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

Sponsor / Study Title:	**Gilead Sciences, Inc. / "A Phase 2, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy and Safety of Filgotinib in the Treatment of Small Bowel Crohn's Disease (SBCD)"**
Protocol Number:	**GS-US-419-4015**
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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 study treatment of Crohn's disease.

This Subject Information and Informed Consent Form explains 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 in 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.

Your decision to participate in this study is completely voluntary.

WHAT IS THE PURPOSE OF THIS STUDY?

You have been asked to be part of this study because you have been diagnosed with Crohn's disease, which is an inflammatory disease of the gastrointestinal tract (digestive tract). The purpose of this study is to see if filgotinib is effective and safe in treating people that have inflammation in at least one section of their small bowel as part of their Crohn's disease. The small bowel is part of the digestive tract that connects to the stomach at one end and the colon (large bowel) at the other and consists of sections

called the duodenum, jejunum, and ileum. In this study, pictures taken with Magnetic Resonance Enterography (MRE) will be used to make scores of how bad your Crohn's disease is. The scores will be checked at the beginning and the end of the study. There will be no endoscopy (camera into the rectum or the mouth to look at the digestive tract) required for participation this study.

HOW DOES THIS STUDY WORK?

If you agree to take part in this study, you will be one of 100 volunteers (subjects). The study will take place at approximately 80 centers worldwide**.** This study is open to men and women with Crohn's disease who are between 18 to 75 years of age and meet the 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 2 out of 5 chances (40%) to receive filgotinib 200 mg, 2 out of 5 chances (40%) to receive filgotinib 100 mg, and a 1 out of 5 chance (20%) to receive placebo.

You will not receive 200 mg at any time during the study if you are a man who has not failed at least 2 prior biologic therapies (any TNFα antagonist and vedolizumab). If you are one of these males, you will have 2 out of 3 chances (approximately 66%) to receive filgotinib 100 mg and a 1 out of 3 chance (approximately 33%) to receive placebo.

Double-blind means you and your study doctor will not know what study drug you will be taking. Placebo-controlled means that you may be taking a tablet with no medicine in it but the tablet looks like filgotinib.

Your study doctor will be assessing how you are responding to the study drug throughout the study. Based on how you are responding to study drug at Week 10, you will either continue on your assigned study treatment for the remainder of the study or may have the option to participate in a separate long-term extension study if you are eligible.

Following Week 10, if your Crohn's disease gets worse, you may be discontinued from the study and may have the option to enter into the separate long-term extension study if you are eligible.

If you complete the study up to and including the visit at Week 24, you may have the option to enter into the separate long-term extension study if you are eligible.

The active filgotinib 200 mg, filgotinib 100 mg, as well as the matching filgotinib placebo will be supplied by Gilead Sciences, Inc., which is also the Sponsor of this study.

HOW LONG WILL YOU BE ON THE STUDY?

Taking part in this study will last about 24 weeks, not including the screening visit or post-study treatment visit (30 days after last dose).

During this time, you will be required to visit the clinic approximately 8 times. However, if you are a woman who can get pregnant, you will be required to visit the clinic at least 9 times.

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 pregnant or get someone pregnant during this study.
- While you are participating in this study, you may have to interrupt study treatment with the guidance of your study doctor. This could happen if you have signs and symptoms of an infection, abnormal blood test results, or need surgery. It is important that you report any signs and symptoms of an infection or plans for surgery to your study doctor as soon as you can.
- 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.
- If you are taking drugs called corticosteroids that are used to control inflammation you may be asked to stop taking these medications at a certain time during the study.
- 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 live vaccines before, during, and after the study for specific periods of time. You may also need to avoid routine household contact with anyone who has recently been vaccinated with certain types of vaccines. Ask your study doctor before getting a vaccine or coming into contact with someone that has recently been vaccinated.
- 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:

Medications that might interact with the study drugs (such as):
- Phenobarbital
- Phenytoin
- Carbamazepine
- Rifabutin
- Rifapentine
- Rifampin
- St. John's wort
- Danshen (Salvia Miltiorrhiza)

Live vaccines (such as):
- Herpes Zoster (shingles) vaccine, Zostavax, and others (ask your study doctor)

Chronic Nonsteroidal Anti-inflammatory Drugs (such as):
- Aspirin
- Ibuprofen
- Naproxen
- Diclofenac
- Indomethacin
- COX-2 inhibitors

