SAGES

South African Gastroenterology Society

CLINICIAN 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, the undersigned, Dr_____(full names and surname), Practice number _____Tel number _____
Fax no_____Email address _____
Practicing at _____ (address)
hereby agree -

1. To enrol patients with inflammatory bowel disease, who are agreeable and who have signed consent forms thereto, to the SAGES Biologics register.
2. To timeously submit all medically relevant patient information to SAGES.
3. To provide SAGES with all data required by the Registry, which may go beyond the initial submission of data relating to safety and serious adverse events.
4. That the notification of adverse event to SAGES will not exempt the gastroenterologist from the obligation of notifying the events to the usual drug monitoring authority and the company concerned.
5. That I understand that my information will be de-personalised and that it may only be used for research purposes and/or studies and/or internal analysis of SAGES. All original forms containing data will be stored safely and securely and destroyed after a reasonable period of time, as set by SAGES from time to time. Only the administrator of the registry and data capturers will have access to raw data and are bound by strict confidentiality and non-disclosure agreements.
6. That my outcomes will not be disclosed to third parties, but that the information may be used to evaluate the achievement of health outcomes overall. The use of the data for practitioner profiling is strictly prohibited.
7. To comply with all requirements of the Registry, and to submit data in a format that is complete, honest and not misleading in any manner or way, and to respond to all reasonable requests by registry staff in connection with the completeness and accuracy of the data submitted.

Signature: _____   Date: _____

Signature: _____   Date: _____
              On behalf of SAGES

Please ensure that SAGES has a copy of this consent and keep the original in a safe place in the practice for future reference.