SUBJECT INFORMATION AND INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

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Study Sponsor:	**Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404**
Protocol Title:	**A Randomized, Double-blind, Placebo-controlled Phase 2 Study to Evaluate the Testicular Safety of Filgotinib in Adult Males with Moderately to Severely Active Ulcerative Colitis**
Protocol Number:	**GS-US-418-4279**

WHAT IS A CLINICAL RESEARCH STUDY?

You have been asked to take part in a clinical research study. This study will test an experimental drug named filgotinib for the treatment of moderate to severe ulcerative colitis. “Experimental” means the study drug has not been approved by regulatory authorities such as the U.S. Food and Drug Administration (FDA).

This Subject Information and Informed Consent Form explain the study to you. Your study doctor or study nurse will go over this form with you. Your study doctor or study nurse will answer all questions you have about the information on this form.

If you agree to take part, you will be asked to sign and date this form. You will be given a signed and dated copy to keep. No one can force you to take part in this study.

WHAT IS THE PURPOSE OF THIS STUDY

The purpose of this study is to see how filgotinib, the experimental drug, affects male sperm and to see if it is a safe and effective treatment for men with moderately to severely active ulcerative colitis.

HOW DOES THIS STUDY WORK?

If you agree to take part in this study, you will be one of up to 250 male volunteers (subjects) in this study. The study will take place in approximately 150 centers worldwide. This study is open to men, 25 to 55 years old, who meet study requirements. Your study doctor has asked you to come to the clinic for a screening visit to see if you are able to take part.

This is a randomized, double-blind, placebo-controlled study.

Randomized means the study treatment you take will be chosen by chance (like flipping a coin). You will have 1 out of 2 chances (50% chance) to receive filgotinib (200 mg daily dose), or 1 out of 2 chances (50% chance) to receive placebo.

Double-blind means that you and your study doctor will not know what study drug you are taking. Placebo-controlled means that you may be taking a tablet with no medicine in it; the placebo tablets look like the filgotinib tablets for this study.

The active study drug filgotinib and matching placebo will be supplied by Gilead Sciences, Inc., who is the Sponsor of this study.

HOW LONG WILL YOU BE ON THE STUDY?

Taking part in the main study will last about 26 weeks, not including the screening visit or safety follow-up visit (30 days after last dose). Participation in the Long Term Extension Phase (LTE), will last about 221 weeks.

Depending on the results of your sperm samples taken at week 13 or week 26, a follow up period of up to 1 year may be added to monitor your sperm concentration.

WHAT ARE YOUR RESPONSIBILITIES?

If you decide to take part in this study, there are some rules you must follow. Some of the rules are listed below. There could be other rules that your study doctor will review with you.

- You must not get anyone pregnant and you must agree to wear a condom while engaging in heterosexual intercourse during the study and for 90 days after your last dose of study drug.
- You cannot donate sperm (other than the study required semen samples) during the study and for 90 days after your last dose of study drug.
- It is very important that you tell your study doctors all of the information you know about your health and medications you are taking now or start taking while in the study. If you do not tell the study doctor everything you know you may be putting your health at risk.

- There are special restrictions on the use of vaccines in this study. You should talk to your study doctor about these restrictions, but you cannot have certain vaccines before, during, and after the study for specific periods of time. Ask your study doctor before getting a vaccine.
- You are not allowed to take certain medications while in this study. If you are currently taking any of these medications, please discuss this with your study doctor. Below are some examples, but this is not a full list. You should check all of your medicines with your study doctor to see if they are allowed.

<table>
<tr><th>Medications that might interact with the study drugs (such as):</th><th>Medications for your ulcerative colitis and related diseases (such as):</th></tr>
<tr><td>➢ Phenobarbital
➢ Phenytoin
➢ Carbamazepine</td><td rowspan="11">➢ Prednisone greater than 20mg/day or a similar dose of any other oral corticosteroids
➢ Infliximab
➢ Adalimumab
➢ Golimumab
➢ Certolizumab
➢ Other TNF inhibiting drugs (including biosimilars)
➢ Vedolizumab
➢ Natalizumab
➢ Ustekinumab
➢ Cyclosporine
➢ Thalidomide
➢ Tacrolimus
➢ Leflunomide
➢ Any JAK inhibitors (for example, tofacitinib)
➢ Any investigational drugs (biologic or non-biologic)</td></tr>
<tr><td>➢ Rifabutin
➢ Rifapentine
➢ Rifampin</td></tr>
<tr><td>Herbal/Natural Supplements:
➢ St. John’s wort
➢ Danshen (salvia miltiorrhiza)</td></tr>
<tr><td></td></tr>
<tr><td>Live vaccines (such as):
➢ Herpes Zoster (shingles) vaccine, Zostavax, and others (ask your study doctor)</td></tr>
<tr><td rowspan="2">Chronic Nonsteroidal Anti-inflammatory Drugs (such as):
➢ Aspirin
➢ Ibuprofen
➢ Naproxen
➢ Diclofenac
➢ Indomethacin
➢ COX-2 inhibitors
➢ Antibody based or other systemic biologics such as denosumab and trastuzumab</td></tr>
<tr><td>Lymphocyte-depleting therapies (such as):
➢ Alemtuzumab
➢ Cyclophosphamide
➢ Total lymphoid irradiation
➢ Rituximab</td></tr>
<tr><td>Sulfa drugs (such as):
➢ Sulfasalazine</td></tr>
</table>

- You must bring back all unused study drug and all study drug containers (even if they are empty or used).
- Do not share the study drug with anyone else. Keep the study drug out of the reach of children and persons of limited capacity to read or understand.

- You must follow all instructions given to you while you are taking part in this study. If you do not, you may be asked to stop participating in the study. If you are unsure about what you are supposed to do, ask your study doctor.

WHAT WILL HAPPEN AT EACH STUDY VISIT?

After you have signed and dated this consent form (indicating that you understand and agree to take part in this study), you will be asked to participate in screening tests and procedures to help the study doctor decide if you are eligible to take part in this study.

If your study doctor determines you meet all study entry conditions, you will be randomized (enrolled) as a participant into the main study.

On Day 1 of the study, you will be assigned to one of two study drug groups as described below. Neither you, nor the sponsor study team, nor your study doctor will know what study drug group you are in:

- You will take one tablet that has 200mg of filgotinib, daily.

  OR

- You will take one placebo tablet that looks like 200 mg of filgotinib, daily.

No matter which group you are in, you will take one tablet every day (your study doctor will give you detailed instructions).

During the main study, you will be asked to provide semen samples at some of the study visits. Two semen samples will be collected at Screening, Week 13 and Week 26. If your sperm concentration decreases (drops) by 50% or more (compared to your sperm concentration at Screening), you will stop taking study drug and you will be asked to provide semen samples every 13 weeks, for up to a year after the week 26 visit to monitor your sperm concentration.

After taking your study drug for 13 weeks, your study doctor will check your ulcerative colitis to see how it is doing compared to the day that you started the study drugs. If your ulcerative colitis shows improvement, as deemed by your study doctor, you will continue receiving your assigned study drug through week 26. If your ulcerative colitis does not show improvement, you will discontinue study drug and begin open-label filgotinib 200 mg once daily, meaning you will be taking active filgotinib.

If you complete 26 weeks in the main study without a decrease (drop) in sperm concentration you will be eligible to enter the Long-Term Extension Phase (LTE) of the study. If you started on open-label filgotinib 200 mg once daily at 13 weeks and do not have a 50% decrease in sperm concentration you will receive open-label filgotinib 200 mg once daily as part of the LTE study.

In the LTE study, if your ulcerative colitis does not show improvement, you will discontinue study drug, complete an early termination visit at that time, and a safety follow-up visit 30 days after your last dose of study drug.

If you experience a decrease of more than 50% in sperm concentration you will be offered standard of care treatment and will enter the monitoring phase.

If you stop participating in the study before the end of the 26 weeks, you will complete an early termination (ET) visit at that time. You will then have a safety follow up visit 30 days after your last dose of study drug.

The table below shows what will happen each time you visit the clinic. The procedures and tests are explained after the table:

Main Study

EVENT	**Screening (screening period may be extended by 14 days only when a 3rd semen sample is required)**							**Safety follow-up**	**ET***
Study days (D)/weeks (W)		**Day 1**	**W2 (±5 days)**	**W4 (±5 days)**	**W8 (±5 days)**	**W13 (±5 days)**	**W20 (±5 days)**	**W26 (±5 days)**	**30 Days after last dose of study drug (±5 days)**	
Informed Consent	X									
Medical History, Number of times subject impregnated women, UC History, & Demographics	X									
Inclusion/exclusion criteria review	X	X								
IBDQ questionnaire		X				X		X		X
Complete PE at screening; Symptom-directed Physical Exam, as needed	X	X	X	X	X	X	X	X	X	X
Vital Signs and Weight	X	X	X	X	X	X	X	X	X	X
Height	X									
12-lead ECG	X					X				
Flexible Sigmoidoscopy	X									
Physician's global assessment	X	X	X	X	X	X	X	X		X
Complete Mayo Clinic Score	X									
Partial Mayo Clinic Score	X	X	X	X	X	X	X	X		X
[a]TB Test	X									
Chest X-ray	X									
Urinalysis	X	X				X		X		X
Urine drug screen	X									
Hematology and Chemistry	X	X	X	X	X	X	X	X	X	X
Lipid profile (fasting) [Total cholesterol and subfractions]		X				X		X		

EVENT	**Screening (screening period may be extended by 14 days only when a 3rd semen sample is required)**								**Safety follow-up**	**ET***
Study days (D)/weeks (W)		**Day 1**	**W2 (±5 days)**	**W4 (±5 days)**	**W8 (±5 days)**	**W13 (±5 days)**	**W20 (±5 days)**	**W26 (±5 days)**	**30 Days after last dose of study drug (±5 days)**	
Serum CRP	X	X	X	X	X	X	X	X		
Serum Immunoglobulin	X					X		X		
Endocrine: TSH, HbA1c	X									
LH, FSH, inhibin B, Testosterone (free and total) collection time between 07:00-11:00 in the morning	X	X		X		X		X	X	X
Uric Acid	X									
PK collection (sparse)			X	X		X		X		
Stool for *C. difficile* toxin, *E. coli*, *Salmonella spp*, *Shigella spp*, *Campylobacter spp* or *Yersinia spp* testing	X									
Stool O&P	X									
Concomitant Medications	X	X	X	X	X	X	X	X	X	X
Assessment of Adverse Events	X	X	X	X	X	X	X	X	X	X
Semen Collection (2 samples as per collection instructions in 6.14)	X					X		X		X
Date of most recent ejaculation	X					X		X		X
HIV, Hepatitis B and Hepatitis C	X									
Randomization		X								
Study Drug Accountability				X	X	X	X	X	X	X
Study Drug Dispensation		X		X	X	X	X	X		

[a]TB test done at screening and then annually *ET=Early Termination

Monitoring Phase

EVENT	**Monitoring Phase (±5 days)**	**ET**
Study days (D)/weeks (W)	**After W 26- End of Study** **Visits occur every 13 weeks**	
IBDQ questionnaire	X	X
Complete PE at screening; Symptom-directed Physical Exam, as needed	X	X
Vital Signs and Weight	X	X
Physician's global assessment		X
Partial Mayo Clinic Score		X
Urinalysis	X	X
Hematology and Chemistry	X	X
Serum CRP	X	
LH, FSH, inhibin B, Testosterone (free and total) collection time between 07:00-11:00 in the morning	X	X
Concomitant Medications	X	X
Assessment of Adverse Events	X	X
Semen Collection (2 samples)	X	
Date of most recent ejaculation	X	

LTE Phase

EVENT	**LTE (±10 days)**	**Safety follow-up (±5 days)**	**ET**
Study days (D)/weeks (W)	**W26, W28, W32 , W39 and every 13 weeks thereafter through W221**	**30 Days after last dose of study drug**	
IBDQ questionnaire	[a]X		X
Complete PE at screening; Symptom-directed Physical Exam, as needed	X	X	X
Vital Signs and Weight	X	X	X
[e]12-lead ECG	X		
[d]TB QuantiFERON	X		
Physician's global assessment	X	X	X
Partial Mayo Clinic Score	X	X	X
Urinalysis	X	X	X
Hematology and Chemistry	X	X	X
Lipid profile (fasting) [Total cholesterol and subfractions]	[b]X		
Serum CRP	X		
Serum Immunoglobulin	X		
LH, FSH, inhibin B, Testosterone (free and total) collection time between 07:00-11:00 in the morning	X	X	X
Concomitant Medications	X	X	X
Assessment of Adverse Events	X	X	X
Semen Collection (2 samples as per collection instructions in 6.14	X		X
Date of most recent ejaculation	X		X
Study Drug Accountability	X	X	X
Study Drug Dispensation	[c]X		

[a]IBDQ Questionnaires annually in LTE phase (W 26, W 78, W 130, and W 182)
[b]Lipid tests done every 6 months in LTE
[c]Drug will not be given at W 221
[d]QuantiFERON testing done annually in LTE phase
[e]ECGs done annually in LTE phase (W 26, W 78, W 130, and W 182)

Procedure or Test	**Description**
Electrocardiogram (ECG)	You will lie down and several small, sticky pads will be placed on the skin of your chest, arms, and legs. A wire from each pad goes to a machine that makes a recording of your heart rhythm. This test takes about 15 minutes.
Physical Exam	A full physical examination will be performed at Screening. Height will be measured at Screening only. Weight will be measured at all visits.
Vital Signs	Includes measurement of your body temperature, heart rate, and blood pressure
Flexible sigmoidoscopy (required if not done within 60 days of Screening)	This is an outpatient procedure where the inside of your colon (large intestine) and rectum are examined. Depending on if you have had one recently, you may or may not be required to have one for this study. You Study doctor will provide you with further instructions about this, including how to prepare for this procedure and you will sign and date a separate consent for this. This may be a separate visit from the visits described in this consent form.
Questionnaires	You will be asked to answer some questions about your health, well-being, and sexual function on a hand held electronic device and/or on paper.

Lab Tests and Biologic Sample Collection	**Description**
Main study test	Samples of your blood will be used to help answer the study questions.
Routine health test	Samples of your blood and urine will be tested to check your health.
Immunoglobulin blood test	Immunoglobulins are antibodies that fight against bacteria, viruses, and toxins. These blood tests will provide important information about your body's immune system.
Semen samples	**At Screening, Week 13 and Week 26 (and every 13 weeks post dosing if applicable):** Samples of your semen will be checked for sperm concentration, sperm count, sperm motility and morphology (sperm movement and shape). At each timepoint where semen is collected, two semen samples should be given (each one on a different day), within 14 days of each other. A third sample semen sample may be requested if needed by the laboratory. On days when a semen sample is collected, subjects should not ejaculate (come) for 2 – 5 days before providing a sample.

Sperm Morphology Slide Retention	At each semen collection visit, four dry slides will be prepared to assess sperm morphology. Two of these slides will be sent to a central analysis lab and will be retained for up to 5 years; two will be kept at the fertility center as backups until study closure. Sperm morphology slides are not live semen samples, these are fixed, dried smears used to assess the sperm shape.
Tuberculosis (TB) test	**At Screening, then annually:** A blood sample will be obtained and tested to find out whether you have TB (an infection that can damage your lungs) or have had TB in the past. If you have had a chest X-ray within 3 months before Screening and if the results are available to the site, an X-ray of your chest may not be needed. If you were previously treated for inactive TB, no blood test will be done, but an X-ray of your chest may be needed. Let your study doctor know if you have ever had TB or have been near another person who had a TB infection.
Blood test for cholesterol	**At Day 1, Week 13 & Week 26 visits (and every 6 months during LTE phase):** You will give a blood sample to check your total cholesterol and types of cholesterol (high density lipoprotein [HDL] and low density lipoprotein [LDL]). You should not have any food or drink (except water) for at least 8 hours before these study visits.
Viral infection blood tests (HCV/HBV/HIV)	**At screening only:** Your blood will be tested for Hepatitis B, Hepatitis C, and HIV.
Blood tests to measure study drug levels (Pharmacokinetic [PK] test)	Samples of your blood will be tested to see how much study drug is in your body at specific time points.

Study Drug	Description
Take study drug	After your study doctor confirms that you can be in this research study, you will be registered as a participant in the study and will be given your first dose of study drug in the clinic on Day 1. You will also be given study drugs to take home with you. Filgotinib or placebo tablets should be stored between 15 to 30°C (59 to 86°F). You will take one tablet of study drug by mouth daily for up to 26 weeks.
Bring back study drug and containers	Bring all unused study drug tablets, and all study drug containers (even if they are empty or used) to each study visit. Your study doctor or study nurse will count how many doses you have taken. Your study doctor or study nurse will ask about any doses you did not take or if you took any extra doses.

WHAT RESTRICTIONS ARE THERE DURING THIS STUDY?

In general, there are no special food and drink restrictions when taking the study drug. There are no additional restrictions during this study, except for the list of medications listed in the "What are your responsibilities" section. It is important you review any medications you wish to start, including over the counter, with your study doctor.

There may be a special diet or temporary restrictions around the time of the flexible sigmoidoscopy. Fasting (no food or drink except water) is required for your blood test at Day 1 and around other selected blood draws (ask your study doctor). You may not eat or drink (except water) for 8 hours before the visit. After your blood test is done, the study site staff will let you know when you can have your usual food and drink.

WHAT SAMPLES WILL BE STORED?
WHAT TESTS WILL BE DONE ON THESE SAMPLES?

Some of your blood and stool (original samples or leftover samples from all previous visits) will be frozen and stored. Your stored samples and the information collected about you during the study may be used by the study sponsor or its research partners to help answer study questions about the study drug or ulcerative colitis and related diseases. At the end of this study, these samples may be held in storage by Gilead Sciences, Inc. for up to 15 years. You may request that your stored samples be destroyed at any time by writing to the study doctor at the address listed on the first page of in this form.

Blinded Results

Some information provided from tests done on your samples will not be given to you or your Study doctor. This information will not be placed in your medical records and will have no effect on your medical care.

WHAT ARE THE POSSIBLE RISKS OF BEING IN THIS STUDY?

FILGOTINIB COMMON ADVERSE EVENTS

Some adverse effects have been reported in studies of filgotinib. Across three completed Rheumatoid Arthritis (RA) or Crohn's Disease (CD) phase 3 studies lasting 20 weeks or longer, the most common adverse events were infections and next most common adverse events were issues related to the stomach and intestines (gastrointestinal tract)

INFECTIONS
Drugs that affect your immune system can lower your body's ability to fight infection. ***There is a possibility that your ability to fight infection will be weakened while taking filgotinib.*** In RA and CD studies, there have been more infections in study subjects who took filgotinib compared to those who took placebo (pill without filgotinib). Pneumonia (a lung infection that can be potentially serious) has been identified as an adverse effect of filgotinib based on RA and CD studies. Serious infections leading to hospitalization, have been reported and in some cases study subjects with an infection have died. Based on the information that is available so far, it is estimated that if 100 subjects take filgotinib for one year, 2 people would develop a serious infection, on average.

Neutrophils are a type of white blood cell that helps to fight infection. The number of neutrophils was lower in the blood of study subjects with RA who were given filgotinib, but only approximately 1.5% of these study subjects had a severe decrease in neutrophils. Other types of infection fighting cells in the blood were not affected.

MALE INFERTILITY
Filgotinib caused damage to the testes (testicles) of male rats and dogs. In these animals, filgotinib caused deterioration and loss of cells that make sperm, resulting in less sperm, or no sperm being produced. As a result, filgotinib caused male rats to be infertile (unable to get a female rat pregnant).

Damage to the testes in rats and dogs was observed at doses producing blood levels of filgotinib slightly higher than blood levels produced by the planned doses in study subjects in this study. At these doses, while sperm counts in rats and dogs increased after filgotinib was stopped, they stayed low overall and did not return to normal. At the highest doses tested in male rats and dogs, these adverse effects did not go away. These adverse effects were not seen in the testes of rats and dogs when these animals were given a dose that produces blood levels of filgotinib similar to blood levels produced by the 200 mg daily dose in humans.

Based on the results in male rats and dogs, there is a risk that men treated with filgotinib may have reduced sperm production, and may become temporarily or permanently infertile (unable to get a woman pregnant). This study is being done to help understand the effect of filgotinib on sperm production. Currently the long term effect of filgotinib on sperm production in humans is unknown.

Do not enroll in this study unless you understand and accept the risk that you may have reduced fertility (a lower chance of getting a woman pregnant) or infertility (unable to get a woman pregnant), and that this side effect may not go away after you leave the study; it could be permanent.

If reduced fertility or infertility is a concern for you it is possible to store a sample of your semen (sperm banking) for future use **before** starting this study. *While sperm banking may be an option for you, it is not considered to be a highly reliable way to preserve future fertility in all cases.* If you are interested in sperm banking, you should talk to your study doctor or regular health care provider. Sperm banking is not part of this study however you can do this on your own before starting this study.

