

SACSOS INFORMATION TO PATIENT

TITLE OF STUDY:	South African COVID-19 Surgical Outcomes Study (SASCOS)
PRINCIPAL INVESTIGATORS:	Hyla-Louise Kluyts, Sefako Makgatho Health Sciences University Bruce M Biccard, University of Cape Town

Dear Patient,

You are being invited to consider participating in a research project/study when you undergo the planned surgical procedure.

The study is being co-directed by the **principal investigators**: Prof Hyla-Louise Kluyts, Sefako Makgatho Health Sciences University, (email: hyla.kluyts@smu.ac.za) and Prof Bruce M Biccard, University of Cape Town (email: bruce.biccard@uct.ac.za).

The **study project office** is Safe Surgery SA NPC, Block A, Willow Wood Office Park, corner 3rd Street & Cedar road, Broadacres, 2021, Cell: +27 67 429 2053, telephone: +27 11 065 9501, Email: admin@safesurgery.co.za www.safesurgery.co.za, CIPC Reg no 2014/057792/08.

The clinical team participating in the study, at each site or hospital, will be the surgeon who will perform the surgical procedure, the anaesthetist for the surgical procedure (these two clinical team members are the **study doctors**) and the hospital manager.

Before you decide if you would like to participate, we want you to know why we are doing the study, including any risks (anything unexpected that might happen), and what you will be expected to do in the study.

This form gives you information about the study. The *study doctor(s)* will also talk to you about the study and answer any questions you have, or refer you to the *study directors/project office*. We encourage you to discuss this study with your family and anyone else you trust before making your decision. We will ask you to agree to take part, and that you understand the study (your consent). It is important that you know:

- You do not have to join the research study.
- You may change your mind and stop being in the study any time you want.
- If we make any important change to the study we will tell you about it and make sure you still want to be in the study.

Why should I participate?

With this study, we hope to better understand the impact of the COVID-19 pandemic on patients (how it affects patients such as yourself) undergoing surgery for other conditions in South Africa. Large numbers of elective surgeries (procedures that are booked early and if done at a later stage or delayed for 3 months will not have a different outcome) are being cancelled during the COVID-19 pandemic. We hope that the research study will help to plan the safe return to surgical activity right after the COVID-19 pandemic.

The research project will:

- Describe the relationship between patients' health status, the surgery you undergo, and how patients recover after surgery
- Count the number of surgical patients who recover and those who do not within 30 days after surgery.
- Discover the extent of delay of booked surgery as a result of COVID-19 disease.
- See if there is a connection between breathing (pulmonary) complications after surgery in patients who recover and those who do not.
- Compare how patients with and without COVID-19 disease recover from surgery.

Who can join the study?

Any adult patient (age 18 years and older) that undergoes non-emergency surgery may be included in this study.

How can I join the research study?

You will capture most of the information yourself on an electronic platform: You will have been invited to join the study by a doctor involved in your care. You will register before your surgery for the Perioperative Shared Health Record (PSHR). This is a patient-centered personalised care platform developed by Safe Surgery South Africa NPC. Upon registration, you will be asked to agree to adding data related to your surgical procedure to a database, for the following reasons:

- For the better management of the patient's health care
- For research purposes, where researchers can use registry information for research projects in which the patient will never be identified if such research is published
- For analytical purposes, e.g. create reports for doctors to evaluate themselves, in which patients will not be identified at all

If you agree to the use of your data for research purposes, you will ALSO be asked specifically to participate in this study.

Once you have registered with the PSHR, you will be asked questions about the state of your health before the operation, and your experience after the surgery, and/or outcomes after surgery.

After your surgery, data will be collected by you using the PSHR, at 7 days, 30 days, 6 months and 12 months. The first follow-up at 7 days after your surgery will remind you/your nominee about the data request. If you are unfit as a result of the surgery at the time of the follow up, follow up will be with your nominee. The data obtained from your nominee will be captured separately (not in the PSHR) during telephonic follow up.

Please note that the PSHR is a web-based platform, and you will need internet connection to complete the different sets of questions. The questions that you will be asked after the operation, will have to be answered by you on a device (mobile phone, tablet, or computer) that requires an internet connection. We are unfortunately not able to compensate you for the use of data bundles required to complete these sets of questions.

What questions will I be asked?

You will be asked:

- Basic personal information (age, height, weight etc.)
- About your general health and any other conditions (co-morbidities) you may be affected by in addition to COVID-19.
- Symptoms you may have when you arrive at the hospital for your surgery
- About your COVID-19 diagnosis before and after your surgery
- How long you have had any health condition (co-morbidity) and how it affects you.
- Specific information about your procedure.
- How well you recover after your surgery.
- Patients enrolled via the PSHR will also be asked questions about quality of life.

You will be asked to answer these questions, using a series of forms, at the following times:

- Before the surgery
- The first day after surgery
- One week or 7 days after surgery
- 30 days after surgery
- 6 months after surgery
- One year after surgery

How safe is it for me to participate?

This study is observational, so no new drug or technique is being studied. The study itself will not affect you physically, so there are no risks. Your personal information will be captured electronically, and there is a risk that the information may be obtained by people not involved in the study (cyber criminals). We will be implementing all possible measures to decrease this risk.

All data will be collected electronically, i.e. by the patient and doctors entering information into a database. The database has been approved by an ethics committee whose job it is to check that measures are in place to protect your privacy.

De-identified data will be extracted from the database at pre-planned intervals by the Safe Surgery South Africa (SSSA) administrator and overseer of the data, and be made available to the principal investigator for analysis. Neither you, the patient, nor your doctors will be identified in the data extracts (de-identified to prevent identification of individual patients and doctors). Only summary data will be presented publicly, and scientific reports issued at intervals throughout the project, including for publication in relevant medical publications as appropriate.

Safe Surgery South Africa, the custodian of the data, will be insured against cyber privacy- or security breach.

Taking part in this research is by your choice and you or your nominee may leave the research study at any point, without any negative outcomes.

In terms of the Protection of Personal Information Act, the following forms are available here:

- Objection to the processing of personal information ([form 1](#))
- Request for correction / deletion of personal information or destroying or deletion of record of personal information ([form 2](#))

There will be no costs to you as the patient to take part in the study and there are no incentives or repayments for joining the study.

Ethics Approval

This study has been ethically reviewed and approved by the Sefako Makgatho Health Sciences University Research Ethics Committee (approval number SMUREC/M/184/2020:IR).

In the event of any problems or concerns/questions you may contact the researchers at Cell: +27 67 429 2053, telephone: +27 11 065 9501 or the SMU Research Ethics Committee, contact details as follows:

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SACSOS ELECTRONIC CONSENT WORDING

The South African COVID-19 Surgical Outcomes Study

I have read the information on the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me: to understand how the COVID-19 pandemic affects patients needing surgical procedures. I have not been pressurized to participate in any way.

I understand that participation in this Study is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor. When I withdraw, the data that I have contributed up to this point will not be used in the analysis for the study.

If I have any more questions/concerns or doubts about the study I understand that I may contact the researchers through the study project office.

I know that this Study has been approved by the Sefako Makgatho University Research Ethics Committee (SMUREC), Sefako Makgatho Health Sciences University. I am fully aware that the results of this results of this Study will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

Subsequent to providing consent, the following information will be requested during registration on the PSHR, and will be linked to this consent process:

- SA ID number of patient or Passport number
- First Name
- Initials
- Last name
- Email
- Surgeon
- Patient date of birth
- Sex
- Emergency contact name*
- Emergency contact mobile number
- Emergency contact email address

I hereby give consent to participate in this Study.

*In the event that I (the patient) am not able to participate due to the impact of surgery (or I am incapacitated or disabled in any way), I appoint "*emergency contact name*" as my nominee to provide information in my place after the surgical procedure.

Yes/No

Date of consent: