The South African Collaborative Surgical Outcomes Study (SACSOS)

A prospective observational cohort study of patient-reported outcomes after surgery using a digital health platform

Study protocol

May 2025

Hyla-Louise Kluyts

Principal investigator

ABSTRACT

Background

Improving quality of perioperative care depends on reliable measurement of clinically important and patient-centred data, that will allow collaborative decision-making between patient and clinician. The use of digital health tools to share person-centric data with the aim of improving quality of care is encouraged by the World Health Organization Global Strategy on Digital Health. With virtual and online communication becoming a universal feature of modern life, there is a promising opportunity to engage patients and clinicians in perioperative data collection using digital health platforms. The Perioperative Shared Health Record (PSHR), developed by Safe Surgery South Africa, provides the opportunity to capture standardised patient-centric postoperative outcomes measures, like Quality of Recovery (QOR), Health Related Quality of Life (HRQOL), the WHO Disability Assessment Schedule (WHODAS). These are all standardised measures and questionnaires, which have been recommended by working groups focused on the patient's experience after surgery. The PSHR enables sharing of data between the surgical patient and his/her clinical team (surgeons and anaesthetists).

Method

A prospective observational cohort study aiming to recruit patients 18 years and older presenting for any surgical procedure at South African hospitals from July 2021 to June 2026. Data will be collected by patients using a digital platform, the Perioperative Shared Health Record (PSHR). De-identified data will be extracted from the database at predetermined intervals and made available to the principal investigator for analysis. Logistic regression models will be constructed to identify factors independently associated with these outcomes and to adjust for differences in confounding factors. The PSHR will be updated to optimise health information exchange between the surgical patient and clinical team members during the study.

Keywords (MeSH terms)

Patient reported Outcome measures

Perioperative care

Patient-centered care

Surgery

Patients

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1 ADMINISTRATIVE INFORMATION

1.1 Roles & Responsibilities

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1.2 Revision Chronology

Date	Protocol Amendment Number	Description
May 2020	1	Original
June 2020	2	Refining research question and objectives. Refining methodology. Refining dataset and variables.
July 2020	3	Additions to Introduction and background. Detailed budget added.
May 2021	4	Minor changes to Introduction. Changes to budget.
June 2021	5	Minor changes to text.
July 2021	6	Change to subtitle. Additions to Steering Committee. Change in Recruitment period.
August 2021	7	Formatting updated. Headings according to STROBE. MRC-approved budget added. MRC-approved timeline & milestones added.
September 2021	8	Adjusted list of secondary outcomes.
January 2022	9	Remove validation of cost prediction model from protocol Add C Steyl as investigator Describe access to data for telephonic patient follow up Describe Well-Architected Review as contributing to data governance and data security.
April 2023	10	Amend title and objectives to allow for recording of long-term patient-reported outcomes ‘post-COVID’.
October 2023	10	Amendment submitted to SMUREC
June 2024	11	Amended to allow for renewed recruitment based on extension of grant funding after enhancement of the data collection tool. Removal of COVID-19 measures from dataset and changes to patient information. Changes to primary and secondary objectives and outcomes. Removing ‘long-term’ from title. Add T Smit as investigator, removing the process of ‘clinical team’ recruitment from the methodology

October 2024	11	Amendment submitted to SMUREC
February 2025	12 Final for SACSOS extension of study	Site list and investigator list finalised to allow recruitment of patients at Dr George Mukhari Academic hospital Variable list and PSHR processes updated based on user experience study by SASUF (South African Swedish University Forum) collaborators Information, broadcasting and consent material reviewed Study registration updated

1.3 Trial Registration

1.3.1 Registry

Registered in ClinicalTrials.gov with reference number: NCT05052021

1.3.2 WHO Dataset

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov: NCT05052021
Date of registration in primary registry	21 September 2021
Secondary identifying numbers	SMU Ethical approval: SMUREC/M/184/2020:IR UCT Ethical approval: HREC REF:533/2020
Source(s) of monetary or material support	SAMRC RCDI grant to SMU NRF-SASUF seed grant for enhancement of PSHR
Primary sponsor	SAMRC RCDI
Secondary sponsor(s)	NRF-SASUF
Contact for public queries	Prof. Hyla Kluyts: hyla.kluyts@smu.ac.za
Contact for scientific queries	Prof. Hyla Kluyts: hyla.kluyts@smu.ac.za
Public title	The South African Collaborative Surgical Outcomes Study
Scientific title	The South African Collaborative Surgical Outcomes Study (SACSOS): A prospective observational cohort study of patient-reported outcomes after surgery using a digital health platform.
Countries of recruitment	South Africa
Health condition(s) or problem(s) studied	Peri-operative outcomes Patient reported peri-operative outcomes

Data category	Information
Intervention(s)	N/A
Key inclusion and exclusion criteria	• Patients 18 years and older presenting for any surgical procedure at South African hospitals accommodating the Deep Health information system, from April 2025 to June 2026. • Exclusion: Patients unable to provide consent to participation; Patients whose legal guardian is unable to provide consent to participation; Patients unable to nominate next-of-kin, guardian or a person of their choice, as their representative during follow up.
Study type	Observational Prospective Cohort Study
Date of first enrolment after extension	June 2025
Target sample size	N/A
Recruitment status	Preparing to recruit
Primary outcome(s)	Quality of life (EQ-5D-5L) score (preoperative and at 6 months)
Key secondary outcomes	Quality of recovery (QoR) at 24-48 hours post-operatively Patient-reported Postoperative Morbidity Survey (POMS)