BIRTH DEFECTS
Filgotinib treatment caused malformations (birth defects) of the bone and internal organs in the fetuses (unborn babies) of pregnant rats and rabbits. These birth defects happened at doses producing blood levels of filgotinib comparable to blood levels produced by the planned doses in study subjects in this study. Other effects were also seen, including increased pregnancy loss and decreased fetal body weights.

Based on this animal data, filgotinib may cause birth defects in humans. Do not enroll in this study unless you understand and accept this risk and are willing to take appropriate measures to avoid pregnancy in a female partner.

To be in this study, highly effective birth control is required. Birth control should also be considered for female partners of male participants; your study doctor can provide details on recommended types of birth control.

CANCER
Lymphoma (a type of cancer of the immune system) and other types of cancers have been seen in study subjects with RA taking filgotinib. Some of these cancers have resulted in death. Based on the information that is available so far, it is estimated that if 100 subjects take filgotinib for one year, 1 person would develop cancer, on average. Some types of cancer, such as lymphoma, are known to happen more often in people with RA, but it is not yet known if filgotinib increases this risk.

OTHER EFFECTS
Increases in cholesterol, including certain types of both good and bad cholesterols, have been seen in study subjects taking filgotinib, but the importance of these findings is not yet known. A small increase in creatinine (which is a measure of how well the kidney is working) was seen in studies with RA patients. The creatinine levels overall, however, stayed within normal limits.

As with any drug, there are unknown risks involved, since only a limited number of people have taken this study drug and not all adverse effects or risks of taking this study drug are known. In the future, more serious and/or long-term adverse effects could happen, including allergic reactions. Also, the risks or discomforts described here could happen more often or be more severe than what has been seen before. Your health will be checked at each study visit by your study doctor, and you will be asked to report any

changes or problems you may have noticed. If you or your partner becomes pregnant during the study, you should let your study doctor know right away. If you have any changes in your health or if you have any health problems, you should let your study doctor know right away.

Talk to your study doctor if you have any questions about the possible side effects of filgotinib.

BLOOD DRAWS
Collecting a blood sample from a vein may cause pain, bruising, lightheadedness, fainting, and very rarely, infection at the site of the needle.

FLEXIBILE SIGMOIDOSCOPY WITH BIOPSY RISKS
Flexible sigmoidoscopies are generally safe procedures but with any procedures there are risks. These risks will be discussed with you by your medical doctor. You will sign and date a separate consent form for these procedures.

Preparation for this test may require use of an enema or laxative, or both, which may cause abdominal discomfort and increased loose stools during the preparation period. Preparation may also include a special diet where you clean your intestines. You may experience cramping from the air used to inflate your colon during the procedure, which will pass. Puncture of the colon is a rare side effect from this test. If you experience fever, chills, severe abdominal pain, or heavy rectal bleeding of more than a teaspoon at a time, call your study doctor immediately.

ECG
After you have an ECG, you may have mild irritation, slight redness, and itching on your skin where the recording patches were attached. You may need to have your chest hair shaved for this procedure.

QUESTIONNAIRES
Some of the questions may seem personal and may make you feel uncomfortable. If you have any questions or concerns while answering these questionnaires, please talk to your study doctor. You do not have to answer any question which you choose not to.

FASTING
Fasting could cause dizziness, headache, stomach discomfort, or fainting.

CHEST X-RAY
You may receive some radiation exposure from a chest x-ray. Generally, the amount of radiation received during this procedure is the same as a person gets from exposure to natural sources of radiation in the environment in a 10 day period.

ALLERGIC REACTION
Allergic reaction is always possible with any drug. Serious allergic reactions that can be life-threatening may happen. Some things that may happen during an allergic reaction to any type of medication are:

- skin rash
- having a hard time breathing
- wheezing when you breathe
- a sudden drop in blood pressure
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS
There may be unwanted side events that are not yet known or may happen rarely when people take these study drugs. You will be told of any new information that might cause you to change your mind about continuing to take part in this study.

As with any new drug, extra care has to be taken to watch for the side effects that are not always obvious. If you feel any side effects or unusual symptoms, please notify your study doctor as soon as possible at the phone number listed in this form.

PREGNANCY
It is very important that you do NOT cause a woman to become pregnant while you are in this study from the time of screening and for at least 90 days after your last dose of study drug. Not having sex is the only certain way to prevent pregnancy.