Medications for your Crohn's and related diseases (such as):
- Prednisone greater than 30mg/day or a similar dose of any other oral corticosteroids
- Infliximab
- Adalimumab
- Golimumab
- Certolizumab
- Vedolizumab
- Natalizumab
- Ustekinumab
- Other TNF inhibiting drugs (including biosimilars)
- Cyclosporine
- Thalidomide
- Tacrolimus
- Leflunomide
- Any JAK inhibitors
- Any investigational drugs (biologic or non-biologic)

Lymphocyte-depleting therapies (such as):
- Alemtuzumab
- Cyclophosphamide
- Total lymphoid irradiation
- Rituximab

- You must bring back all unused study drug and all opened or unopened study drug bottles.
- You will be given an e-Diary which you must bring back to every clinic visit. You need to complete your e-Diary entries daily as instructed by the study staff. You must return your e-Diary at study completion or earlier if you early terminate (finish the study early).
- You must follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part 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.

You will be assigned to one of three study treatment groups as described below. Even though you will only be assigned to one of three study treatments, you will have to take 2 pills at a time (your study doctor will give you detailed instructions). You and your study doctor will not know what study treatment group you are in:

- Study Treatment 1: 1 x filgotinib 200 mg tablet + 1 x placebo tablet daily
- Study Treatment 2: 1 x filgotinib 100 mg tablet + 1 x placebo tablet daily
- Study Treatment 3: 2 x placebo tablets daily

If you are a man who has not failed at least 2 prior biologic therapies (any TNFα antagonist and vedolizumab), you will be assigned to one of two study treatments and take only 1 pill at a time (your study doctor will give you detailed instructions). You will not receive 200 mg in this study at any time. You and your study doctor will not know what study treatment group you are in:

- Study Treatment 1: 1 x filgotinib 100 mg tablet daily
- Study Treatment 2: 1 x placebo tablet daily

After taking your study drug for 10 weeks, your study doctor will check your Crohn's disease to see how it is doing compared to the day that you started the study drugs. If your Crohn's disease shows improvement as deemed by your study doctor, you will continue on your current study treatment assignment for the remainder of the study.

If you were taking corticosteroids at the start of the study and you have shown improvement on study drug at Week 10, your study doctor will start to decrease your dose of corticosteroids gradually until you are no longer taking them.

If your Crohn's disease has not improved as deemed by your study doctor by Week 10, you will stop taking the current study drug. You may then be eligible to enter a separate long-term extension study. More information is available in a separate consent form.

Following Week 10, if your Crohn's disease gets worse, you may be discontinued from the study and may have the option to enter into the separate long-term extension study.

If you complete the study up to and including the visit at Week 24, you may have the option to enter into the separate long-term extension study if you are eligible.

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

Period:	Screening	Study Treatment									Follow-Up	
Visit	1	2	3	4	5	6	7	8	9	10		
Procedure (what will happen)	Screening (To see if you qualify)	Day1	Week 2	Week 4	Week 6	Week 10	Week 14	Week 18	Week 20	Week 24	PT	ET
Review your health, medical, and Crohn's disease history (including prior treatments)	X											
Review any changes in your health since last visit		X	X	X	X	X	X	X		X	X	X
Review medications you are taking	X	X	X	X	X	X	X	X		X	X	X
Physical examination (including weight; your height will only be taken at screening)	X	X	X	X	X	X	X	X		X	X	X
Measure your "vital signs: (blood pressure, heart rate, breathing rate, and temperature)	X	X	X	X	X	X	X	X		X	X	X
Blood samples for routine health tests (chemistry, hematology)	X	X	X	X	X	X	X	X		X	X	X
Blood sample for bacterial and viral infection test (TB, HBV, HCV, HIV screening) *Chest x-ray may be needed to confirm TB results*	X											
Blood samples for biomarker and immunoglobulin tests		X		X		X				X	X	X
Blood samples to measure study drug levels				X		X		X		X		
Blood sample for peripheral blood mononuclear cell (PBMC) test		X		X		X				X		
Blood sample for genomic test - OPTIONAL		X										
Urine sample for routine health tests and drug screen (drug screen at screening only)	X									X		
Pregnancy test (for female subjects) (blood sample at screening; urine sample for all other visits)	X	X		X	X	X	X	X	X	X	X	X
Stool sample for routine health and biomarker tests	X									X		
Electrocardiogram (ECG) *ECG at the ET visit is not needed if you have the ECG at Week 10*	X					X						X
Answer health questionnaires about your overall well-being		X				X				X		
Bring back your e-Diary for review		X	X	X	X	X	X	X		X		X
MRE	X									X		
Study drug provided		X		X		X	X	X				
Bring back unused study drug and all containers since last visit			X	X	X	X	X	X		X	X	X
Approximate total amount of blood taken	21.5 ml 1.5 tbsp	38.5–53.5 ml 2.6–3.6 tbsp	12 ml 0.8 tbsp	44.5–54.5ml 3–3.7 tbsp	12 ml 0.8 tbsp	44.5–54.5ml 3-3.7 tbsp	12 ml 0.8 tbsp	18 ml 1.2 tbsp	0 ml 0 tbsp	44.5–54.5ml 3-3.7 tbsp	18 ml 1.2 tbsp	18 ml 1.2 tbsp

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 only. A focused physical examination based on your symptoms will be performed at all other study visits. Height will be measured at screening only. Weight will be measured at most study visits.
Vital Signs	Includes measurement of your body temperature, heart rate, breathing rate, and blood pressure
Electronic Diary (e-Diary)	An electronic diary will be provided to you to record how many liquid or very soft stools you have every day. You will also record how bad your abdominal pain is every day. Bring your e-Diary with you to every clinic visit.
Questionnaires	You will be asked to complete questionnaires about your overall well-being on a handheld electronic device when you visit the clinic. Your study doctor will also ask questions about the severity of your abdominal pain and the frequency of your stool.
MRE	Magnetic Resonance Enterography (MRE) is an imaging test that can evaluate the insides of the body including the digestive tract using a large magnet. It will take detailed pictures of your organs. For example, it can show areas of inflammation (swelling and damage) that can go along with active Crohn's Disease. It can also show fistulas, or connections, between your intestines and other organs or the skin. MRE also shows areas of narrowing (stricture) anywhere in the bowel (stomach) and it shows areas of ulcers and of bleeding. The MRE will be conducted at Screening and at the Week 24 visit. You will be asked to fast for at least 4 hours prior to arriving at the imaging site (only water is allowed during this period). You will also have an intravenous (IV) catheter placed and a contrast agent will be injected into your vein (on your hand or arm) midway through the

Procedure or Test	Description
	study to help in outlining different structures in your gut. You will also drink solution to help fill your bowels to take clear pictures.

Lab Tests and Biologic Sample Collection	Description
Main study test	Samples of your blood, urine, and stool will be used to help answer the study questions.
Routine health test	Samples of your blood, urine, and stool will be tested to check your health. **At screening only:** Your urine sample will be screened for possible drugs of abuse.
Pregnancy test	If you are a woman who can get pregnant, a sample of your blood (at screening) and urine (at all other visits) will be taken to test for pregnancy. To take part in this study, the pregnancy test must be negative. Urine pregnancy tests will be performed every 2 to 4 weeks in the clinic. If a urine pregnancy test is positive, then a blood test will be done.
Viral infection blood test (HCV/HBV/HIV)	**At screening only:** Samples of your blood will be collected to see if you are infected with these specific viruses. If you are positive for these viruses, the results may be reported to health authorities as required by local laws.
Tuberculosis (TB) test	**At screening only:** A blood sample will be obtained and tested to find out whether you have TB or have had TB in the past (an infection that can damage your lungs). If you had a chest X-ray (a commonly performed picture of your chest using a small amount of radiation) 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 tests to measure study drug levels	Samples of your blood will be tested to see how much study drug is in your body
Biomarker blood and stool test	Your blood and stool samples for biomarker testing will be collected. Biological markers (biomarkers) are substances in the body that can offer clues as to how the study drug is affecting the body and a disease.

Lab Tests and Biologic Sample Collection	**Description**
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.
Peripheral blood mononuclear cell (PBMC) blood test	Peripheral blood mononuclear cells (PBMC) are blood cells that help defend the body against infection. The purpose of this test is to see if the study drug affects these immune blood cells in Crohn's disease
Genomic blood test – OPTIONAL	Genomics is the study of genes and their function (factors inherited from our parents and how they work). If you agree, an extra blood sample will be collected once at the Day 1 visit for genomic testing. If a blood sample is not collected during this time, then a sample may be taken any time after the first dosing visit. If you do not agree, you can still take part in the main study.
Future research test - OPTIONAL	If you agree, leftover blood and stool samples collected during the study may be used for future testing to help answer questions that are not part of the main study. If you do not agree, you can still take part in the main study. More information is below.

