Subject Information and Informed Consent Form

Sponsor:	Janssen Biotech Inc 800 Ridgeview Drive Horsham PA 19044
Protocol Number:	CNTO148UCO4001
Protocol Title:	An Observational Prospective Long-term Exposure Registry of Adult Patients with Moderate-to-Severe Ulcerative Colitis
Simplified Title:	OPAL
Study Doctor:	Satinder Gill, M.D.
Telephone:	(703) 723-3670 (24 Hours)
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Please read this document carefully

You are invited to be in an observational study because you have ulcerative colitis and take Simponi or thiopurines. Taking part in an observational study is voluntary. An observational study is a type of study where your health is observed over time in order to collect information on your ulcerative colitis. Before you decide, you should know why the study is being done and what it involves. Please read this form carefully and take your time to decide. Ask your doctor (or his or her staff) any questions you may have. You may take an unsigned copy of this form

home with you to read again. Take your time to think and talk about it with your family and friends before making your decision.

Why is this study being done?

The purpose of this observational study is to collect information about certain safety events in subjects with ulcerative colitis.

About 6000 subjects will take part in this worldwide study.

Your participation will start when you have signed this informed consent form and if your doctor decides you are eligible.

If you are in another research study, please discuss with your doctor. Your doctor will let you know if you can also be in this study.

If you want to take part in another study, please inform your doctor.

The Study Doctor is doing this study for the sponsor.

An independent ethics committee or institutional review board has reviewed the study.

What happens during the study?

Your doctor will consult your patient file to see if you are a good match for this study.

The most appropriate treatment for your condition was chosen by your doctor. Your doctor will continue to make treatment decisions. This study will not influence how your doctor chooses to treat your condition.

If you agree to participate, before any study related procedures or information is collected, you will be asked to review and sign this informed consent.

While you are in this study, you will continue to be routinely followed by your doctor, in accordance with the normal course of your care. At each follow-up visit, your doctor will collect information concerning your health, disease and medications you are taking.

You are being asked to participate in this study for 10 years.

This study does not require any specific testing or additional visits, but your doctor may capture medical information that is collected as part of your normal care. This study does not change the way in which your doctor delivers your care.

What do I have to do?

While you are in the study you should:

- Tell your doctor if you have been sick or about any changes to your health.
- Tell your doctor if you become pregnant (information on your pregnancy and the outcome of the pregnancy will be requested).

- Inform your doctor of any changes in your medications.
- Complete a diary to record ulcerative colitis related symptoms.
- Complete surveys about your quality of life and health care use.
- Inform your doctor if you want to take part in any other medical research studies.
- Be willing for the sponsor's representative and if required the sponsor's auditor(s), and regulatory or ethics authorities, to be granted direct access to your original medical records for verification of your study data, without violating confidentiality.

What are the possible risks and inconveniences of being in the observational study?

There are no additional tests performed while enrolled in this observational study; however, your doctor may capture results of testing performed for your normal clinical care. The risk of this study is the potential loss of confidentiality of your private medical information. The sponsor will take steps to protect against this risk as described below.

This study is designed to collect information and does not require your doctor to change treatments or therapies beyond what you already receive for your normal care. Any change in your treatment is a decision made by your doctor that is not related to your taking part in this study.

What are the benefits of being in the study?

You will not personally benefit from taking part in this study; however, it is possible that the results of this study may help future patients.

What if something goes wrong?

You will not receive any additional medication, treatment, or undergo any medical procedures as a result of your participation in this study. Accordingly, you will not experience study-related injuries from participating in this observational study. If you become ill while participating in this study, you should contact your doctor. If any new information about this study becomes available that may affect your decision to continue your participation, you will be informed as soon as possible.

You do not give up any legal rights by signing this consent form.

Who pays for this study?

The sponsor will pay the study doctor/clinic for doing this study.

Will I be paid?

The sponsor will not pay for your doctor visits, or other medication or tests. The sponsor will not provide your ulcerative colitis medication. Therefore, you will not receive ulcerative colitis medication free of charge.

You will be compensated for your extra time during your visits to your doctor in the total amount of $50 (for additional transportation/parking cost and for completing the study questionnaires) for each in office visit or $25 (for completing the study questionnaires) if the visit is performed by phone. You will be paid at the end of your participation in the research study.

What happens to the information collected about me?

A description of this observational study will be available on http://www.ClinicalTrials.gov. 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.

The personal information collected may be transmitted to countries outside your local or home country, such as the United States. In some instances, your local or home country may have determined that the country to which your information may be transmitted lacks adequate privacy laws. Nonetheless, Janssen and its affiliates and agents will apply adequate privacy safeguards to protect such personal information.

The following information explains how your medical and health records and the research data collected about you for the study may be used and disclosed.

Regulatory authorities, such as the Food and Drug Administration, as well as members of the ethics committee/institutional review board ("IRB"), employees at the study site and representatives of the Sponsor, Janssen, may review your medical records to verify study procedures and/or data. The Sponsor may also use your information for registration of the drug in different countries.

Your study doctor will keep your personal medical records and a list that links each subject's name to his or her code number for at least 5 years following the completion or termination of the study. Your study records, including confidential information about you collected during the study, will be kept at a secure location.

After your encoded Protected Health Information is disclosed to the Study Sponsor, the results of the study may be reanalyzed at a later date and may be combined with the results of other studies. The Study Sponsor and people who work with the Study Sponsor may use the results of this study for other research purposes, including:

- reviewing the safety or effectiveness of other products or therapies;
- evaluating other products or therapies for patients;
- developing a better understanding of disease;

If you are participating in a multi-site research study, your information may also be shared, if necessary, with researchers at associated sites for purposes of data analysis.

Some of this information, called Protected Health Information ("PHI"), is protected by federal privacy laws. By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. After the Study staff or the Study doctor discloses your PHI to others, it could be re-disclosed and no longer protected by federal privacy laws.

Your records will be kept by the Sponsor for as long as necessary. During that time they will be kept confidential to the extent permitted by law.

The results of the study may be published in a medical book or journal, or presented at meetings for educational purposes. If the results of the study are published, you will not be personally identified and your identity will not be disclosed.

By signing this form, you are permitting direct access to and use of your medical records and information by the individuals and entities identified above for the purposes described.

By signing this document, you also give permission to the study doctor to disclose the study results to the Sponsor and representatives of the Sponsor. The study results will not contain information that directly identifies you. The Sponsor will prevent those that do not need to access the results from viewing the results. The Sponsor will not attempt to identify the study subject. You do not have to sign this information and consent form, but if you do not, you will not be able to take part in this research study.

What if I change my mind and do not want my information used or disclosed?

The permission to use or disclose your protected health information for this study does not have an expiration date.

If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the study staff and/or the Study doctor at the address listed on the first page of this form.

If you cancel your permission after you have started in the study, the study staff and the Study doctor will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results.

Can I change my mind?

Your taking part in this study is voluntary. You do not have to be in this observational study. You can agree to be in the study now and change your mind later. You may stop your participation at any time. Your decision will not affect your normal care. It will not affect you getting all the normal care you should be getting.

Can I be removed from the study?

Your doctor has the right to take you out of the study at any time with or without your agreement. The sponsor has the right to direct your doctor to take you out of the study at any time with or without your agreement. The sponsor may decide to cancel the study.

What happens after the study is over or if I stop the study early?

Taking part in this study is voluntary. You may choose not to take part in the study, or choose to leave the study at any time. The quality of your medical care will not change should you decide not to take part in the study or if you decide to leave the study early.

If you decide to stop seeing your doctor or move to another city, every effort will be made to make sure you have an opportunity to continue taking part in this observational study. An attempt will be made to transfer your observational study responsibilities to another doctor participating in the observational study, in your new location. If this happens, you will have to sign another Informed Consent Form with the new doctor.

If you decide to stop seeing your study doctor or move to another city and if a new study doctor is not available in your area, you may choose to continue taking part in this study through 2 options:

- The **Direct to Health Care Provider (HCP)** process is available as an option to continue to collect data of interest for the study. This process can be managed by either your study doctor, another study doctor or by a HCP of your choice (Doctor, Nurse Practitioner, Physician's Assistant). The goal of the Direct to HCP process is to collect limited data about your health and medicines about once a year. It would be your decision to use or not use this option if you cannot see your study doctor.

- The **Direct to Patient Contact (DPC)** process is also available as another option to continue to collect information from you. This will be by direct contacts with you to obtain follow-up data for the rest of the duration of your participation in the study. The contact will focus on the information collection of any surgeries, hospitalizations, use of medication for your ulcerative colitis, etc. Thesecontacts will be performed by dedicated and trained staff from the sponsor's designee, ProClinica, specialized in direct contact with subjects in studies.

  In order to have your correct contact details, we would like to start collecting your contact details once you start your participation in the study and agree to these processes. If you agree, your study doctor will ask you to complete a Contact Order Form (COF). This form collects your contact details and those of extended family members/relatives and your HCP.

  The COF will be collected at your first visit and the information will be checked with you every year. You may also provide updates at any time during the study as needed. This will allow the sponsor's designee, ProClinica to be able to contact you and to obtain information from you when necessary. If you do not want to participate in these 2 processes, the COF would not be required.

  The contact details you provide on the COF will be sent to an independent unit of the sponsor's designee, ProClinica, and will be kept confidential. Any data that identifies you directly will not be shared outside of this dedicated unit nor used for any other purpose but the contacts for this study. The sponsor will not have access to your personal contact information. You will have the right at any time to request access and modification of your contact details.

To protect your privacy, your health data will be labeled with your study identification number without identifying you by name. Your contact details are never linked to your health data and will be erased at the end of the study from all data support systems (computer and paper).

Taking part in **Direct to Health Care Provider (HCP)** process or the **Direct to Patient Contact (DPC)** process is voluntary. You may choose not to take part in this process now or at any time during your participation in the study. Your decision will not impact your participation in the study.

If you decide to change your decision to participate or not participate in the **Direct to Health Care Provider (HCP)** process and/or **Direct to Patient Contact (DPC)** process, please contact your study doctor and/or sponsor's designee, ProClinica. Please see below for contact details in the "Who do I contact for information?" section. This will not impact your participation in the study.

If you decide to stop the study early, you agree not to limit our use of your study information. The sponsor will not collect any new information from you.

May we contact your other doctors?

We would like your permission to contact the doctors you see regularly to obtain additional information needed for the study. While you are in the study, the doctor will ask about your symptoms. If you have symptoms after the study ends or if you stop the study early your other doctors may want to contact the study staff.

Who do I contact for information?

If you have any questions about the study, please contact the study doctor or the study staff at the telephone number listed on the first page of this form

Please contact IRB Services, which is not affiliated with the research or the research team, if you have questions about your role and rights as a research participant, or have concerns, complaints or general questions about the research, by phone:
1-866-449-8591 or by email: subjectinquiries@irbservices.com

For any updates or changes related to the Direct to Health Care Provider (HCP) process and/or Direct to Patient Contact (DPC) process, please contact your study doctor or:

ProClinica:
Phone: 1-866-897-4888
Email: contact.na@proclinica.info

If you consent, please read and then sign below.

This consent form contains important information. It will help you decide if you want to take part in this study. If you still have questions, please ask your doctor, before signing this form.

Agreement to take part in the study

- I have read this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study have been answered to my satisfaction.
- Based on this information, I volunteer to take part in this study.

I have been informed that my doctor will inform my other doctors, if any, about my participation in this study, and I agree to this.

Yes ☐ No ☐ NA, I have no other doctors ☐

(Please check yes, no, or NA)

I have been informed about my participation in the Direct to Patient Contact (DPC) process and Direct to Health Care Provider (HCP) process, and I agree to these. I understand I have to complete a Contact Order Form (COF) to begin the Direct to Patient Contact (DPC) process and the Direct to Health Care Provider (HCP) process.

Yes ☐ No ☐

(Please check yes or no)

You will receive a copy of this signed Subject Information and Informed Consent Form.

_____

Printed Name of Subject, in full

_____

Signature of Subject Date (dd-MON-yyyy)

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date (dd-MON-yyyy)

At least one **impartial** witness is mandatory when the subject is unable to read or write. An **impartial** witness must be present during the entire informed consent discussion.

Impartial Witness Statement

I confirm that the information in the consent form was accurately explained to and apparently understood by the subject and that consent was freely given by the subject.

Printed Name of Impartial Witness, in full

Signature of Impartial Witness Date (dd-MON-yyyy)