2 INTRODUCTION

2.1 Background

Improving quality of perioperative care depends on reliable measurement of clinically important and patient-centred data, that will allow collaborative decision-making between patient and clinician.[1] Patient-reported outcomes measures after surgery are useful in adding to clinical outcomes measures such as the Postoperative Morbidity Survey (POMS)[2] in assessing quality of care. Immediately postoperatively, surgical patients can report on Quality of Recovery (QOR).[3,4] Patient reported outcome measures to assess longer term outcome after surgery include the EuroQol 5 Dimension scale to assess Health Related Quality of Life (HRQOL) at 6 or 12 months[5] and the WHO Disability Assessment Schedule (WHODAS)[6] 12 item version to assess functional outcome after surgery at 6 or 12 months.[7]

Virtual and online communication has become a global standard of living for people with access to the necessary technology. Patient engagement using an electronic patient-centric platform for perioperative data capture has the potential to contribute significantly to data on perioperative care in South Africa. There is also the opportunity to record outcomes that are currently accepted as the standard for understanding recovery after surgery, from a South African patient perspective. The use of digital health is an important step in exploring opportunities for innovative ways to accelerate progress in global health, as described by the World Health Organization.[8] South Africa is implementing digital health to support universal health coverage through National Health Insurance.[9,10]

Safe Surgery South Africa (SSSA) is a research-driven non-profit organisation aiming to enhance the role of perioperative clinicians in health information exchange to promote safe perioperative care. SSSA developed a digital health tool called the Perioperative Shared Health Record (PSHR). The PSHR allows patients to share their health information with their surgical team before a procedure. Patients can record their medical history, medications, allergies, functional status and other relevant information that can help inform their perioperative care. In addition to the preoperative data, the PSHR also allows for the capture of standardised patient-reported postoperative outcomes measures, like quality of recovery and HRQOL. This should enable healthcare providers to assess patients' recovery progress and outcomes after surgery and to identify any potential complications or issues that may arise during the recovery period. It is expected that by providing patients with the ability to share their health information and participate in their perioperative care, the PSHR may help improve communication and coordination between patients and their healthcare providers, ultimately leading to better outcomes and improved patient satisfaction.

The PSHR was used as the data collection tool in the South African Covid-19 Surgical Outcomes Study (SACSOS), a previous version of the current study. To date, patients have been recruited in the private health care sector in South Africa, pending efforts to optimise the data collection tool for use in the more diverse and challenging setting of the South African public health care sector. Patient recruitment for the study has been slower than expected, due to difficulties in integrating the PSHR in the workflow of surgical and anaesthetic practices, and use of the PSHR was impeded by usability issues associated with the platform from both the patient and the clinician perspective. End-users (both clinicians and patients / carers) were not included in the

initial design process of the PSHR, resulting in a lack of user-centeredness in its development. The omission of these key stakeholders in the design process may have led to an insufficient consideration of user needs and preferences, potentially hindering the adoption and effectiveness of the platform. The current iteration of the study protocol is the result of postponing recruitment to allow for enhancement of the PSHR after investigation by a South African Swedish University Forum (SASUF) collaborative, funded by an NRF-SASUF seed grant.

2.2 Research question

How can patient reported outcomes be used to inform decision-making in clinical practice in South Africa?

2.3 Aim and Objectives

2.3.1 Aim

To describe questions constituting a preoperative health survey, validated patient reported outcomes and adapted patient-centered outcomes in a patient platform to enable digital sharing of information with healthcare providers.

2.3.2 Primary objective

To describe the relationship between preoperative and 6-month postoperative health-related quality of life in South African surgical patients.

2.3.3 Secondary objectives

To describe the relationship between patient comorbidities, surgical characteristics and postoperative patient-reported outcomes measures (quality of recovery, health-related quality of life).

To assess data quality (accuracy) of the adapted patient-reported POMS by comparison with completed provider POMS.

To compare data quality (completeness) for patient-reported outcomes and provider POMS between public and private sector settings.

3 METHODS

3.1 Study Design

SACSOS is a prospective observational cohort study.

3.2 Setting

Dr George Mukhari Academic Hospital, Gauteng Department of Health and private sector hospitals in South Africa accommodating the use of the Bespoke Surgical Institute (BSI) Deep Health clinical data platform.[9]

Recruitment will take place during the period April 2025 to June 2026.

3.3 Participants

Patients will be invited to participate in the study using email notifications and/or Whatsapp messages generated by health information systems (BSI Deep Health) used by clinicians. Patients will participate by capturing data on a web-based patient platform (the PSHR). A preoperative health status survey is included on the platform. Postoperative follow up using the PSHR is enabled at 24-48 hours, 7 days, 30 days, 6 months and 12 months.

3.3.1 Inclusion criteria

- Patients 18 years and older presenting for any surgical procedure at South African hospitals accommodating the Deep Health information system, from April 2025 to June 2026.

