SUBJECT INFORMATION & INFORMED CONSENT FORM

Study Title:	Open label exploratory phase IIa trial to investigate the safety and efficacy of IFX-1 in treating Subjects with Pyoderma Gangrenosum (OPTIMA)
Short Title:	Exploratory study of IFX-1 in Pyoderma Gangrenosum
Study No.:	IFX-1-P.2.7
Sponsor:	InflaRx, Winzerlaer Strasse 2, 07745 Jena, Germany
Investigator:	Dr. Afsaneh Alavi
Address:	[redacted]
Telephone Number:	[redacted]

INTRODUCTION

You are invited to participate in a drug research study for pyoderma gangrenosum. Participation in this study is voluntary (your choice). If you join this study, you can stop at any time. You have the right not to sign this consent form. If you do not sign, you cannot take part in this research study. If you decide to participate, you will be asked to sign and date at the end of this form.

Please read the following information carefully. It contains important information to help you decide whether to participate in this research study. The study staff will have a detailed interview with you to inform you about the study and the possible benefits and risks of your participation. Ask questions about anything that is not clear at any time.

You may take home an unsigned copy of this information to think about and discuss with your family, friends or family doctor before you make your decision to participate or not.

For your information, this study is being paid for by InflaRx and the study doctor is paid by the sponsor to conduct this study.

WHAT IS A RESEARCH STUDY?

A research study is an experiment whose purpose is to answer specific questions, such as:

- Does this drug work? Is it safe?
- What kind of treatment is better?

Being in this study does not replace your regular medical care.

WHY HAVE YOU BEEN INVITED TO TAKE PART IN THIS STUDY?

You have been invited to take part in this study because you have been diagnosed with an ulcerative form of pyoderma gangrenosum.

Pyoderma gangrenosum is a rare skin condition that causes painful ulcers (open sores). It is usually treatable but could take some time to heal and may leave some scarring. Pyoderma gangrenosum usually appears suddenly as either a small pimple, red bump or blood blister. The reaction may sometimes be triggered by minor skin damage or an injury – for example, it may develop around a wound, a needle prick, or an insect bite.

The skin then breaks down into a painful ulcer with a purple or blue edge that may ooze fluid. The ulcer can grow quickly and several ulcers may develop in the area. If the ulcer gets infected, patients also feel unwell and develop a high temperature (fever). Pyoderma gangrenosum usually occurs on the legs, although it can affect any area of skin. It sometimes develops around an injury or surgical wound.

The exact cause of pyoderma gangrenosum is not understood, but it's thought to be a reaction to a disease or illness. However, many people have no related condition and there is no obvious reason for it.

When the affected skin tissue is tested, it usually has a high concentration of neutrophils (white blood cells), which are a sign of inflammation. In pyoderma gangrenosum, the body appears to have an overactive inflammatory system. This means pyoderma gangrenosum may be related to over activity of the immune system.

WHAT MEDICATION IS BEING TESTED?

IFX-1 is an antibody that is being developed for the treatment of various diseases in which an overactive inflammatory system plays a role. It blocks certain pathways in the activation of inflammation. This treatment is administered via intravenous infusions.

IFX-1 has not been approved as a treatment for any disease in any country and it is not available to people who are not participating in research studies like this one. Thus, its use in this research study is considered experimental.

WHAT IS THE PURPOSE OF THE STUDY?

The overall purpose of this study is to assess the safety, tolerability and effectiveness of different doses of IFX-1 in subjects with the ulcerative form of pyoderma gangrenosum over an extended period of time.

In addition, this study will investigate some additional scientific measures that may give an insight into how the drug is working.

The study will also investigate antibodies produced by your body in response to the study drug and their effect on its effectiveness and safety.

HOW MANY PATIENTS WILL TAKE PART IN THE STUDY?

This study is being conducted in a few research centers in Canada (and potentially the USA) and is expected to enroll approximately 18 subjects.

HOW LONG WILL YOU BE IN THE STUDY?

If you decide to participate in this study, your participation in this study is anticipated to be approximately 9 months.

The study will consist of a visit for screening, then about [redacted] to [redacted] weeks later you will be started on the intravenous infusions of IFX-1. You need to return [redacted] times at [redacted] days, and then every 2 weeks for further infusions. At the end of the study, there will be 2 further visits after 30 days and 60 days to see how you are getting on.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to sign this informed consent form before any study-related procedures are performed. A flow chart summarizing the study procedures can be found at the end of this section.

An overview of what is done at each study visit is given below.

