



South African Gastroenterology Society

SOUTH AFRICAN INFLAMMATORY BOWEL DISEASE REGISTRY

PATIENT INFORMATION AND CONSENT

SPONSOR: SAGES

What is the purpose of the South African IBD Registry?

Many advancements in medicine have resulted from research involving the collection and analysis of the medical record information of patients with a certain disease or condition. Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel disease or IBD, are important, emerging health conditions in South Africa. The South African Gastroenterology Society is asking for your permission to allow us to place your past, current and future medical record information into the SA IBD Registry. By placing the medical record information of many patients such as you, into a research registry, researchers will be able to conduct research studies aimed at increasing our knowledge about ulcerative colitis and Crohn's disease in South Africa. Results of these studies could lead to better care for IBD patients in South Africa.

What will my participation in this IBD Registry involve?

If you agree to participate in the SA IBD Registry, your past, current and future medical record information will be placed into the Registry. This will permit research studies to be conducted on the medical record information contained within the registry.

What are the possible risks of my participation in the SA IBD Registry?

There are no risks of physical injury associated with your participation in the SA IBD Registry. Participation in this Registry does involve the possible risk that information about your health might become known to individuals other than your usual healthcare providers. We will attempt to preserve your medical record confidentiality by assigning a code number to your medical record information stored in the Registry, and by removing personal identifiers (for example, your name, address, contact details) from information stored about you in the Registry. Only the SA IBD Registry staff will have access to this information.

What are the possible benefits of my participation in the SA IBD Registry?

It is unlikely that you will receive any direct benefit as a result of your participation in the SA IBD Registry. However, medical record information contained within the Registry will be used for research studies directed at improving our knowledge and treatment of Crohn's disease and ulcerative colitis and this knowledge may benefit patients with these diseases in the future.

Will I or my medical aid be charged for my participation in the SA IBD Registry?

There will be no costs to you or your medical aid to participate in this Registry.

Will I be paid for my participation in the SA IBD Registry?

No, you will not receive any payment for participating in this Registry.

Who will know about my participation in the SA IBD Registry?

Information from your medical records that is placed into this Registry will be kept as confidential (private) as possible. In addition, you will not be identified by name in any publication of the results of research studies involving the use of your medical record information.

What is the nature of my medical record information that will be placed into the SA IBD Registry?

All of your past, current and future medical record information related to your IBD will be recorded into the Registry. Since medical conditions and treatments not related directly to your IBD may affect IBD and/or its treatment, it is likely that all of your existing and future medical record information will be placed in the registry. This information can be submitted personally, or obtained from your hospital or private healthcare provider's medical records.

Who will have access to my identifiable medical record information contained in the SA IBD Registry?

Access to your identifiable medical record information contained within this Registry will be limited to investigators and staff associated with SA IBD Registry. A current, complete listing of these individuals will be provided to you upon your written request.

For how long will my medical record information continue to be placed in the SA IBD Registry and for how long will this information be used for research purposes?

We will continue to place your medical record information into the SA IBD Registry until 1) you are no longer living; or 2) you withdraw your permission for participation in the Registry. Your medical record information contained within the Registry will be used for research purposes for an indefinite period of time.

Is my participation in the SA IBD Registry voluntary?

Your participation in the Registry, to include the use of your medical record information for the research purposes described above, is completely voluntary. Whether or not you provide your permission for participation in this Registry will have no effect on your current or future medical care.

May I withdraw, at a future date, my consent for participation in the SA IBD Registry?

You may withdraw, at any time, your consent for participation in the Registry, to include the additional collection of your medical record information and its further use for the research purposes described above. To formally withdraw your permission for participation in the Registry you should provide a written and dated notice of this decision.

Has the SA IBD Registry project been approved by an ethics committee?

The SA IBD Registry protocol has been approved by the University of Cape Town, Faculty of Health Sciences, Human Research Ethics Committee (Ref: R048/



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SAGES IBD REGISTRY

PATIENT CONSENT

STUDY TITLE: A Non-interventional Registry Study for Treatment with Biologic agents in patients with Moderate to Severe Active Inflammatory Bowel Disease (Ulcerative colitis and Crohn's disease): Long term outcome and Surveillance of adverse events.

PROTOCOL NUMBER: SAGESBIOL 001

SPONSOR: SAGES

I, _____ (insert full name), a patient of Dr _____ (insert initials and surname), with my ID number: _____, of address: _____ and Tel no: _____ and email address: _____,

Hereby confirm and acknowledge that:

Please ask if you are unsure about anything

- I have read and understood the patient information sheet provided for the above study and my inclusion in the SAGES registry. I understand the importance of this, and the implications of my information being included.
- My participation is voluntary and I am free to withdraw at any time, without my medical care or legal rights being affected.
- I agree that my information may be included into the SAGES biologics registry, irrespective of whether I am being treated with a biologic or not.
- I agree to participate in the above mentioned study and Registry and to complete the questionnaires and survey or assist the doctor in completing it.
- My treating doctor may provide the SAGES researchers with information that is relevant for the study and Registry, from my health records.
- I understand and agree that my data, as entered into the Registry, may be used for future studies and analysis, in the manner described on this form, in the interest of health information, health planning and in the ultimate interest of all patients with rheumatic diseases.

- I agree to my personal information to be held in a registry by SAGES and the data base administrator E2 solutions (or its successor), together with data that is collected during the study.
- I agree to and understand that no identifiable information will be released to any third party. My information may be included with those of other patients in a de-personalised format as part of research reports, articles, presentations and the like. I understand that this is for scientific purposes and advancing the understanding of the disease and its treatment.

Name of participant

Date

Signature

Name of Person taking consent

Date

Signature