To be in this study, you must agree to protect your partner from becoming pregnant before, during, and after the study. Men with female partners who may become pregnant, must use effective methods of birth control. Your study doctor will need to discuss what type(s) of birth control you are using.

Other not yet identified side effects could happen to you, and/or to the embryo or fetus (unborn child) if your partner becomes pregnant during the time you are in the study and for 90 days after your last dose of study drug. Let your study doctor know right away if you think that your partner has become pregnant.

It is possible that the study drugs may harm an unborn baby if your female partner is pregnant during the study or within 90 days of your last dose of study drug. If you have a female partner who is pregnant or suspects that she has become pregnant while you are in the study or within 90 days after your last dose of study drugs, you must stop taking the study drugs immediately and tell your study doctor. As the risk to your partner and unborn baby are not known, it is recommended for your partner to receive appropriate prenatal care from her own doctor. Your partner will be asked to sign a consent form to allow her to give the study doctor information about the pregnancy and its outcome.

Your study doctor may need to tell your partner details about this study and about your taking part in it. The Study Sponsor and the study doctor will not be responsible for the costs related to the pregnancy, delivery, or care of your child.

You must also agree not to donate sperm during the study (except for required study sperm collection) and until 90 days after your last dose of study drugs. Your sexual activity and sexual behaviors are not restricted except for the periods around the time you are donating sperm for the study. Please share this information with your partner, if applicable.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

While taking part in this study, your health will be monitored closely and your ulcerative colitis may improve. But, you may not receive any benefit from taking part in this study. It is possible that your ulcerative colitis does not improve, or it may worsen. Studies are a way for doctors to see if a drug is useful in fighting a disease.

By taking part in this study, you contribute to the understanding of the disease and how it could be treated.

WHAT ARE YOUR TREATMENT OPTIONS?

Your study doctor will discuss appropriate treatment options and the risks and benefits with you.

You can discuss if you want to have any treatment or if you want to choose another treatment for your disease. These treatments include those that are already approved by government agencies and sold in your country.

WHAT HAPPENS IF YOU DO NOT WANT TO TAKE PART IN THIS STUDY? WHAT HAPPENS IF YOU NO LONGER WANT TO TAKE PART IN THE STUDY?

Your decision to take part in this study is voluntary. You can refuse to take part or stop taking part in this study at any time without giving a reason. If you decide to stop the study at any time, your exit from this study will not affect the medical care you would otherwise receive.

Your participation in this study may be stopped at any time by your study doctor, Gilead Sciences, Inc., or regulatory authorities.

Your study doctor may decide for your medical safety to stop your study drug(s) or take you off the study. Or you may be taken off the study if your study doctor learns that you did not give a correct medical history or did not follow instructions for the study. If you are taken off the study, you will no longer receive the study drug(s). If your study drug(s) is stopped, your study doctor will closely monitor your overall health.

HOW MUCH WILL STUDY TREATMENT COST YOU?

The study drugs used in this study will be given to you at no cost. All study visits and fees for lab tests, X-rays and other procedures that are part of this study will be provided at no cost to you.

You or your usual health care payer (such as an insurance company) will be responsible for any other health care costs.

WILL YOU BE PAID TO BE PART OF THIS STUDY?

You will not be paid to take part in this study.

WHAT HAPPENS IF YOU ARE INJURED?

If you become sick or injured as a direct result of taking the study drug and/or following the study procedures, the study site will provide you with medical treatment. The Sponsor, Gilead Sciences, Inc., will reimburse you or the study site for the reasonable and necessary costs of such medical treatment, *provided* that you have followed the instructions of the Study Doctor. No other form of reimbursement for study-related injury or illness is offered by the Sponsor. You should immediately contact your Study Doctor at the contact information shown on page one of this form in the event you experience any study-related illness or injury.

If you receive Medicare benefits, the Sponsor, Gilead Sciences, Inc., is required by law to report payments made to you for treatment, complications, and injuries that arise from this Study. Information that you are taking part in the Study, medical treatments received, Medicare claims, and other personal information about you such as your name, social security number, and date of birth, will be provided to the Centers of Medicare and Medicaid Services and its agents and/or contractors for this purpose.

You do not give up any legal rights by signing this form. You are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

WHO CAN YOU CONTACT FOR MORE INFORMATION ABOUT THIS STUDY?

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who 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 study subject;
- Eligibility to participate in the research;
- The study doctor’s or study site’s decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff listed on the first page of this form with any questions, concerns or complaints.