Study Drug	**Description**
Get study drug	At the visits marked on the table, you will be given study drug to take home with you. Filgotinib and placebo filgotinib tablets should be stored at room temperature (25°C or 77°F) and should stay between 15 to 30°C (59 to 86°F). Keep the container tightly closed to protect from moisture.
Take study drug	Take your study drug tablet(s) as instructed by mouth every day with or without food. On the days you have study visits, do not take your dose at home.
Bring back study drug and bottles	Bring back all unused study drug tablets and all study drug bottles (even if they are empty or used). Your study doctor or study nurse will count how many tablets you have taken. Your study doctor or study nurse will ask about any tablets you did not take or if you took any extra tablets.

WHAT RESTRICTIONS ARE THERE DURING THIS STUDY?

In general, there are no special food and drink restrictions when taking the study drug. Your study doctor may advise you if any blood draws require fasting. 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 medications, with your study doctor.

Fasting (no food or liquids except water) is required for routine health tests collected at the Day 1 visit, Week 10 visit, and Week 24 visit. You may not eat or drink (except water) for 8 hours prior to each of those visits.

For the MRE at Screening and the Week 24 Visit:
You will be asked to fast for at least 4 hours prior to arriving at the imaging site (only water is allowed during this period).

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 questions about the study drug or Crohn's disease and related conditions. 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 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 SIDE EFFECTS

As of 07 April 2017, filgotinib has been taken by more than 1400 study subjects, including more than 950 study subjects with rheumatoid arthritis (RA) and more than 150 study subjects with Crohn's Disease (CD), and has been generally well tolerated.

Some adverse effects have been reported in studies of filgotinib. Across three completed RA or CD Phase 2 studies lasting 20 weeks or longer, the most common adverse events were infections and the 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 subject 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). An additional separate study will be done in men to measure the effect of filgotinib on sperm production. Until results from that study are available, 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. 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 study 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 these 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. To be in this study, highly effective birth control is required for both men and women. Birth control should also be considered for female partners of male subjects; your study doctor can provide details on recommended types of birth control. If you are planning to become pregnant in the future, you should discuss this with your study doctor before entering the study.

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 subjects. 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 adverse effects of filgotinib.

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

ECG
After you have an ECG, you may have mild irritation, slight redness, and itching on your skin where the recording patches are attached. You may have your chest 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 questions, please talk to your study doctor.

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

ALLERGIC REACTION
Allergic reaction is always possible with a drug you have not taken. Serious allergic reactions that can be life-threatening may occur. Some things that happen during any allergic reaction to any type of medication are:

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

MRE
The MRE imaging machine creates a strong magnetic field around your body. If you have any implanted metal devices, this magnetic field may interfere with the proper functioning of the implanted device. You should not participate in this study if you have an implanted metal device, such as a pacemaker or a cochlear implant. You should tell your study doctor about any implants, piercings, tattoos, prior surgeries, especially on your bones, and dental work.

You will need to drink a solution to fill your bowels to make the pictures clearer. In addition, you might receive a medicine to quiet down the movement of the gut during the pictures. You will also get a contrast agent via your veins to help make the pictures clearer. The contrast agent that's injected into your vein contains gadolinium. There have been cases of a rare medical condition associated with this agent in patients with decreased kidney function. There is also a risk of allergic reaction with any drug injected into your body.

The IV catheter inserted into your hand or arm may cause local pain, bruising, occasional lightheadedness, fainting, and very rarely, damage to the nerves or infection at the site of the IV.

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.

UNKNOWN/UNEXPECTED RISKS AND DISCOMFORTS
There are adverse events that are not known or happen rarely when subjects 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 study drug, extra care has to be taken to monitor 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 AND BREAST-FEEDING

Because we do not fully know the effects of the study drugs (filgotinib) in this study on the developing embryo, fetus (unborn baby) or on nursing infants, women who are pregnant or breast feeding cannot participate in this study. In animal studies, filgotinib caused birth defects at similar doses to the dose that will be given to people in this clinical trial.

If you are a woman of child-bearing potential (which means if you are a woman who can become pregnant), it is very important that you do NOT become pregnant while you are in this study and for at least 35 days after your last dose of study drug. If you are a male, it is very important that you do NOT cause a woman to become pregnant while you are in this study and for at least 90 days after your last dose of study drug. Not having sex is the only certain way to prevent pregnancy. It is also important to prevent pregnancy in female partners of men who are in this study from the time of screening to 90 days after the last dose of study drug.

