and is as legally binding as a handwritten signature on paper.

Printed Name of participant:	
Signature of participant :	Date (dd/MON/yyyy):
Printed Name of person obtaining consent:	
Signature of person obtaining consent:	Date (dd/MON/yyyy):