Screening Visit (Visit is expected to take approximately 3 hours)

The screening visit will be performed to see if you are suitable for the study. If you agree to be in this study, the following tests and evaluations will be performed at this visit. Depending on when your last visit to the doctor was, you may not need to have all of the following procedures performed:

- Review criteria to see if you qualify.
- Demographics – your date of birth, gender, race, ethnicity, and disease status.

- Review of your health and all medications (including prescription, over the counter, and herbal remedies) you are currently taking.
- Complete physical examination including measurement of vital signs (blood pressure, pulse rate, breathing rate and body temperature).
- Your weight will be measured.
- An ECG (electrocardiogram), a test of the electrical activity of your heart will be performed.
- A chest X-ray will be performed (unless a recent one is available) to see if you have any problems with you lungs such as tuberculosis.
- A test for tuberculosis will be performed to check to see if you have tuberculosis.
- Blood and urine samples will be collected for safety laboratory testing (i.e, liver or kidney function).
- If you are a woman who can have a child, a pregnancy test on a blood sample will be performed. Results of the pregnancy test must be negative for you to participate in this study.
- Blood samples will be also taken to check if you have AIDS or hepatitis. A positive HIV or Hepatitis test result will be reported to health authorities as required by local law and you may be referred to public health for counseling.
- The severity of your pyoderma gangrenosum will be evaluated visually by the study doctor using different clinical assessments.
- A digital colour photograph of one of your ulcers will be taken. Any identifying features will be blurred or covered, your face will not be shown and people who see the photographs will not be able to recognise you. The purpose of the photograph is to show your pyoderma gangrenosum before and after the trial treatment, and how it may be changing during the trial.
- You will be asked to complete a questionnaire about your overall health and quality of life.
- The ulcer will be dressed using a standard dressing and compression.

Visit V1 (Visit is expected to take approximately 3 hours)

At visit V1 it will be confirmed that you are suitable for the study. The following tests and evaluations will be performed at Visit V1:

- If there are any updates or new information for your medical history, this information will be collected.
- Review of your health and all medications you are currently taking.
- You will be asked to complete a questionnaire about your overall health and quality of life.
- Complete physical examination including measurement of vital signs (blood pressure, pulse rate, breathing rate and body temperature).

- Your weight will be measured.
- An ECG will be performed.
- As applicable, a urine pregnancy test will be performed.
- A stool sample will be given for scientific evaluation.
- You will be questioned about any changes to your health and side-effects (adverse events) that might have occurred since the last visit.
- The photograph of the ulcer will be repeated.
- A small sample of tissue will be cut from your ulcer (biopsy). The biopsy site will first be carefully cleaned and disinfected. A local anaesthetic will then be injected just under your skin, using a thin needle, so that you will not feel any pain during the biopsy procedure. The injection may cause a burning and painful feeling for a few seconds. The biopsy will then be taken using a 4.5 mm hollow needle (biopsy punch). Some bleeding is to be expected. The wound will be closed with a single stitch, if necessary, and bandaged. If a stitch is used, it will be removed at your next trial visit. When the wound is completely healed, only a thin scar, maximum 2 mm long, is likely to visible on the skin.
  The purpose of the skin biopsy is to assess and describe the pyoderma gangrenosum of your lesions.
- A stool sample will be collected to look at various aspects of the inflammatory process.
- If your ulcer is draining fluid, some fluid will be collected from your ulcer to look at various aspects of the inflammatory process.
- The ulcer (open sore) will be dressed using a standard dressing and compression.
- Blood samples will be also taken to look at various aspects of the inflammatory process, to see if your body is producing antibodies against IFX-1.
- The first dose of IFX-1 will be given into a vein over 30 to 60 minutes.
- You will be observed for about 30 minutes following the infusion for any reaction to the study drug.

Treatment Period (Visit V2 to Visit V15 and End of Treatment (EOT) Visit) (Visits expected to take approximately up to 3 hours)

The following tests and evaluations will be performed at each of the above planned study visits during the treatment period:

- Review of your health and all medications you are currently taking.
- Measurement of vital signs.
- Assessments of the ulcer will be made.
- A photograph of the ulcer will be taken.

- You will be questioned about any changes in your health or side-effects (adverse events) that might have occurred since the last visit.
- The ulcer will be dressed using a standard dressing and compression.
- IFX-1 will be given into a vein over 30 to 60 minutes (except for Visit EOT).
- At Visit V2 you will be observed for about 30 minutes following the infusion for any reaction to the study drug.
- Pregnancy tests (either urine or blood) will be performed every 4 weeks.