To be in this study, you must agree to protect yourself or your partner from becoming pregnant before, during, and after the study. Women, and 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 your embryo or fetus (unborn child) if you or your partner becomes pregnant during the time you are in the study and after your last dose of study drug (35 days for women, and 90 days for men in the study). Let your study doctor know right away if you think that you or your partner has become pregnant.

Female subjects:
If you are sexually active and able to become pregnant, you must agree to practice abstinence (not having sexual intercourse that could get you pregnant) if this is in line with your usual lifestyle OR must agree to use one of the birth control methods listed below, starting from the time of screening throughout the study and for 35 days after the

last dose of study drug. During the study women of childbearing potential must have at minimum a urine pregnancy test every 4 weeks.

Birth control methods include:

- Intrauterine device (IUD) with a failure rate of less than 1% per year
- Tubal sterilization (having your tubes tied by surgery)
- Essure micro-insert system (with confirmation of success 3 months after procedure)
- Vasectomy in male partner (provided that the partner is the only sexual partner and had confirmation of surgical success at least 3 months after procedure)

Subjects who use a hormonal contraceptive as one of their birth control methods must have used the same method for at least three months prior to the first dose of study drug. Hormonally-based contraceptives permitted for use in this protocol are as follows:

- Hormonal methods (each method must be used with a barrier method such as a condom, preferably a male condom)
    - Oral contraceptives (either combined estrogen/progestin or progesterone only)
    - Injectable progesterone
    - Implants of levonorgestrel
    - Transdermal contraceptive patch
    - Contraceptive vaginal ring
- Barrier methods (must be used with a hormonal method):
    - Male or female condom with or without spermicide
    - Diaphragm with spermicide
    - Cervical cap with spermicide
    - Sponge with spermicide

Birth control methods that are unacceptable include periodic abstinence (for example, calendar, ovulation, symptothermal, post-ovulation methods), withdrawal (coitus interruptus), spermicides only, and lactational amenorrhea method (LAM). Female condom and male condom should not be used together.

You must also agree to refrain from egg donation and in vitro fertilization during the study and until at least 35 days after the last dose of study drug.

You must stop taking the study drugs immediately and tell your study doctor if you become pregnant or think you have become pregnant, at any time while in this study and for 30 days after the last dose of study drug. The study doctor will tell you about the possible risks to your unborn child and options available to you. In the event of a positive urine pregnancy test, you will be told to stop study drugs immediately and asked to return to the clinic as soon as possible for a serum (blood) pregnancy test. Your study doctor will need to know what happens to the pregnancy. You will be asked to tell your study doctor the outcome of pregnancy, including any premature loss of pregnancy.

You should be counseled and followed by your own doctor as well. As the risk to the unborn baby is unknown, you should seek medical care from your own doctor during the pregnancy and for the baby after it is born. Neither the study sponsor nor the study doctor will be responsible for providing routine medical care for the pregnancy, delivery, or care of your child.

Male subjects:
Male subjects should use male condoms during the study and for 90 days after last dose of study drug.

It is possible that the study drugs may harm an unborn baby if your female partner becomes 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 and date a consent form to allow her to give the study doctor information about the pregnancy and its outcome.

Female partners of male subjects who are able to become pregnant should also consider using an accepted contraceptive method. Please refer to the 'female subjects' section for the recommended contraceptive methods.

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.
Men must also agree not to donate sperm during the study and until 90 days after your last dose of study drugs. 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 Crohn's disease may improve. But you may not receive any benefit from taking part in this study. It is possible that your Crohn's disease does not improve, or it may worsen. Studies are a way for doctors to see if a study drug is useful in fighting a disease.

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

WHAT ARE YOUR TREATMENT OPTIONS?

You do not need to take part in this research study. Your study doctor will discuss appropriate treatment options and the risks and benefits with you.

You can discuss if you don't 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 do not have to be in it if you prefer not to). You can refuse to take part or stop taking part at any time without giving a reason without penalty or loss of benefit. If you decide to stop the study at any time, your exit from this study will not affect medical care which you otherwise may 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. You may be taken off the study if your study doctor learns 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 drug used in this study will be given to you at no cost. All study visits and fees for lab tests and procedures that are part of this study will be provided at no cost to you.

You or your usual health care payer 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 listed on the first page 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 and dating 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.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE 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.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH 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: Pro00019563.

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 and dating 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 and dating 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, the Sponsor and the 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 and dating 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 at the address listed on the first page of this form. 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.

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.