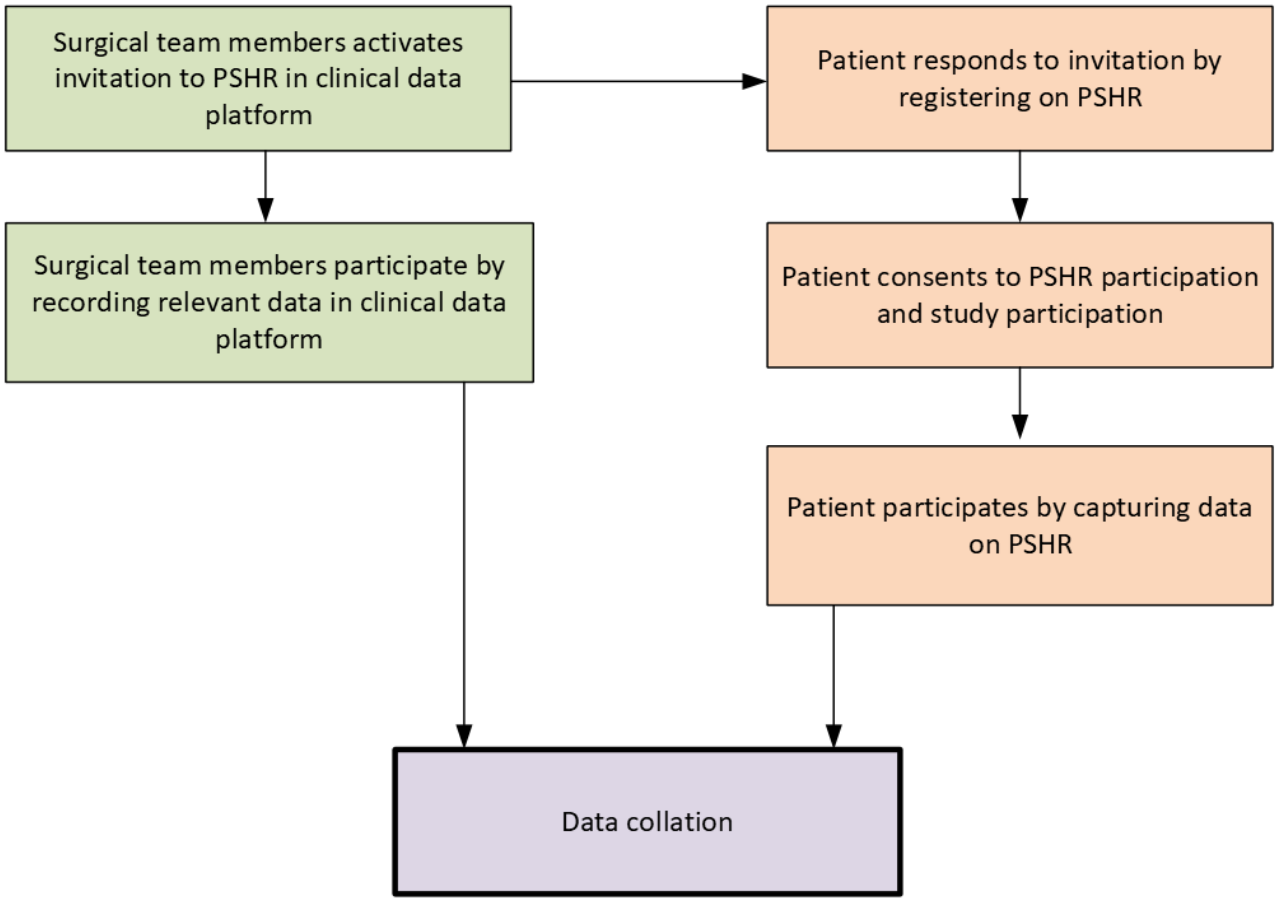
3.3.2 Exclusion criteria

- Patients unable to provide consent to participation
- Patients whose legal guardian is unable to provide consent to participation

3.4 Data collection and collation

Patients will be recruited during the period April 2025 to June 2026.

The study will focus on patient participation with the web-based platform as the primary recruitment method. Patient participation and data capturing require internet access to the web-based platform. The proposed recruitment process is illustrated in the following flow diagram:



Legend:
Green: Participation by surgical team members
Orange: Patient participation
PSHR = Perioperative Shared Health Record

3.4.1 Patient data collection:

Data will be collected by patients using the PSHR, a patient-centric platform developed by Safe Surgery South Africa NPC (CIPC registration number 2014/057792/08). Clinicians at the participating sites will invite patients to register on the PSHR via email and/or WhatsApp. When following the link sent by the system, patients will be able to register and provide consent to participate in the study. The patient will also consent to access of data for the surgical procedure by the clinicians in the team involved, e.g. the surgeon and anaesthetist. Postoperative data will be collected by the patient, using the PSHR, at 24-48 hours, 7 days, and 6 months postoperatively. Reminders will be sent to patients to complete the necessary forms, when they become available. Patients will also be able to register on the PSHR independently, and choose their care team in order to facilitate patient recruitment.

The PSHR is a patient platform that requires patients to register, consent to use, and enter complete demographics including patient identifiers. The platform is a secure web-based platform hosted on a server maintained by a company contracted with Safe Surgery South Africa (SSSA). For the platform to remain relevant to users, it requires intermittent updating based on user experience.

De-identified data will be extracted from the database at predetermined intervals by the named SSSA administrator and made available to the principal investigator for analysis.

3.5 Dataset & Variables:

All data will be captured electronically. The variables to be collected for the purposes of this study, are displayed in Table 1. Additional variables have been added to the PSHR to support user (patient and clinician) experience of the tool and enhance the exchange of information between patient and clinician.

Table 1: Study variables

Variable set	Variable	Definitions / Questions
Demographics	Date of Birth	YYYY/MM/DD
	Sex	Male / Female
	Weight	What is your weight? (in kg)
	Height	What is your height? (in cm)
	BMI	Calculation: weight in kilograms divided by height in meters squared.
Preoperative Self-Assessment	Adapted ASA-PS category	Physical status self-assessment as reported by the patient, based on the ASA-PS classification. Choose ONE of the following to describe your health in general: - You are healthy. - You have an on-going (chronic) condition/illness that affect your daily life only mildly; that is, you can continue with your daily life as previously, e.g. hypertension. - You have an on-going (chronic) condition/illness that affect your daily life severely, that is, the disease does not allow you to continue with your daily life as previously, e.g. a stroke with disability. - You have an on-going (chronic) condition/illness that is a constant threat to life, so severe that you must stay in bed to survive.
Comorbid Disease ***Preoperatively***	Hypertension	Do you have high blood pressure? If yes, since when? Do you take medication for high blood pressure regularly?
	Diabetes Mellitus	Do you have diabetes (high blood sugar)? If yes, since when? Do you use insulin for the diabetes (high blood sugar)? If yes, for how long?
	Smoking history	Have you been smoking cigarettes in the past year? Did you smoke before but stopped? If yes: how many years have you been smoking/did you smoke? If yes: how many cigarettes per day do you smoke/did you smoke?
	Stroke	Have you had a stroke?

	Transient Ischaemic Attack	Have you suffered from short-lived weakness in your arms or legs, or short-lived blindness?
	Chronic Obstructive Lung Disease	Are your lungs damaged due to smoking?
	Asthma	Do you have asthma?
	Tuberculosis	Have you ever been treated for tuberculosis?
	HIV infection	Do you have HIV? If yes, since when?
	Cancer	Have you ever been told you have cancer? If yes, have you ever had an operation for cancer? If yes, have you ever received medication or radiation for cancer? If yes, are you currently receiving medication or radiation for cancer? If yes, have you been told that the cancer is not under control, or has spread?
	Chronic Kidney Disease	Have you ever had any kidney problems? Do you currently have kidney problems? Have you ever received dialysis? Are you currently receiving dialysis?
	Congestive heart failure	Do you wake up at night because of difficulty breathing? Do you get short of breath when lying flat on your back? Do your ankles or legs swell? Do you get short of breath when climbing stairs? Do you wake up coughing at night?
	Ischaemic heart disease	Have you ever been told that you have a problem with the blood supply to your heart? If yes, when? Have you ever had a heart attack? If yes, when? Have you ever received a stent in the blood supply to your heart? If yes, when? Have you ever had a bypass or surgery of the blood supply to your heart? If yes, when?
	Vascular disease	Do you have 'bad circulation' in your hands or feet? For example cold or blue hands or feet? Have you been diagnosed with disease of the large blood vessels such as the aorta? Have you had surgery to the large blood vessels? Have you had a blood clot in the deep veins or in your lung previously?
	Mental Health	Have you been feeling sad or depressed much of the time? Do you take medication for depression?
	Chronic Pain	Are you in constant pain for any reason? If yes, are you taking medication or receiving treatment for the chronic pain?

Procedural data ***Obtained from clinical records***	Time from admission to operation	Date of admission to hospital
		Date of surgical procedure
	Surgical procedure codes	E.g. Standardised codes used in Deep Health system
	ICD10 codes (surgical diagnosis)	E.g. Standardised codes used in Deep Health system
Health-Related Quality of Life (EQ-5D-5L)[11] ***Preoperatively, postoperatively 6 months***	Mobility	I have no problems in walking about I have slight problems in walking about I have moderate problems in walking about I have severe problems in walking about I am unable to walk about
	Self-care	I have no problems with washing or dressing myself I have slight problems with washing or dressing myself I have moderate problems with washing or dressing myself I have severe problems with washing or dressing myself I am unable to wash or dress myself
	Usual activities (e.g. work, study, housework, family or leisure activities)	I have no problems doing my usual activities I have slight problems doing my usual activities I have moderate problems doing my usual activities I have severe problems doing my usual activities I am unable to do my usual activities
	Pain / Discomfort	I have no pain or discomfort I have slight pain or discomfort I have moderate pain or discomfort I have severe pain or discomfort I have extreme pain or discomfort
	Anxiety / Depression	I am not anxious or depressed I am slightly anxious or depressed I am moderately anxious or depressed I am severely anxious or depressed I am extremely anxious or depressed
	EQ-5D-5L score	Calculation based on answers to above 5 questions
	EQ-5D-5L Overall quality of life	Please indicate how good or bad your health is TODAY. The scale below is numbered from 0 to 100. 100 means the BEST health you can imagine. 0 means the WORST health you can imagine. Move the slider to indicate how your health is TODAY.
Quality of Recovery (QoR-15) ***Preoperatively and 24-48 hrs postoperatively***	Physical comfort	How have you been feeling in the last 24 hours? 0 to 10, where 0 = none of the time (poor) and 10 = all of the time (excellent): - Able to breathe easily - Feeling rested - Have had a good sleep - Been able to enjoy food Have you had any of the following in the last 24 hours? 10 to 0, where 10 = none of the time (excellent) and 0 = all of the time (poor):

		- Nausea or vomiting
	Pain	Have you had any of the following in the last 24 hours? 10 to 0, where 10 = none of the time (excellent) and 0 = all of the time (poor): - Moderate pain - Severe pain
	Physical independence	How have you been feeling in the last 24 hours? 0 to 10, where 0 = none of the time (poor) and 10 = all of the time (excellent): - Able to look after personal hygiene unaided - Able to return to work or usual home activities
	Psychological support	How have you been feeling in the last 24 hours? 0 to 10, where 0 = none of the time (poor) and 10 = all of the time (excellent): - Able to communicate with family or friends - Getting support from hospital doctors and nurses
	Emotional state	How have you been feeling in the last 24 hours? 0 to 10, where 0 = none of the time (poor) and 10 = all of the time (excellent): - Feeling comfortable and in control - Having a feeling of general well-being - Feeling worried or anxious - Feeling sad or depressed
Postoperative Morbidity	Adapted Postoperative Morbidity Survey (POMS) (After day 7)	Were there any complications after the procedure? If yes to above: - Did you develop an infection of the wound? - Did you need a procedure to take care of wound complications? - Did you have to, for the first time, use oxygen or require support to breathe? - Did you have any new heart or circulation problems? - Did you receive antibiotics? - Did you have any problems with eating, or use of your gut? - Did your kidneys stop working well? - Did you have a blood clot anywhere in your body? - Did you have any new neurological problems? - Did you require any blood product transfusion? - Did you have any new/unexpected pain after recovering from your procedure?

3.6 Data Security, Management and Ownership

Safe Surgery South Africa NPC (SSSA) will act as custodian of data captured using the PSHR platform.

The PSHR platform is secure, and the data server is provided by Microsoft Azure and maintained by Deep Health. Access to the database is through secure login by authorized personnel. The personnel with

authorized access are the PI, Prof Hyla Kluyts, and the Safe Surgery SA Research and Development Assistant, Ms Hanel Duvenage. Apart from data export for analysis, data will be accessed to obtain information to monitor recruitment and participation. This process will be managed by SSSA.

Sites leads and clinicians will also have access to the data entered into the system by themselves/their sites. For Dr George Mukhari Academic Hospital, the site leads will be Dr Mlimi and Prof Kluyts. For the private hospitals, no site level access will be granted and clinicians will only have access to their own patient's data. SSSA will have access to all study data for data quality management, recruitment monitoring and patient follow-up.

SSSA's research support for this project includes assisting researchers, clinicians and (when requested) patients with the data collection tool. User management will also include adding clinicians to the PSHR system to allow them to invite patients.

3.7 Statistical Methods

Categorical variables will be described as proportions and will be compared using chi-square tests. Continuous variables will be described as mean and standard deviation if normally distributed or median and inter-quartile range if not normally distributed. Comparisons of continuous variables between groups will be performed using t-tests, one-way ANOVA or equivalent nonparametric tests as appropriate. Univariate analysis will be performed to test factors associated with postoperative complications, morbidity and mortality at 30 days.

Missing data patterns will be investigated, and multiple imputation will be considered if it is deemed appropriate to impute variables.

Logistic regression models will be constructed to identify factors independently associated with these outcomes and to adjust for differences in confounding factors. Factors will be entered into the models based on their univariate relation to outcome, biological plausibility and low rate of missing data. We will also investigate predictors simultaneously using a combination of a LASSO and a Ridge penalty in order to do variable selection.

Results of logistic regression will be reported as adjusted odds ratios (OR) with 95% confidence intervals. The models will be assessed through the use of sensitivity analyses to explore possible interacting factors and examine any effect on the results.

Poisson models will be used to model the length of stay outcomes with relative risk ratios as measure of association. The cox proportional hazards model may be considered if outcomes are seen as time to event where Hazard ratios will be reported.

Models will be adjusted for clustering if many sites are included in the data.

Prediction models will be internally validated using bootstrapping, as well as cross-validation. Both leave-one-out and K-fold cross validation will be considered. Bayesian models may be considered in order to have distributions of model parameters, rather than only point estimates with 95% confidence intervals. This may

provide a different way of understanding the uncertainty in the model parameters changes as more and more data is collected.

3.7.1 Sample size

There is no specific sample size. Statistical models will be adapted to the event rate found in the cohort and updated as the sample increases.

3.7.2 Primary outcomes

- Health Related Quality of Life, measured with the EQ-5D-5L score, preoperatively and at 6 months postoperatively

3.7.3 Secondary outcomes

- Quality of recovery (QoR) preoperatively and at 24-48 hours postoperatively
- Amended Postoperative Morbidity Survey (POMS) postoperatively after 7 days
- POMS recorded by surgeon at discharge from hospital after surgical procedure

3.8 Timeline & Milestones

3.8.1 Milestone table for initial funding application

Milestones not met, or only partially met, are indicated in red text in the Key Tasks column, without amendments included.

Year 1		
Milestone 1: *Clinical Team Recruitment*		
Key Tasks	Duration (Start-End Date)	**Deliverable(s)***
Recruitment of 25 clinical teams from diverse surgical specialities	July to September 2021	Team registration on platform Agreements in place Study material in clinic/consultation rooms
Milestone 2: *Patient Recruitment*		
Key Tasks	Duration (Start-End Date)	**Deliverable(s)***
Recruitment of 20 patients per clinical team	October to December 2021	Patient participation and data capturing in platform for surgical procedure Telephonic follow up during first postoperative month
Milestone 3: *Preliminary report on 6 month patient follow up*		
Key Tasks	Duration (Start-End Date)	**Deliverable(s)***
Data analysis of first 500+ patients	January to July 2022	Report on primary and secondary outcomes 1 & 6 months postop
Milestone 4: *Digital health (platform) development*		
Key Tasks	Duration (Start-End Date)	**Deliverable(s)***
Source funding based on results of study Engage developers	October 2021 to July 2022	Develop platform to be used for patient engagement in low resource settings

Year 2		
Milestone 1: *Clinical Team recruitment*		
Key Tasks	Duration (Start-End Date)	Deliverable(s)*
Increase number of clinical teams participating and increase diversity of teams (specialty, geographical location, health sector)	July 2022 to July 2023	Data for 500+ patients included in database
Milestone 2: *Patient Recruitment*		
Key Tasks	Duration (Start-End Date)	Deliverable(s)*
Recruit additional patients to the study and increase diversity of patients (social- and cultural backgrounds)	July 2022 to July 2023	Data for 500+ patients included in database
Milestone 3: *Increase reporting of results*		
Key Tasks	Duration (Start-End Date)	Deliverable(s)*
Data analysis	July 2022 to July 2023	Report on all outcomes including 1 year postoperative Validation and updating of clinical prediction model

Year 3		
Milestone 1: *Data Science*		
Key Tasks	Duration (Start-End Date)	Deliverable(s)*
Open Science approach to data management, analysis and reporting	July 2023 to July 2024	Impact analysis & implementation of clinical prediction models/risk stratification tools Machine Learning

		algorhythms
Milestone 2: *Complete recruitment*		
Key Tasks	Duration (Start-End Date)	Deliverable(s)*
Last patients recruited to study to allow for 12 month follow up.	July 2023 to July 2024	Final report

3.8.2 Timetable for proposed funding extension

Year 4		
Milestone 1: ***PSHR development and maintenance***		
Key Tasks	Duration (Start-End Date)	**Deliverable(s)***
Finalise and deploy upgraded data collection tool	August 2024 to May 2025	PSHR ready for patient recruitment
Monthly assessment of PSHR performance during recruitment	June 2025 to June 2026	Bug fixes and other maintenance as required
Milestone 2: ***Patient Recruitment***		
Key Tasks	Duration (Start-End Date)	**Deliverable(s)***
Recruitment of patients	June 2025 to June 2026	Patient participation and data capturing using PSHR
Milestone 3: ***Monitoring & evaluation***		
Key Tasks	Duration (Start-End Date)	**Deliverable(s)***
Monthly investigator meetings	June 2025 to June 2026	Review of recruitment status and revision of recruitment strategy as needed.

Year 5		
Milestone 1: ***Patient Recruitment***		
Key Tasks	Duration (Start-End Date)	Deliverable(s)*

Recruit patients from private and public healthcare sector to the study	June 2025 to June 2026	Data for patients included in database
Milestone 2: *Reporting of results*		
Key Tasks	Duration (Start-End Date)	Deliverable(s)*
Data analysis and publication	July 2026 to December 2026	Publication in peer-reviewed journal Presentation at conferences
Advocacy	Ongoing	Stakeholder (patients and policy makers) engagement on data-driven surgical decision-making

4 BUDGET

Item	Year 1	Year 2	Year 3	Total Amount requested from the MRC
A. Running Cost				
Consumables				
1. Materials, and supplies				
PSHR maintenance costs	60 000.00	60 000.00	-	120 000.00
PSHR hosting costs	60 000.00	60 000.00	-	120 000.00
2. Laboratory including reagents, kits disposable labware /field costs				
3. Patient participation cost				
4. Office supplies, printing & photocopies, data, sim cards, telephone cost	12 000.00	12 000.00	-	24 000.00
Sub Total	**132 000.00**	**132 000.00**	**-**	**264 000.00**
B. **Personnel cost**				
1. Research Assistants	132 000.00	132 000.00	-	264 000.00
2. Field workers				
3. Consultants (only allowed with motivation)				
Sub Total	**132 000.00**	**132 000.00**	**-**	**264 000.00**
C. Publication cost (if not covered by university)				
D. Research travel				
1. Travel to sites				
2. Participant /patient transport				
3. Other, specify				
Sub Total				
E. Minor Equipment Cost				
F. Conferences and Workshops				
1. Local Conferences	**36 000.00**			**36 000.00**
Travel				
Accommodation				
Living expenses				
2. International Conferences		**36 000.00**	**-**	**36 000.00**
Travel				
Accommodation				
Living expenses				
3. **Workshops**				
Travel				
Accommodation				
Living expenses				
Sub Total	**36 000.00**	**36 000.00**	**-**	**72 000.00**
VAT 15% (TO BE PAID BY SAMRC)				
TOTAL	**300 000.00**	**300 000.00**		**600 000.00**

5 ETHICS AND DISSEMINATION

5.1 Ethics approval

Primary ethics approval for the study has been obtained from the Sefako Makgatho Health Research Ethics Committee (SMUREC), Reference number: SMUREC/M/184/2020:IR. SMUREC also approved the Perioperative Shared Health Record (PSHR) database and registry and the BSI: Deep Health database (Appendix A). Amended protocols will be submitted for approval by SMUREC.

The study has been registered on ClinicalTrials.gov, with the Identifier NCT05052021. The registration will be updated after approval of extension of the study.

Patient consent to participation will be captured in the PSHR. Upon using the PSHR, the patient will also be asked to agree to the Safe Surgery South Africa database Terms and Conditions and consent to data capture in PSHR.

The protocol, and ethics approval, will be circulated to the research oversight committees of hospital groups outside of the academic sector, as required by involvement, and agreement, of hospital managers.

The prepared patient information and electronic consent to the study is attached as Appendix B.

5.2 Dissemination

The result of the study will be published in peer-reviewed journals and presented at conferences. Depending on availability of additional funding, the results will also be disseminated to the general public in appropriate format.

6 REFERENCES

1. Roberts GP, Levy N, Lobo DN. Patient-centric goal-oriented perioperative care. *Br J Anaesth*. 2021;126(3):559-564. doi:10.1016/j.bja.2020.12.004

2. Grocott MPW, Browne JP, Van der Meulen J, et al. The Postoperative Morbidity Survey was validated and used to describe morbidity after major surgery. *J Clin Epidemiol*. 2007;60(9):919-928. doi:10.1016/j.jclinepi.2006.12.003

3. Stark P, Myles P, Burke J. Development and psychometric evaluation of a postoperative quality of recovery score. *Anesthesiology*. 2013;118(6):1332-1340. Accessed January 31, 2019. www.anesthesiology.org

4. Chazapis M, Walker EMK, Rooms MA, Kamming D, Moonesinghe SR. Measuring quality of recovery-15 after day case surgery. *Br J Anaesth*. Published online 2016. doi:10.1093/bja/aev413

5. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res*. 2011;20(10):1727-1736. doi:10.1007/s11136-011-9903-x

6. Andrews G, Kemp A, Sunderland M, von Korff M, Ustun TB. Normative data for the 12 item WHO disability assessment schedule 2.0. *PLoS One*. 2009;4(12):1-6. doi:10.1371/journal.pone.0008343

7. Myles PS. More than just morbidity and mortality – quality of recovery and long-term functional recovery after surgery. *Anaesthesia*. 2020;75(S1):e143-e150. doi:10.1111/anae.14786

8. The World Health Organization. Global strategy on digital health 2020 - 2025. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

9. Seebregts C, Dane P, Parsons AN, et al. Designing for scale: optimising the health information system architecture for mobile maternal health messaging in South Africa (MomConnect). *BMJ Glob Heal*. 2018;3:e000563. doi:doi:10.1136/bmjgh-2017-000563

10. Farao J. Digital health communication in South Africa during COVID-19. *Glob Heal Innov*. 2020;3(1):1-3. doi:10.15641/ghi.v3i1.891

11. EQ-5D-5L | EuroQol [Internet]. [cited 2024 Jun 16]. Available from: https://euroqol.org/information-and-support/euroqol-instruments/eq-5d-5l/

7 APPENDICES

7.1 Appendix A: Ethics Approval and Database & Registry Approval

SEFAKO MAKGATHO
HEALTH SCIENCES UNIVERSITY

Postgraduate Studies, Research Development, Integrity & Ethics
Sefako Makgatho University Research Ethics Committee
(SMUREC)

APPROVAL NOTICE - NEW APPLICATION

21 July 2020

Prof H Kluyts
Department of Anaesthesiology
P.O Box 205
Medunsa
0204

MEETING:	**03/2020**
SMUREC Ethics Reference Number:	**SMUREC/M/184/2020: IR**

The new Application received was reviewed by members of Sefako Makgatho University Research Ethics Committee.

Title:	The South African COVID-19 Surgical Outcomes Study
Principal Investigator:	Prof H Kluyts
Co-workers:	Prof B Biccard (Department of Anaesthesiology & Perioperative Medicine, University of Cape Town Dr H Malherbe (Rare Diseases South Africa)
Department:	Anaesthesiology
School:	Medicine
Type of Research:	Independent Research
Approval Period:	**02 July 2020 – 02 July 2021**

After Ethical Review: Kindly remember to use your protocol number **SMUREC/M/184/2020: IR** on any documents or correspondence concerning your research protocol with the REC. The REC has the prerogative and authority to ask further questions, seek additional information, require further modification, or monitor the conduct of your research and the consent process. A template of the progress report is obtainable from the Research Office and is due on an annual basis for your study irrespective of the approval period. Please note that a number of projects may be selected randomly for an external audit every year. Translation of the consent document in the language applicable to the study participants should be submitted if required.

International Organisation (IORG0008691), **Institutional Review Board** (IRB000010386) Expiry date: 07 December 2021, **Federal Wide Assurance** (FWA000023943) Expiry date: 03 March 2021 and **NHREC No: REC 210408-003**

Sincerely

PROF C BAKER
CHAIRPERSON SMUREC

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UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

G50, G Floor, Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 650 1236
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

14 September 2020

HREC REF:533/2020

Prof Bruce Biccard
Department of Anaesthesia and Perioperative Medicine
D23, New Groote Schuur Hospital
Faculty of Health Science
Email: bruce.biccard@uct.ac.za

Dear Prof Bruce Biccard

PROJECT TITLE: ***SOUTH AFRICA COVID-19 SURGICAL OUTCOMES (SACSOS)***

Thank you for submitting your request to the Faculty of Health Sciences Human Research Ethics Committee for review.

The HREC are comfortable and **approve** the study via the reciprocal process subject to:

- Groote Schuur Hospital institutional approval.

We note that the study has been approved by the relevant HREC at Sefako Makgatho University.

Therefore, the UCT-HREC notes that the primary oversight committee would be Sefako Makgatho University.

Approval is granted for one year until the 30th September 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

HREC REF 533/2020 SC

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

SEFAKO MAKGATHO
HEALTH SCIENCES UNIVERSITY

Postgraduate Studies, Research Development, Integrity & Ethics
Sefako Makgatho University Research Ethics Committee (SMUREC)

Prof H Kluyts
Department of Anesthesiology
P.O Box 205
Medunsa, 0204

Dear Prof H Kluyts

RE: APPLICATION FOR REGISTRY AND DATABASE APPROVAL

Researcher: Prof H Kluyts
Department: Anaesthesiology

SMUREC **NOTED** the request for database and registry approval.

Motivation:

Title: The Perioperative Shared Health Record (PSHR) database and data warehouse

The purpose of the PSHR is to collect national multicentre data in the South African healthcare sector on perioperative care with full patient participation (i.e. including patient-generated health data), and to report on this data in such a way as to enable clinicians and groups of clinicians involved in perioperative care to identify areas for quality improvement in surgical- and anaesthesia care.

SMUREC **NOTED** and **APPROVED** the request for the database and registry.

Yours Sincerely,

PROF C BAKER
ACTING CHAIRPERSON SMUREC

06 June 2019

SEFAKO MAKGATHO
HEALTH SCIENCES UNIVERSITY
Research Ethics Committee
Chairperson
Date 06/06/2019

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HEALTH SCIENCES UNIVERSITY

Research & Innovation
Sefako Makgatho University Research Ethics Committee (SMUREC)

APPROVAL NOTICE - NEW APPLICATION

16 November 2023

Dr J Smit
Department of General Surgery
Medunsa, 0204

MEETING: **10/2023**
SMUREC Ethics Reference Number: **SMUREC/M/519/2023: IR (Database Registration)**

The New Application received was reviewed by members of Sefako Makgatho University Research Ethics Committee on **16 November 2023.**

Title: BSI Deep Health: Database

Principal Investigator: Dr J Smit
Sub-Investigator(s): Dr J Breytenbach
Prof H Kluyts
Prof Z Koto
Department: General Surgery
School: Medicine
Type of Research: **Database Registration (IR)**

Please note the following information about your approved research protocol:

Approval Period: **16 November 2023 – 16 November 2024**

After Ethical Review: Kindly remember to use your protocol number (**SMUREC/M/519/2023: IR Database Registration**) on any documents or correspondence concerning your research protocol with the REC. The REC has the prerogative and authority to ask further questions, seek additional information, require further modification, or monitor the conduct of your research and the consent process. A template of the progress report is obtainable from the Research Office and is due on an annual basis for your study irrespective of the approval period. Please note that a number of projects may be selected randomly for an external audit every year. Translation of the consent document in the language applicable to the study participants should be submitted if required.

Sefako Makgatho University Research Ethics Committee follows the ICH GCP guidelines and Standard Operating Procedures (SOP) of the Ethics Committee. **International Organisation** (IORG0008691) **Institutional Review Board** (IRB0000010386) Expiry date: 27 November 2024, **Federal Wide Assurance** (FWA000023943) Expiry date: 03 November 2026 and **NHREC No: REC 210408-003**

Sincerely

PROF C BAKER
CHAIRPERSON SMUREC

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7.2 Appendix B: Patient Information Leaflet & SACSOS Consent Form

Note: The information will be provided electronically, and electronic consent will be obtained. This information and consent is specific to SACSOS, and in addition to the usual information and consent for a patient using the perioperative shared health record (PSHR) developed by Safe Surgery South Africa.

SACSOS INFORMATION TO PATIENT

TITLE OF STUDY:	**South African Collaborative 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, Safe Surgery South Africa, (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 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. Any questions you have can be referred 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 your experience of surgical care, using measures that are called patient-reported outcomes or patient-centric measures.

The research project will:

- Compare measures of your health-related quality of life before and 6 months after surgery
- Describe the relationship between your health status, the surgery you undergo, and your recovery after 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 be invited to join the study by a doctor involved in your care. You will register before your surgery on 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 24 to 48 hours after surgery and at 7 days, 30 days, 6 months and 12 months. You will receive reminders about the data request after surgery. 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)
- Symptoms you may have when you arrive at the hospital for 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.

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 using mobile number +27 67 429 2053 or the SMU Research Ethics Committee, contact details as follows:

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Email: lorato.phiri@smu.ac.za

SACSOS ELECTRONIC CONSENT WORDING

The South African Collaborative 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 compare measures of your health-related quality of life before and 6 months after surgery. 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
- Mobile number
- Surgeon
- Patient date of birth
- Emergency contact name
- Emergency contact mobile number
- Emergency contact email address

eConsent

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: