SAFE SURGERY DATABASE

TERMS AND CONDITIONS ("Ts and Cs")

What these Ts and Cs mean

- By logging into, submitting information and using the Safe Surgery Database ('the Database") you confirm that
 you understand these terms and conditions and that you agree to abide by it. The latest version of these Ts &
 Cs will always be available from the Safe Surgery SA office and the <u>Safe Surgery SA website</u>.
- 2. The Database includes data related to the health status and care of a patient during, before and after surgery and anaesthesia. The data are gathered using various mechanisms or data collection tools, stored in a secure environment.

Why this Database?

- 3. The Database comprises health information and reports by practitioners and patients on their experiences relating to surgery (before, during and after).
- 4. It aims to, record on a single database:
 - a. information that will allow anaesthetists and other healthcare professionals to timely access information about patients prior to surgery,
 - b. important data during surgery,
 - c. outcome measures of surgery so as to allow benchmarking of data and drive practice enhancements. In the case of contracted arrangements, such as the Anaesthesiology Event-Based Contract (EBC), to capture and share the data as contracted by the practitioner and consented by the patient,
 - d. patient satisfaction measures after surgery,
 - e. any other relevant information that will assist the health sector, healthcare professionals and patients in assessing and enhancing the healthcare environment where surgery is concerned.
- 5. The Database forms a platform from which authorised research projects could be undertaken.

How will this Database be used?

- 6. The main objective is to ensure better patient care. Every person who contributes their data to this system therefore assists in the achievement of this goal for the greater good of the health sector.
- 7. SAFE SURGERY SA and its affiliated bodies or authorized researchers, may use the aggregated data, or aggregated data-subsets for further research purposes, reports to relevant stakeholders, presentations to government or regulatory entities, healthcare funders, healthcare policy makers, at conferences and at meetings, so as to assist those entities and the providers of healthcare in creating better health systems and better health outcomes.
- 8. The Database will also allow doctors to compare themselves with others on the system, without seeing the identities of such other patients or other practitioners.
- 9. The use of the data and the database for any purpose outside of what is listed in these Ts & Cs is strictly prohibited.

Who is SAFE SURGERY?

10. SAFE SURGERY SA is a not-for-profit entity established in the public interest. It is a programme of SAPORG, the South African Peri-operative Research Group, and associated professional organisations, who are the "affiliated bodies" referred to in these Ts and Cs.

Confidentiality

- 11. The Database and its owners will never release any identifiable information from any patient or healthcare practitioner without obtaining specific consent to do so by the individual.
- 12. The information submitted to the Database by patients and practitioners, as well as the data subsequently generated by the Database are subject to strict confidentiality controls in line with the Protection of Personal Information Act, 2013, the National Health Act 2003 and the HPCSA Ethical Rules of 2006.
- 13. Patient and healthcare data will be stored on the Database, but only used and released in an aggregated, deidentified manner for the uses as outlined in these Ts and Cs.
- 14. Participating healthcare practitioners may see information that relates to themselves and their patients only.

15. Patients (or those authorized to consent on their behalf) can only see their own information, including historical information, but cannot access another patient's information.

Access to the database or information on the database

- 16. No third party outside of SAFE SURGERY SA, its affiliated bodies and their authorized members and users, database administrators and expert advisors, may access and/or use the Database for any purpose whatsoever. Only the SAFE SURGERY SA and its authorized users may use the Database for the purposes as set out above.
- 17. The Database may not be used by any party other than the owner thereof, for any commercial purpose.
- 18. A practitioner may authorize practice staff to include and/or update information on the database.
- 19. Authorisation for use of the Database will be in the sole discretion of the Board of SAFE SURGERY SA, and application must be made in the format and by providing information as set by the Board from time to time. Permissions may be subject to conditions, such as compliance with other legal or policy provisions, such as ethics committee approval.
- 20. Permission must be sought and may also be granted for the use of the Database and/or SAFE SURGERY SA logo on presentations or publications that result from the use of the data on the database.