At Visits V4, V6, V10, and EOT the following tests and evaluations will also be performed:

- You will be asked to complete a questionnaire about your overall health and quality of life.
- If your ulcer is draining fluid, some fluid will be collected from your ulcer for scientific evaluations.
- Blood and urine samples will be collected for safety laboratory testing (side-effects that can be tested in your blood/urine).
- Blood will be taken to measure the concentration of IFX-1.
- Blood samples will be also taken for scientific evaluations.
- A stool sample will be given for scientific evaluation.

At Visit V10 and EOT the following tests and evaluations will also be performed:

- Complete physical examination including measurement of vital signs (blood pressure, pulse rate, breathing rate and body temperature).
- Your weight will be measured.

At Visit EOT the following evaluation will also be performed:

- ECG (electrocardiogram).

At Visit V7, the dose of IFX-1 may be increased by the investigator.

Follow-Up Period (Visits expected to take approximately 1 – 2 hours)

You will also return to the study clinic 30 days and 60 days after the last dose of study medication for the 2 observation visits. These will be your last visits.

The following procedures (see flow chart) will be performed during the follow-up period:

- Review of your health and all medications you are currently taking.
- You will be asked to complete a questionnaire about your overall health and quality of life.
- Complete physical examination including measurement of vital signs (blood pressure, pulse rate, breathing rate and body temperature).

- Your weight will be measured.
- Assessments of the ulcer will be made.
- A photograph of the ulcer will be taken.
- Pregnancy test (either urine or blood).
- Blood and urine samples will be collected for safety laboratory testing.
- Blood will be taken to measure the concentration of IFX-1.
- Blood samples will be also taken for scientific evaluations.
- The ulcer will be dressed using a standard dressing and compression.
- You will be questioned about any changes to your health or side-effects (adverse events) that might have occurred since the last visit.

STUDY FLOW CHART

Visit	Screening	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	EOT	Ob1	Ob2
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Informed consent	X																		
Demographics	X																		
Medical History	X																		
Prior/concomitant therapy	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Physical Examination	X	X									X						X		X
Body weight	X	X									X						X		X
Vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Quality of life questionnaire	X	X			X		X				X						X		X
Pyoderma gangrenosum assessments		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Photograph of ulcer	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Ulcer biopsy		X																	
Collection of ulcer fluid		X			X		X				X						X		
12 lead ECG	X	X															X		
Chest X-ray	X																		
Safety laboratory blood tests	X				X		X				X						X		X
HIV and hepatitis serology	X																		
Tuberculosis test	X																		
Pregnancy test	X	X			X		X		X		X		X		X		X		X
IFX-1 concentrations					X		X				X						X	X	X
Immunology Blood		X			X		X				X						X	X	X
Urinalysis	X				X		X				X						X		X
Stool sample		X			X		X				X						X		
Tolerability and adverse event assessment	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Standard dressing and compression therapy	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
IFX-1 administration		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Possible dose increase								X											

Unscheduled visits

At any time during the study, your study doctor may ask you to attend the study clinic to repeat any of the above tests if he/she feels it is necessary for your safety and well-being. In some cases, it may be necessary to take additional blood samples (e.g., for safety tests). If this occurs, the total blood volume taken may be increased.

How much blood will be taken from you during the study?

The total amount of blood taken from you will not exceed [redacted] mL (about [redacted] tablespoons). This is about half of the amount of blood taken if you donate blood. The maximum at any single visit will be 75 mL (about 5 tablespoons).

WHAT HAPPENS IF YOU STOP THE STUDY EARLY?

If you stop taking the study medication early and you cannot or will not continue in the study, you will be asked to return for an End of Treatment (EOT) visit. If you decide to stop the study during a planned study visit, you will have the End of Treatment (EOT) visit instead of your planned visit. You will have the applicable procedures listed above for the Follow-up Period performed for your EOT visit.

WHAT WILL YOU HAVE TO DO?

In order for this study to provide good information about how the study drug works in subjects with your condition, you will be expected to do the following:

- Attend all study visits and have any assessments scheduled (as documented above). Missing scheduled study visits and/or injections may lead to invalid research data and you may be discontinued from the study and unable to receive any more treatments.
- Tell the study doctor if you experience any side effects or any health problems, even if you do not know if it is related to the study.
- Tell the study doctor about any therapies you are currently taking, including over the counter medications, herbal or alternative remedies, and if you have any changes in or start any new medications. Any drug interactions need to be documented.
- Follow the directions of the study doctor and study team, including use of appropriate birth control.
- If you are a woman of childbearing potential you must agree to use highly effective methods of contraception as discussed with your study doctor.
- If you are a man and you have a female partner who is able to have children, you must accept to use contraception (condom), as discussed with your study doctor.
- Carry your subject card with you as long as you are in the study and show it to any medical staff that may be involved in your healthcare.

- Refrain from participating in other research studies while you are in this study.
- Tell the study doctor or study team if you wish to stop being in the study.

WHAT ARE THE POSSIBLE ADVANTAGES/BENEFITS, AND POSSIBLE DISADVANTAGES, RISKS OR DISCOMFORTS OF TAKING PART IN THIS STUDY?

You may or may not receive a direct health benefit from participating in this study. It is possible that the symptoms of your condition will not improve during the study or may even worsen.

The ability of IFX-1 to treat your pyoderma gangrenosum ulcers has not yet been demonstrated. It is important for you to understand that your condition may improve, remain the same, or worsen.

Treatment with this study drug may also involve risks to your future health that we currently don't know about.

Participating in a clinical research study involves some unforeseeable risks of side effects that could occur.

You will have the opportunity to discuss any questions you might have about the severity and frequency of risks and other potential discomforts. In addition to the side effects listed, there is always the risk of developing side effects which are not known at this time.

If you are not sure what the side effects described below are, ask your study doctor to explain them to you.

If you suffer any of these side effects (or any others not listed) or you think you are experiencing a side effect, during this study, please tell your study doctor immediately (see 'Who should I contact for more information?').

You will be monitored carefully to check for these risks. Your study participation may be stopped if any signs that the drug is harmful to you or other damage occurs. You need to tell your study doctor or a member of the study team immediately if you experience any side effects.

Any side effects or other health issues occurring during the study will be followed up by the study doctor.

The information we get from this study may help improve the treatment of people with the same condition in the future.

Study Drug Risks:

As of 01 November 2019, approximately [redacted] people ([redacted] healthy adults and [redacted] patients) have received IFX-1 in 5 other research studies. Based on the study data available, IFX-1 was well

tolerated when administered to healthy subjects and patients with hidradenitis suppurativa (also known as acne inversa) or other conditions.

Taking the study drug in this study may cause you to have one or more of the side effects as listed below.

The following side effects were reported as possibly related to IFX-1:

Common (may affect up to 1 in 10 people):

- impaired healing,
- headache.

Uncommon (may affect up to 1 in 100 people):

- leukocytosis (high level of white blood cells),
- atrial fibrillation (rapid and irregular heart beating),
- nausea,
- acute (severe and sudden) liver failure,
- liver damage,
- nasopharyngitis (common cold),
- C-reactive protein (unspecific inflammatory blood marker) level increased,
- blood pressure decreased,
- heart rate decreased,
- pulmonary embolism (blockade of a lung artery by a blood clot),
- hypertension (high blood pressure).

Risks related to how IFX-1 works:

The potential risks associated with IV administration of IFX-1 due to how it works include the following:

- There is a theoretical risk of an increased rate of infections with IFX-1. Current data do not suggest that subjects treated with IFX-1 are at significantly increased risk of infection, but it could happen.
- Meningitis can rapidly become life-threatening or fatal especially if not recognized and treated early. It happens when the lining that covers the brain and spinal cord (called the "meninges") gets inflamed or infected. If you experience any of the following symptoms, you should immediately call your study doctor. If you cannot reach your study doctor, go to an emergency department immediately:

Fever (but some people have a temperature that is lower than normal instead of a fever); headache; stiff neck; nausea or vomiting; acting confused, or being hard to wake up; having light bother a person's eyes; a rash that looks like red or purple spots on the skin that do not go away when touched; seizures (waves of abnormal electrical activity in the brain. They can make people pass out, or move or behave strangely).

- Development of anti-drug antibodies may result in lack of effectiveness or could lead to allergic reactions.
- Hypersensitivity (allergic) / Anaphylactic reactions: Because IFX-1 is an antibody/protein, a general risk for allergic reactions exists. An allergic reaction may cause symptoms such as rash, difficulty breathing, drop in blood pressure and if severe (called anaphylactic reaction), could be life threatening. Administration of IFX-1 in clinical Phase I and II studies has been associated with a low frequency of infusion-related reactions.
- Since IFX-1 works, in part, in the same way to an already approved medicine, eculizumab, some known side effects of eculizumab could also occur during treatment with IFX-1. These side effects include: leukopenia (decreased level of white blood cells), thrombocytopenia (decreased level of platelets in blood), anaphylactic reactions, diarrhea, vomiting, swelling, infusion-related reactions, chest discomfort, fever, and chills.

Allergic Reactions:

All drugs have a potential risk of an allergic reaction. Allergic reactions may vary from mild (rash, hives, itching) to severe reactions such as anaphylaxis (which may include difficulty breathing, swelling of the face or throat, low blood pressure, or loss of consciousness). A severe allergic reaction requires immediate medical treatment and could result in permanent disability or death. It is important to tell your study doctor about any past allergic reactions that you may have had to other drugs including antibody drugs (which are usually given by IV or injection under the skin).

If you seek medical care for a possible severe allergic reaction, please request the treating health care provider to contact the study physician.

Overdose

The consequences of an overdose with IFX-1 are not known

Infusion of study drug

It is possible that you may have an infusion-related reaction (e.g. local pain, swelling, reddening).

Blood Sampling

Blood draws may cause pain, bleeding, and/or bruising at the puncture site. Furthermore, there is a small risk of light-headedness and/or fainting. In rare cases, the puncture site can also become infected or nerves may be damaged, inducing long-lasting abnormal sensations (paresthesia), impaired sensation of touch and persistent pain. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Electrocardiogram (ECG)

Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used. To do the ECG, you will have pads placed on different parts of your chest. There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.

Ulcer biopsies

The injection of the local anaesthetic may cause a burning and a painful feeling for a few seconds. Some bleeding is to be expected. The biopsy may be painful.

Questions/Questionnaires

Answering the study doctor or study staff's questions and filling out questionnaires could lead you to feel uncomfortable or upset. Please tell the study doctor or study staff if you feel uncomfortable or upset at any time during your study visit. You have the right to refuse to answer any questions.

Blood pressure test (a measure of the pressure in your arteries as the heart pumps)

The squeezing of an inflated blood pressure cuff on your arm may be uncomfortable. It usually takes only a few seconds.

Women of childbearing potential

Currently we are not fully aware of the effects of the study drug on unborn babies, or pregnant or breastfeeding women. If you are pregnant, or may become pregnant, treatment with the study drug may lead to new, previously unknown, side effects that we currently don't know about and this may involve risks to you or your unborn baby. Because of this, women who can have children must have a negative pregnancy test at the start of the study. A serum or urine pregnancy test will be performed approximately monthly during the study.

If your partner is not sterilized (i.e. vasectomy), you must agree to use a highly effective method of contraception such as combined (estrogen and progesterone containing) hormonal contraception during the entire study participation and for at least one month after last administration of study drug.

Highly effective birth control includes:

- oral contraceptive pill (estrogen and progestogen containing or progestogen only)
- combined (estrogen and progestogen containing) vaginal hormone ring
- combined (estrogen and progestogen containing) hormone contraceptive transdermal patch
- progestogen only hormonal injections
- progestogen contraceptive implant in combination with intrauterine device (IUD), intrauterine hormone-releasing system (IUS) or bilateral tubal occlusion

A vasectomized partner is a highly effective contraception method provided that the partner is the sole male sexual partner of the woman of child-bearing potential and the absence of sperm has been confirmed. If not, an additional highly effective method of contraception should be used.

Sexual abstinence is accepted as highly effective method of contraception only if defined as refraining from heterosexual intercourse during the entire study participation and for at least one month after last administration of study drug, and if it is your preferred and usual lifestyle.

If you become pregnant during the study or within 1 month of you stopping the study drug or treatment, you should immediately tell the study doctor. You will be asked by the study doctor to monitor your pregnancy throughout, and until conclusion. Information will be collected if you give permission.

If you are currently breastfeeding, you cannot participate in the study.

As a precaution, please do not donate eggs during the entire study participation and for at least one month after last administration of study drug.

Men of childbearing potential

We do not know if taking the study drug will affect sperm. As a result, men who have not had a vasectomy must either (a) abstain from reproductive sexual intercourse or (b) use a condom during intercourse. These precautions should be taken during the entire study participation and for at least one month after last administration of study drug.

As a precaution, please do not donate sperm during the entire study participation and for at least one month after last administration of study drug.

WHAT HAPPENS IF YOU DO NOT TAKE PART IN THE STUDY?

Your participation in this study is voluntary. You do not have to be in this clinical study to receive treatment. If you choose not to participate in this study, there will be no negative consequences for the healthcare you receive, and your access to regular medical care will not be affected.

WHAT ALTERNATIVE TREATMENTS ARE AVAILABLE?

Most people with pyoderma gangrenosum need to take steroids, either applied to the ulcer or by mouth. Some people need to take immunosuppressants. for other conditions (an immunosuppressant is any drug or substance that suppresses the immune response). As pyoderma gangrenosum is thought to be caused by an overactive immune system, these may be able to reduce pain and help the ulcers to heal.

Your doctor can provide you with medical treatments for pyoderma gangrenosum, which includes, but is not limited to:

- Corticosteroids. These drugs may be applied to the skin, injected into the wound or taken by mouth (prednisone). Using corticosteroids for a long time or in high doses may cause serious side effects. Because of this your doctor may prescribe steroid-sparing (nonsteroidal) drugs if you need long-term treatment.
- Steroid-sparing drugs. An effective nonsteroidal drug is cyclosporine. Other options include mycophenolate (Cellcept), immunoglobulins, dapsone, infliximab (Remicade) and tacrolimus (Protopic), which is a calcineurin inhibitor. Depending on the type of drug used, it may be applied to the wounds, injected or taken by mouth.
- Pain medication. Depending on the extent of your wounds, you may benefit from pain medication, especially when dressings are being changed.
- In addition to applying medicine directly to your wounds, your doctor or wound care specialist will cover them with a non-sticky, moist (not wet or dry) dressing and, perhaps, an elasticized wrap. You may be asked to keep the affected area elevated.

Each of these alternative treatments have some benefits and some risks. Please talk to the study doctor about your options before you decide whether you will take part in this study. The study doctor will further discuss with you the risks and benefits of the alternative treatments.

WHAT IF NEW INFORMATION ABOUT THE STUDY BECOMES AVAILABLE?

Sometimes new information about the study is received. You will be told if any relevant new information becomes available that may affect your willingness to carry on taking part in the study. If this happens, your study doctor will contact you as soon as possible, and will discuss whether you should continue in the study. If you decide not to carry on, your study doctor will make arrangements for your care to continue. If you decide to continue in the study you may be asked to sign a new consent form.

Also, if new information becomes available, your study doctor may stop your participation without your consent. If this happens the reasons will be explained and arrangements made for your care to continue.

WILL YOU BE PAID FOR TAKING PART IN THIS STUDY?

There will be no cost to you for taking part in this study. You will be provided with all study drugs, examinations and medical care related to the study at no cost to you. [redacted] Reimbursement for travel is also possible. This will be paid upon study completion or discontinuation or per visit, whichever you choose. Your study doctor will explain this in more detail, including the method and frequency of reimbursement payments.

COMPENSATION FOR RESEARCH RELATED INJURIES

You may experience bad or harmful reactions or other injuries resulting from the study drug or a study procedure. The Sponsor will pay for the cost of medical treatment for any injury that is due to

treatment with the study drug or study procedure (that has been used as described in the study protocol) that are not covered by the public health care system.

Any compensation payable for any injury caused to you by taking part in this study will be in line with local guidelines. The Sponsor will not compensate you where the injury has happened because a procedure has been carried out that is not in line with the study protocol or where the study doctor has not acted with the care or skill that is expected. .

The Sponsor has taken out an insurance policy to cover compensation for any personal injury resulting from your taking the study drug, provided such personal injury is not due to fault or carelessness of the study doctor or his team.

If you have medical insurance please check with your insurance company that taking part in this study will not affect your policy.

You will not lose any of your legal rights or release the sponsor, the study doctor, or the research team from liability for mistakes or intentional misconduct by signing this consent document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

WILL YOUR TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL AND HOW WILL YOUR PERSONAL INFORMATION BE USED?

This confidentiality section describes your rights and explains how your personal health information will be collected, used, and disclosed.

To help answer the research questions, the study doctor and research team will collect certain personal health information about you from your original medical records and any data resulting from your participation in this study. Your personal health information will be collected, used and shared with others as explained in this section. If you don’t give this permission, you will not be able to participate in the study.

The following are examples of personal health information that may be collected:

- your name, address, telephone number, date of birth, medical record numbers and/or other identifying information.
- results of tests and procedures such as physical examination details, as well as the results of any blood testing, x-rays, other medical procedures or tissue sample testing.
- your biological samples.
- information about your medical conditions and history including dates relating to various medical procedures.
- photographs of your ulcers. You will not be able to be identified by these photographs as only the affected skin will be photographed. Tattoos or other identified marks will be

removed in photos to protect your identity. The photographs may be additionally used for the following purposes:

- as part of scientific presentations to other researchers.

- to be published in scientific books or journals.

- as part of training materials for training and education purposes.

If anyone uses the photographs in scientific meetings, journals, books or similar, or for training purposes, you will not be paid. The sponsor will own the rights to the photographs.

Your identity will be protected to the extent possible, and your name will never be used if the photographs are published or shared with researchers or the general public. Please ask the trial staff if you would like to know more about how your information will be protected while you are participating in this trial.

By signing this document, you are allowing InflaRx and anyone working on its behalf, the study doctor and his/her representatives, the research team, Research Review Board Inc. (the ethics committee that reviewed the ethical aspects of this study), and organizations that regulate research in Canada or other countries (such as the Food and Drug Administration [FDA] and the Health Products and Food Branch of Health Canada) to have access to your identifiable personal health information at the study site to verify that the data is correct and check that the study is being conducted properly.

Your study records, biological samples and accompanying data will receive a unique code in place of information that can be used to identify you (such as your name or address).

The sponsor will not be able to link the assigned code number with your identity.

Your coded study records, samples and accompanying data will be transferred, stored and processed by the sponsor and anyone working on its behalf and the people and companies that it works with on the study, the ethics committee and/or organizations that regulate research. These organizations may be located outside of Canada, such as the United States, where data protection requirements may be less restrictive than in Canada. Once such coded information is transferred outside of Canada, it will be subject to the laws of that country where it is stored. That country may have laws that require that such coded information be disclosed to the government under different circumstances than would your country of residence.

Recognizing that your privacy is important to you, the study doctor, the sponsor and anyone working on their behalf employs technical security measures to protect your personal information. The study doctor, the sponsor and anyone working on their behalf will take all reasonable steps to keep secure any personal information they hold about you against loss or theft, as well as unauthorized access, use, copying, modification, disclosure or disposal, and to keep this information accurate and up to date. Your study records, including confidential information about you collected during the study will be kept in a secure location.

After this study has been completed, it is possible that your coded health information may be used by the sponsor and/or people or companies working with the sponsor for further research relating to the study drug, your disease or similar diseases and medical conditions.

Your personal health information will be kept as confidential as possible. If the results of the study are used or published in a study report or scientific presentation, your identity will remain confidential. By signing this informed consent form, you give permission for the collection, use and disclosure of your personal health information as described in this form or as permitted by law.

Access to your personal health information begins as soon as you sign this form. Your personal health information will be kept for a minimum of 25 years, as required by Canadian law.

You have the right to see and get a copy of your study records, subject to certain exceptions prescribed by law. However, by signing this informed consent, you agree that you may not get to see your records until after the study is over if this would impact the integrity of the study.

With your permission, your primary care physician/family physician/other physicians may be informed if you agree to be in this study. If you grant permission the study doctor may contact your other physicians to obtain medical records.

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.

WHAT WILL HAPPEN TO ANY SAMPLES YOU GIVE?

As part of this study we are obtaining blood samples from you. They will be sent to central laboratories for analysis. They will only be used for tests and exams listed in this consent form. Additional blood samples collected for Anti-Drug Antibodies and for Biomarkers assessments will also be stored for possible future analysis for up to 20 years after the end of the study at InflaRx GmbH in Germany. These will include analyses directly related to this study.

Biomarkers are naturally occurring substances in the body which may affect how a disease responds to the study drug. Your blood samples may be analyzed for different types of biomarkers: proteins, peptides (pieces of proteins), or other types of factors like lipids (fat molecules) that could help predict how Pyoderma Gangrenosum disease develops or help understand why the disease may be more severe and how it responds to IFX-1. They may also be used for the development of diagnostic tests related to IFX-1.

To protect your privacy, your samples will be labeled only with your study number and will be stored securely and confidentially. No genetic testing will be performed on your samples.

WHAT HAPPENS IF INFLARX WANTS TO PERFORM OTHER TESTS ON YOUR BLOOD SAMPLES AT A LATER TIME?

Your permission will be required for carrying out any new analysis on the samples not connected to this study – you will be asked to agree in this consent form to allow further use of the samples. You have the right to refuse. This refusal will not stop your taking part in this study.

These blood samples will be stored for possible future analysis for up to 20 years after the end of the study at a suitable storage facility.

You can withdraw your consent for your samples to be used for future analyses. In this case your samples will be destroyed only after they are no longer needed for the main study. You would need to tell your study doctor that you are withdrawing your consent for your samples to be used for future analyses. This can be done at any time, for any reason. This will not affect your access to the care, medicine, and equipment you would otherwise be getting. Your study doctor will then tell the sponsor to destroy all your samples when they are no longer needed for the main study.

If you withdraw your consent for samples to be kept and used after the study is over, it is possible that your study doctor may have already discarded the medical records that link your name to your study number. In this case, your samples would no longer be linked to you. It would not be possible to find your samples to destroy them.

WHAT HAPPENS TO YOUR SAMPLES IF YOU WITHDRAW FROM THE STUDY?

If you withdraw from the study, the samples and data collected prior to your withdrawal will still be used to assess the objectives of the study, to guarantee that your personal interests are not negatively affected, and to comply with the requirement to provide complete documentation when seeking marketing authorization.

WHAT WILL HAPPEN IF YOU DON'T WANT TO CARRY ON WITH THE STUDY OR THE YOU ARE WITHDRAWN?

Participation in the study is voluntary. You may refuse to participate in this study, and if you decide to participate you may stop at any time without further explanation. This will not affect your future treatment or your relationship with your study doctor. If you stop taking part, please tell your study doctor immediately. You will be asked to return to the study center for an end-of-study assessment

If you take back your permission to collect, use, or disclose your personal information, you will be withdrawn from the study. If you want to stop participating in the study for any reason or want to take back your permission to collect, use or disclose your personal information, you must let the study doctor know.

The study may be stopped early by the sponsor, the study doctor, Research Review Board Inc., or organizations that regulate research in Canada or other countries. Under certain circumstances, your study doctor might decide to stop your study drug or study participation early without your consent when, in the study doctor's judgment, it is in your best health interest to do so or under certain circumstances listed below:

- Your condition worsens or does not improve and an alternative treatment is medically indicated.
- The study treatment or procedures are found to be unsafe or ineffective.
- Your inability to take the study drug / participate as instructed.
- Cancellation by the sponsor or regulatory authority (e.g., if new side effects become known that preclude continuation of the clinical study).
- The study is stopped by the Research Review Board Inc. (RRB) (a group of people who review the research to protect your rights) or by a regulatory agency (such as Health Canada).
- Or for other unforeseen reasons that make it necessary to stop your participation in the study.
- If you are removed from the study, the study doctor will explain to you why you were removed.

If you withdraw or are withdrawn from the study:

- You can't continue in the study.
- We will stop collecting new information from you, except for long term follow up as may be described in this consent form or pregnancy follow up as described above in the event you become pregnant during the study, but will still use and disclose information that we gathered while you were a participant in the study.
- There will not be any penalty or loss of benefits to which you are otherwise entitled.

If you are withdrawn from the study because you become pregnant, with your permission we will continue to follow up and collect information about your pregnancy, as described in this consent form. If you do not want to be contacted by your study doctor or have your medical records reviewed to collect information on your pregnancy after you have stopped participation in the study, you should inform your study doctor about this when you are withdrawn from the study.

WHAT IF YOU HAVE QUESTIONS AND WHO SHOULD YOU CONTACT FOR MORE INFORMATION?

If you have any questions about your rights as a study patient, please contact your family doctor, lawyer, or the committee that reviewed the ethical aspects of this study:

[redacted]

The Research Review Board (RRB) Inc. is a group of people who review research studies to protect the rights and welfare of research subjects and is not affiliated with the study doctor or the sponsor.

If you have any questions concerning your participation in this study, or if at any time you feel you have experienced a research-related injury or reaction to the study drug, you may contact:

Dr. Afsaneh Alavi [redacted]

In case of an emergency, you may contact Dr. Alavi at the above phone number or go to the nearest hospital emergency department.

CONSENT FORM

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject.

You are also authorizing study staff to use and disclose your health information for study purposes. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive.

Do you give your permission to the study doctor to inform your family doctor of your participation in this clinical research study?	□ YES □ NO	Patient to initial
Do you give your permission for your stored blood samples to be used for future research as described in the section "What happens if InflaRx wants to perform other tests on my blood samples at a later time"?	□ YES □ NO	Patient to initial

Your continued participation should be as informed as your initial consent. You will be informed in a timely manner if information becomes available that may affect your willingness to continue participating in this study. You should also feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact the study doctor or study staff.

You will receive a copy of this signed and dated informed consent form.

Signature of Participant	Name (printed)	Date (dd/mmm/yy)*
Signature of Person Conducting Consent Discussion	Name (printed)	Date (dd/mmm/yy)*

If applicable per ICH Guideline Section 4.8.9:

Signature of Witness	Name (printed)	Date (dd/mmm/yy)*

*PLEASE PERSONALLY DATE YOUR SIGNATURE

INVESTIGATOR'S STATEMENT

I, or a member of my research staff, have carefully explained to the subject the nature and purpose of the above study. The subject signing this form has been given enough time and an adequate place to read and review this form. The subject has had an opportunity to ask questions and receive answers regarding the nature, risks, and benefits of participation in this research study. The subject appears to understand the nature and purpose of the study and the demands required of participation.

Signature of Investigator	Name (printed)	Date (dd/mmm/yy)