Patient Information Sheet and Consent Form

SARAA Registry for Patients Receiving Biologic and Targeted Synthetic Disease-Modifying Anti-Rheumatic Drugs (DMARDs)

Patient Information

Why have I been given this information?

Your doctor has recommended treatment with a biologic or targeted synthetic disease-modifying anti-rheumatic drug (DMARD) to help manage your rheumatic condition.

SARAA is inviting you to allow information about your condition and treatment to be included in a confidential national registry. Before you decide whether to participate, it is important that you understand what the registry is, why it exists, and how your information will be used.

Please read this information carefully and ask your doctor any questions you may have. Take as much time as you need before deciding.

What is the SARAA Registry?

The South African Rheumatism and Arthritis Association (SARAA) is the professional society representing rheumatologists in South Africa.

Since biologic therapies became available in South Africa in 2000, and more recently with the introduction of targeted synthetic therapies, SARAA has maintained a registry of patients receiving these medications.

The registry includes patients with conditions such as:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis and other spondyloarthritides
- Juvenile idiopathic arthritis
- Connective tissue diseases
- Other inflammatory rheumatic diseases

A registry is a secure database that collects information about patients receiving specific treatments. Similar registries exist in many countries around the world and are valuable tools for improving healthcare.

Why is the registry important?

By collecting information from many patients over time, the registry helps us to:

- Better understand rheumatic diseases
- Monitor how well treatments work in everyday practice
- Identify possible side effects of medications
- Improve the quality and safety of patient care
- Help ensure that effective treatments remain available to patients
- Support research that may improve care for future patients

The information collected helps doctors, researchers and healthcare funders make informed decisions that ultimately benefit people living with rheumatic diseases.

Is this research?

The registry may be used for approved medical research aimed at improving the understanding and treatment of rheumatic diseases.

All research using registry information must comply with strict ethical standards and applicable South African laws. These include internationally accepted ethical principles such as the Declaration of Helsinki and local research ethics requirements.

Do I have to participate?

No.

Taking part is entirely your choice.

If you decide not to allow your information to be included in the registry, your medical care will not be affected in any way. Your doctor will continue to provide you with the same treatment and care.

Can I change my mind later?

Yes.

You may withdraw your consent at any time without giving a reason.

If you withdraw, no new information about you will be added to the registry. Information that has already been collected may continue to be used in an anonymous form where permitted by law and ethical guidelines.

What do I need to do if I agree?

You do not need to attend any extra visits or undergo additional tests.

Your doctor will simply record information that is already collected during your routine medical appointments.

Will my information remain confidential?

Yes.

Protecting your privacy is extremely important.

The registry contains information about your condition, treatment and general health. However, information that can identify you personally is kept strictly confidential.

To protect your privacy:

- Your information is stored using a unique study number rather than your name.
- The registry is stored on secure, password-protected and encrypted computer systems.
- Only authorised registry personnel can access identifiable information when necessary.
- The registry complies with the South African Protection of Personal Information Act (POPIA).

Information from the registry may be combined with information from other patients and used in medical reports, scientific publications or conference presentations. Your name or any information that could identify you will never be published.

Will participating affect my healthcare?

No.

The registry simply records information about your treatment and does not influence the medical care you receive from your doctor.

Who can I contact if I have questions?

If you would like more information about the SARAA Registry or have any concerns, please contact your treating doctor.

Doctor: _____

Email: _____

Telephone: _____

Patient Consent Form

SARAA Registry for Patients Receiving Biologic and Targeted Synthetic Disease-Modifying Anti-Rheumatic Drugs (DMARDs)

I,

(Full name)

a patient of Dr _____,

ID number _____,

Address _____

Telephone _____

Email _____

confirm that:

Please initial each statement to show that you agree. If there is anything you do not understand, please ask your doctor before signing.

□ I have read and understood the Patient Information Sheet and have had the opportunity to ask questions.

□ I understand why the SARAA Registry has been established and how my information will be used.

□ I understand that my participation is entirely voluntary.

□ I understand that choosing not to participate, or withdrawing my consent later, will not affect my medical care or my legal rights.

□ I agree that my personal and medical information may be entered into and stored in the SARAA Registry by the appointed database administrator, Nuvoteq (or its successor).

□ I understand that my information may be analysed and used for healthcare planning, quality improvement and ethically approved medical research aimed at improving care for patients with rheumatic diseases.

□ I understand that my identity will remain confidential and that no personally identifiable information will be released in reports, publications or presentations.

Participant	**Date**	**Signature**

Person obtaining consent	**Date**	**Signature**