WHO CAN YOU CONTACT ABOUT YOUR RIGHTS AS A STUDY SUBJECT?

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

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

Please reference the following number when contacting the Study Subject Adviser: Pro00021124.

WHO WILL HAVE ACCESS TO YOUR MEDICAL RECORDS?

Records identifying you will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. In the event of any publication regarding this study, your identity will remain confidential.

Representatives from government agencies, including the U.S. Food and Drug Administration ("FDA"), institutional review boards, the Sponsor and/or the Sponsor's authorized representatives may need access to your original medical records and study records for the purpose of checking data collected for the study. By signing this consent form, you authorize this access.

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation).

By signing this consent form you agree that you will not be able to have access to your personal health information related to this study until the study is over. This is done to maintain the scientific integrity of the study. After the study is complete, you can obtain access to your information through your Study Doctor.

Authorization to Use and Disclose Records

During this study your Study doctor, study nurses and other study site personnel will record information about you, your health and your participation in the study on forms provided by Sponsor. These forms are known as case report forms. You will not be able

to participate in this study if you do not consent to the collection of this information about you.

The information collected about you, will be held by the study site, Sponsor and Sponsor's authorized representatives. To ensure that your personal information is kept confidential, your name and any other information that allows you to be identified directly will not be entered on the case report forms or included in any records or samples your study doctor provides to Sponsor or Sponsor's authorized representatives. Instead, you will only be identified by your initials and a code. The code is used so that your study doctor can identify you if necessary.

The Sponsor and its authorized representatives will analyze and use the coded information they receive for the purposes of this study. Such purposes include:

- checking your suitability to take part in the study,
- monitoring your study treatment with the study drug,
- comparing and pooling your study treatment results with those of other subjects in clinical studies,
- establishing whether the study drug meets the appropriate standards of safety set by the authorities,
- establishing whether the study drug is effective,
- supporting the development of the study drug,
- supporting the licensing application for regulatory approval of the study drug anywhere in the world,
- supporting the marketing, distribution, sale and use of the study drug anywhere in the world, and/or
- as otherwise required or authorized by law.

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation).

If necessary for these purposes, the Sponsor may share your information with its affiliates, people and companies with whom the Sponsor works, and regulatory or other governmental agencies. Although efforts will be made to protect your privacy, absolute confidentiality of your records cannot be guaranteed. Your medical information and records may be re-disclosed and no longer protected by federal privacy law.

As explained in this consent form, your participation in this study is voluntary and you may withdraw from the study at any time by informing your Study doctor. By signing this consent, you authorize the collection and use of information about you as described in this consent. You may revoke (take back) this authorization for the collection and use of information about you by informing your Study doctor in writing. If you withdraw from the study or if you revoke your authorization for the collection and use of information about you, your participation in the study will end and the study personnel will stop collecting information from you. The Sponsor will need to keep and use any research results that have already been collected. The Sponsor must do this to comply with its legal obligations and to maintain the scientific integrity of the study. Your decision to withdraw from the

study or to revoke your authorization for the collection and use of information about you will not result in any penalty or loss of access to treatment or other benefits to which you are entitled. This authorization has no expiration date, unless and until you revoke it. In California and any other state that requires an expiration date, the authorization will expire 50 years after you sign and date this authorization document.

You will be given a signed and dated copy of this form to keep.

If you have any questions about the collection and use of information about you, you should ask your Study doctor.

WHERE CAN YOU FIND MORE INFORMATION ABOUT THIS STUDY?

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

AGREEMENT TO BE IN THE STUDY

By signing this informed consent form, I agree that:

(1) I have carefully read and understand the information in this form.
(2) The purpose and procedures of this research study have been fully explained to me. I was able to ask questions and all of my questions were answered to my satisfaction.
(3) I have been told about the procedures of the study and the drugs that are being tested. I have been told about possible risks as a result of taking part in this study that could happen from both known and unknown causes.
(4) I understand that I am free to withdraw my consent and to stop my participation in this study at any time. The possible effect on my health, if any, of stopping the study early has been explained to me.
(5) I understand that leaving the study will not affect my usual medical care or treatment options.

Subject

Subject Printed Name	Signature	Date

Person Obtaining Consent

Printed Name & Title	Signature	Date

Witness (if applicable)

Witness Printed Name	Signature	Date