Information on this study will also be posted in a similar format on a European Web site at www.clinicaltrialsregister.eu

AGREEMENT TO BE IN THE STUDY

By signing and dating this informed consent form, I acknowledge 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 informed of the study drugs and procedures of the study that are being tested. I have been informed of 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 stopping the study will not impact my medical care and treatment options.

Subject

Subject Printed Name	Signature	Date

Person Obtaining Consent

Printed Name & Title	Signature	Date

Witness (if applicable)

Witness Printed Name	Signature	Date

Optional Future Research Consent

You are being asked to take part in optional future research. If you decide to not take part in this future research, you can still take part in the main study.

This research may help scientists to better understand:

- How your disease and related diseases work
- The effect of the study drug and/or other medications on the body
- How the study drug is processed by the body
- Who could benefit from the study drug
- Why some people have adverse events

The results of the tests done on your blood and stool samples (also called biologic sample(s)) will not be given to you or your study doctor. Information from these tests may be printed in a medical journal or presented at scientific meetings. Only a summary of data from all subjects will be used.

The results of this research may lead to an approved product for the treatment, prevention, or confirmation of disease. You understand and agree that by consenting to the storage and testing of your samples for possible future research, you authorize the use of your sample, the by-products of the sample, and any products developed from the sample as described by this form. The study sponsor, other researchers, or companies may patent or sell discoveries that result from this research. You will not be paid any money if this happens.

If you decide you no longer want to take part in this future testing of your biologic sample(s), your unused sample(s) will be destroyed. The study sponsor may continue to use and disclose the results from samples that were tested before you withdrew your consent.

If you decide to no longer take part in the main study or are taken off the main study by your study doctor, the biologic samples you provided for future research will still be kept and may be used for future testing. If you decide you no longer want to take part in this future testing, then your unused sample(s) will be destroyed. You may request that your stored samples be destroyed at any time by writing to the study doctor at the address listed on page one of this form.

For this study, you are being asked to let the study sponsor store and use the samples listed below for future testing.

Carefully read the sentences below and think about your choice.
Check the 'Yes' or 'No' box and initial next to your choice.

Store and use your leftover blood and stool samples collected during this study for future research outside of the main study. Your samples may be stored and used for up to 15 years after the end of the study.

I agree to allow my leftover biologic samples to be stored after the main study testing is complete and used for future research outside of the main study.

☐ Yes_____ (initial) ☐ No _____ (initial)

Optional Genomic Research

As an optional part of this study, you are being asked to allow the study sponsor to collect, store and use your blood sample for genomic research. Genomics is the study of genes (factors inherited from our parents and how they work). Your sample may be stored and used for this research for up to 15 years after the end of the study. The blood sample will be stored in a secure laboratory. The optional genomic research may help scientists to understand better the nature of your disease and related diseases and/or the effect of the study drug and/or other medications on people's bodies. The results of this research on your sample will not be given to you or your study doctor. Information from this research may be published in a medical journal or presented at scientific meetings, so that other doctors can find out about the results. However, your individual results will not be revealed to anyone and only aggregate results will be used for these publications.

The sponsor and other researchers who may study your biological sample may derive economic benefit by developing new drugs and medical tests. The results of this research may lead to a commercial product for the diagnosis, cure, treatment, or prevention of disease. You understand and agree that by consenting to the storage and analysis of your sample for possible future research, you authorize the use of your sample, the by-products of the sample, and any products developed from the sample as described by this form. The sponsor or other researchers or diagnostic companies may patent discoveries that result from this research. You will not be paid any money if this happens.

If you participate in the optional genomic research, and your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data. This risk is minimized by protections described below.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

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

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

Withdrawing consent to the storage and future testing of your sample will result in destruction of your sample. However, if you withdraw your consent after the sample has been tested, the test results and research study/sample-related information must remain in any database(s) that were created for the research study. The reason for this is to comply with regulations that require the sponsor to make data available for review by the United States Food and Drug Administration (FDA) or other appropriate regulatory authorities, or if this research is used to support an application for FDA approval to market the study drug.

If you withdraw consent for participation in the main study or are discontinued from the main study, the biological sample you provided for optional genomic research will continue to be available for storage and future testing unless you also withdraw your consent for this purpose as stated above.

Please initial next to one of the statements below to indicate whether or not you agree to allow use of your sample for optional genomic research outside of the main research study.

Yes_____ *(initial)* I agree to allow my blood sample to be used for optional genomic research outside of the main research study

No_____ *(initial)* I don't agree to allow my blood sample to be used for optional genomic research outside of the main research study