

## SOUTH AFRICAN RHEUMATISM AND ARTHRITIS ASSOCIATION (SARAA) BIOLOGICS REGISTRY: TERMS AND CONDITIONS

### **Application of these terms and conditions**

1. By submitting information to the SARAA biologics registry practitioners agree to abide by these terms and conditions (Ts & Cs), which includes fulfilling certain duties, such as that to obtain written consent from patients, and adhere to certain rules (e.g. those on use of the database) diligently.
2. These Ts & Cs also apply to entities that buy and/or use, with SARAA permission, the dataset or selected parts thereof.
3. The SARAA Executive Committee may, from time to time, develop application forms for access to data from the database, and may determine fees to be paid by those wishing to access data from the Registry.

### **Data processing: Purpose of the SARAA biologics registry**

4. The SARAA biologics registry is a register of patient health information, which includes information on the use of biologic disease modifying anti rheumatic drugs (bDMARDs), the impact thereof, treatment outcomes and adverse events.
5. The SARAA biologics registry is a project of SARAA, which has been established in the public interest, and in particular, to:
  - 5.1. Collect data regarding biologics use, its safety and the effect thereof;
  - 5.2. Work with, publish, analyze and deal extensively with the data collected in order to establish, amongst others, health outcomes;
  - 5.3. Work with, publish, analyze and deal with the data collected in order **to make submissions** to relevant bodies, and to conduct **further research** using the database and to publish such research;
  - 5.4. Sell anonymised datasets, on application and subject to the payment of a fee, to researchers, pharmaceutical and medical device companies and other persons or entities with a legitimate interest in the broader trends recorded as part of the registry, which sale may be subjected to any condition deemed necessary by SARAA;
  - 5.5. Enhance the understanding of the use of biologics within the South African health sector;.
6. The use of the SARAA biologics registry for any purpose outside of what is listed in these Ts & Cs is strictly prohibited.

### **Data fields**

7. The SARAA biologics registry and the data fields are not a diagnostic or treatment tool, nor a recommendation to treat any patient in any particular manner, with any particular product or for any period.

### **Confidentiality**

8. The SARAA biologics registry will never release any identifiable information from any practitioners or any patient.
9. Participating healthcare professionals may access information that relates to themselves and their patients only. The data may not be used by any person, or entity, as a mechanism to conduct peer review or practice profiling.
10. The data submitted to the SARAA biologics registry, as well as the data subsequently included in the Registry are subject to strict confidentiality controls in line with the Protection of Personal Information Act, 2013. If practitioners keep copies of the data they have submitted, they take responsibility to keep such data sheets in the securest manner possible and subject to strict confidentiality.
11. Patient data as well as information pertaining to the treating practitioner will be de-identified on the registry.

### **Use and further use (refer Annexure A)**

12. Subject to terms and conditions relating to types of persons and/or entities who may access information contained in the registry, what types of information may be access and at what fees, qualifying third parties may be provided with reports relating to data contained in the registry.
13. Data use is limited to that which corresponds with the objectives of the registry. The registry and data from it may not be used for any commercial purpose, such as on-selling, promotion of or against any product, exclusion of products from funding protocols or rules, denial of care in individual patient cases, etc.
14. The registry may not be used for any commercial purpose whatsoever.
15. Permissible uses include data for internal company use; bona fide research projects, with due recognition to SARAA and the registry if the research is published; conference presentations; used by SARAA to protect and advance the rights of patients in terms of funding of care; refinement of what would be evidence-based medicine; etc. Permission may also be granted for the use of the SARAA logo on such presentations or publications.
16. Patients and consumers should not be granted access to the registry or any part thereof. In terms of the Promotion of Access to Information Act (PAIA) and the POPI Act, the patient or consumer is entitled to know what information is being kept on him/her and any such request must be made on the PAIA Requester form.

#### **Law and ethics**

17. The records stored by- and on the SARAA registry databases are health records like any other and constitutes the keeping of personal- and health information of both the doctor and patient. As such it is subject to the POPI Act, the National Health Act and the HPCSA Ethical Rules and policies on confidentiality.
18. It remains the duty of the practitioner to adhere to these legal- and ethical duties imposed on them by various laws and rules.

Each practitioner who participates in the registry agrees to ensure that patients or those authorized to provide consent, are sufficiently informed about the registry, its purposes and to obtain consent from such patients or informed persons before providing any information to the registry. A failure to do so will render the practitioner liable and may lead to the information submitted by the practitioner to be excluded, as such information would have been obtained unlawfully. Template information sheets and consent forms are available from the SARAA office and website.

#### **Data security and accuracy**

19. SARAA has taken care in ensuring that all data is stored in a secure manner and all reasonable precautions are being taken to ensure that the data is secure. However, no absolute guarantee can be made in relation to the registry being safe from all hacking, free from crashing or other system errors, etc.
20. The registry is hosted *[on a server in/at.... describe and also describe access control]*.
21. The source codes, logos, text, menus, lists and all other aspects of the platform that constitutes the registry is the exclusive and sole property of SARAA. The copying and unauthorised use of any such materials are strictly prohibited, and SARAA reserves the right to institute any appropriate action should any of these rights be violated. SARAA may use third party software, which is similarly protected.
22. All SARAA and registry designs, marks, logos, texts, examples of documents and so forth are subject to copyright and trademark law. The unauthorized use thereof is strictly prohibited.

#### **Duration of data storage**

23. SARAA will store data included in the Registry database indefinitely, as well as the consents and agreements that authorize such processing.

The data sheets submitted and from which the registry is compiled, will be destroyed from time to time in accordance with the policy as set by SARAA from time to time.

#### **Cessation of data submission**

24. If a practitioner decides to no longer submit data to the registry, all data previously submitted will remain on the registry.

**Disclaimer and Reservation of rights**

25. Practitioners and users of the registry do so at their own risk and by participating and/or using registry data indemnify SARAA from any claim, loss, damage or liability (including legal costs on an attorney and own client basis) for or in relation to any claims arising from such participation or use
26. SARAA reserves the right to:
  - 26.1 Discontinue the registry without prior notice, should it be appropriate.
  - 26.2 Terminate the participation of any practitioner, should the practitioner violate any of the Ts &Cs and conditions contained herein.
  - 26.3 Take any action reasonably required in order to ensure compliance, or enhanced compliance, with legislation and ethics, and/or to ensure data and/or platform integrity.
  - 26.4 Refuse any entity to access data contained in the Registry, if such data is being used, is intended to be used or has been used in the past in contravention of these Ts and Cs.
  - 26.5 Institute any action necessary to protect the integrity and use of the registry.

**ANNEXURE A:**

**APPLICATION FOR ACCESS TO DATA / DATASETS OF THE SARAA BIOLOGICS REGISTRY**

Name of applicant: \_\_\_\_\_

Name of legal entity on behalf of which application is made: \_\_\_\_\_

Intended use of the data (please describe fully. Note sections 12 – 16 of the Ts and Cs): \_\_\_\_\_

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Exact data required, including data field(s), geographical region(s), date(s), etc.: Note that no data that is so narrowly defined that practitioners and/or patients could be identified or areas that may lead to possible adverse conclusions drawn against practitioners and/or patients in certain areas, at certain dates, etc.:

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Signature of applicant, whereby signatory declare that s/he will abide by the decision of SARAA in relation to access, will not use the data in contravention of the SARAA registry Terms and Conditions.

**FOR OFFICE USE ONLY:**

Access granted / refuses: \_\_\_\_\_

Reasons for refusal: \_\_\_\_\_

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Fees levied:

Application fee: R \_\_\_\_\_ Database record fee: \_\_\_\_\_