# PATIENT INFORMATION SHEET AND CONSENT FORM

**STUDY TITLE : COVID-19 Global Rheumatology Alliance - Registry of rheumatic patients infected with COVID-19 - SARAA cohort**

**PROTOCOL NUMBER**: 001

**SPONSOR**: SARAA

The South African Rheumatology and Arthritis Association (SARAA), an association of doctors specialising in the field of rheumatology, would like to enrol you onto the COVID-19 GLOBAL RHEUMATOLOGY ALLIANCE and SARAA Register and invite you to participate in a research study on COVID-19 infection in patients with rheumatic disease. This patient information leaflet contains the details of the Registry and the research study and what is being requested of you. Please read the information provided. If there is any information that is unclear, please ask your doctor for this to be explained. Participation in this study is your choice. If you do not wish to take part, you do not have to. You will receive the best standard of care whether you take part or not. You will be given a copy of the signed Patient Information and Consent Form to keep.

## What is the reason for the study?

The COVID-19 pandemic is a cause for major concern. It has been suggested in studies so far, that patients with immunocompromised states are at increased risk of poor outcomes. Patients with rheumatic diseases are immunocompromised by their disease, but more importantly by the medications used to treat their disease. This study is to establish the risk and impact of COVID-19 infection on patients with rheumatic diseases. The aim is to assess whether patients with rheumatic disease are in fact, at an increased risk of COVID-19 infection, and is the COVID-19 disease course and prognosis affected by the underlying rheumatic disease and its treatment. It will also establish the safety of continued use of immunosuppressive treatments during COVID-19 infection.

The Registry will contain details on how patients are treated, and will allow us to better understand the condition and how it is being treated. SARAA will use this information to make presentations, compile reports and to analyse the information to make recommendations on the future treatment of rheumatic diseases. This is, in the end, in the interest of the country's healthcare and all patients.

## Why have I been chosen?

You have been chosen to participate because you have a rheumatic disease and have tested positive for coronavirus (COVID-19). Your participation is entirely voluntary. It will not influence any treatment that you will receive. Your treatment will be determined by your clinical condition and will be started and stopped as appropriate. If you do agree to participate, then you will be requested to sign the consent form. You are free to withdraw from the study at any time without any penalty or loss of benefit to which you are entitled. If you decide to withdraw from the study your information collected before you withdraw will still be part of the study data. However no new information about you will be collected.

**What does it involve?**

1. You will have to provide relevant details of your chronic illness and current infection, including therapies used.
2. You will have to agree that your doctor will provide relevant information from your medical records to the researchers.
3. You will have to agree that your information will be registered in a database held by SARAA. SARAA will however never release information that could be used to identify an individual and will not give any third party access to the database.
4. SARAA will keep the information on the registry indefinitely, so as to ensure that South Africa builds up a good understanding of the disease and its treatment.

**Is my personal information kept confidentially?**

Any information obtained in connection with the study that can identify you will remain confidential. Your study doctor will include information about you medical history, procedures, test results and response to therapy. Your identifiable information can only be accessed by the SARAA research team which includes the investigators, research nurse and database managers. Your name and other personal information will be coded. You can only be identified by a unique number which will be allocated to you. Your identifiable information will be kept secret from every-one else and will not be disclosed without your permission. All the staff and contractors that will work on this project will be bound by the strictest rules of confidentiality and non-disclosure.

**Will my participation affect my healthcare?**

The Registry and study is only about your healthcare information, and will not influence the care you have received, or will receive. This is what one calls a "non-intervention" study, which means that SARAA in no way determines or prescribes what treatment you get. It merely documents what happens in your care.

Will I be reimbursed for participation in this registry?

The registry will only capture information regarding your condition as part of your regular care by your doctor. Your participation is completely voluntary. As such, there will not receive payment or reimbursement of any kind for participation in the registry.

What are the benefits and risks to myself when participating in this registry?

There are no direct benefits to yourself for participating in this registry. The benefits are to the society at large, more specifically patients with rheumatic diseases, and especially pertaining to COVID-19 infection in patients with rheumatological conditions.

There are no risks to your physical health and well-being. There is an unlikely, however potential harm of unlawful access to your personal information. This is abated by very secure software, specifically designed for capturing private details.

What will happen to the results of the registry?

Results obtained from the registry will be used to compile reports, research articles and presentations to educate the medical community and public. Access to registry information will be made available to participant's treating doctors, who can then communicate this information to their respective patients, without divulging individual participant specific details.

**ETHICS APPROVAL OF TRIAL**

The Protocol of this clinical trial was submitted for approval to the Pharmaethics, a research ethics committee registered with the National Health Research Ethics Council. Written approval has been granted by Pharmaethics for the conduct of the trial. The study has been structured in accordance with the Guidelines on Clinical Trials and Ethics in Health Research, published by the Department of Health and the Declaration of Helsinki (last updated 2013), adopted by the World medical Association (WMA), which deals with the recommendations guiding doctors in biomedical research involving human participants. Copies of these documents may be obtained from the study doctor should you wish to review it.

**Contact person for the study**

You can contact your treating doctor should you require more information about the study or the Registry. His/her contact details are:

Dr _____

Email: _____ Telephone: _____

**Contact information for Pharma-ethics Independent Research Ethics Committee:**

Chairperson: Dr CSJ Duvenage (marzelle@pharma-ethics.co.za)
Administrator: Marzelle Haskins (marzelle@pharma-ethics.co.za)

**Telephone number:** 27 12 664 7977

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# PATIENT CONSENT FORM

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**PROTOCOL NUMBER**: 001

**SPONSOR**: SARAA

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

Hereby confirm and acknowledge that -

*Please initial or mark each box to indicate your agreement with each statement. 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 COVID-19 GLOBAL RHEUMATOLOGY ALLIANCE/SARAA 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 registry, irrespective of whether I am being treated or not. ☐
- I agree to participate in the above mentioned study and Registry and to assist the doctor in completing all necessary clinical and demographic information. ☐
- My treating doctor may provide the SARAA researcher with information that is relevant for the study and Registry, from my health records. ☐
- I understand that the information provided surrounding my condition does not directly benefit me, however has larger benefits for all people suffering with rheumatological conditions and the society at large, by helping us better understand how COVID-19 affects patients with rheumatological disease. ☐
- I understand that there is an unlikely however, potential risk of unlawful access to my personal information. ☐

- 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 SARAA 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-identifiable 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. This will be available to me by way of these. ☐

| Name of participant | Date | Signature |
|---|---|---|
| Name of Person taking consent | Date | Signature |

In the event that the participant is physically unable to provide consent, a legally acceptable representative (spouse, parent, child of consenting age, sibling) may give consent on their behalf. If this is so, please sign below:-

| Name of legally accepted representative. | Date | Signature |
|---|---|---|
| Name of Person taking consent | Date | Signature |