Security

- 22. The Database uses all reasonable measures to protect the data from unauthorized- use, access, hacking, cyber-spying, malware, data corruption, abuse and all similar threats to the security of the data. SAFE SURGERY SA has agreements in place with service providers to not only protect the confidentiality and integrity of the data, but also to ensure that adequate levels of security is maintained. In spite of these steps no absolute guarantee can be made in relation to SAFE SURGERY SA being safe from all hacking, free from crashing or other system errors, etc.
- 23. The SAFE SURGERY SA database is hosted on a server accessible via a webpage, protected by SSL security built into the system.
- 24. It is the responsibility of every person with log-in access to ensure that their log-on details are kept safe. The Database cannot be held responsible if users share these with third parties and confidentiality is subsequently violated. Such violations are offences under privacy legislation and could also lead to legal action and/or complaints at the Information Regulator and/or the HPCSA.

Property rights

- 25. SAFE SURGERY SA may at any stage, without prior notice, change the Database, its layout, categories and the likes and may make any upgrade, change or modify the platform, service, software or any aspect of the Database as it may require from time to time.
- 26. The source codes, logos, text, menus, lists and all other aspects of the platform that constitutes the Database is the exclusive and sole property of SAFE SURGERY SA. The copying and unauthorised use of any such materials are strictly prohibited, and SAFE SURGERY SA reserves the right to institute any appropriate action should any of these rights be violated. SAFE SURGERY SA may use third party software, which is similarly protected.
- 27. All 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

- 28. The Database will store data indefinitely, as well as the consents and agreements that authorize and relate to such processing of personal- and health information.
- 29. A patient's information can be removed from the Database when he/she revokes his/her consent to store and share identifiable, personal information. Click here to request removal from the database. According to the Protection of Personal Information Act, any person can also object to the processing of personal information.

Donations, sponsors, grants and advertisements

30. SAFE SURGERY SA and/or the Database may receive donations and sponsorships so as to ensure the sustainability and viability of the project, which will be subject to corporate governance and due diligence controls. No sponsor, grantor or donor will, as a result of such contribution, have access to the database, or through that mechanism secure the use of the database or data-subsets. Publication of such support will be

- agreed with each sponsor, donor or grantor. Such publication must not be seen as SAFE SURGERY SA, the Database or its Affiliated Bodies endorsing that entity or any of its products or services.
- 31. The Database reserves the right to sell advertisements that would appear when the database is used or logged into.
- 32. Donations, sponsors, grants and advertisements should not be seen or construed as SAFE SURGERY SA or the Database endorsing such entities, their products or services, or that SAFE SURGERY SA prefers one entity, product or service provider over another.

Termination of agreement

- 33. Should circumstances arise that threaten the continued existence of the database, data will be made available per research project according to the agreement with investigators.
- 34. Should circumstances arise that threaten the continued existence of the database, in cases where data were collected for the purpose of sharing such data between patient and healthcare practitioners, for use during management of the patient, or benchmarking of individual healthcare practitioner practices, consent will be sought for any successor in title or any other entity identified by the Safe Surgery Board as suitable to manage the database on the same basis as before, and provision will be made for individuals to opt out at that time.
- 35. Should circumstances arise that necessitate the termination or closure of the Database, SAFE SURGERY SA will transfer the existing data, de-identified with regards to patient, healthcare professional and healthcare facility, to associated professional organisations. SAFE SURGERY SA would transfer the same confidentiality and protection criteria along with the data. The organisation would accept the data on those same terms.
- 36. SAFE SURGERY SA will not be responsible or liable for any consequence flowing from the termination and the subsequent deletion of information stored on the Database.

Disclaimer and Reservation of rights

- 34. Patients, practitioners and entities participate and, where so authorized, use the Database and/or the data contained therein at their own risk. By participating in the Database, patients, practitioners and entities indemnify SAFE SURGERY SA 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 the participation in, use of, or any allegedly unethical, negligent act or omission of SAFE SURGERY SA and/or any allegation that SAFE SURGERY SA operates in- or facilitates contravention of the ethical- or applicable legal rules.
- 35. SAFE SURGERY SA reserves the right to:
 - a. Discontinue the Database without prior notice, should it be appropriate.
 - b. