

CONSENT TO ACT AS A PARTICIPANT IN THE SOUTH AFRICAN INFLAMMATORY BOWEL DISEASE REGISTRY

PRINCIPAL INVESTIGATOR: Dr D Epstein

CO-INVESTIGATORS: Complete, current listing available upon request

SOURCE OF SUPPORT: SA Gastroenterology Society

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: R048/2013)

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of my participation in the SA IBD Registry at any time, and that such future questions will be answered by the doctors associated with the SA IBD Registry or their research staff. I understand that a copy of this consent form will be given to me.

By signing below, I agree to participate in the SA IBD Registry.

Participant's (or guardian's) Signature

Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of the SA IBD Registry to the above-named individual, and I have discussed the possible risks and potential benefits of participation in this Registry. Any questions the individual has about this Registry have been answered, and the doctors and research staff associated with SA IBD Registry will be available to address future questions as they arise.

Name of Person Obtaining Consent

Signature of Person Obtaining

Consent Date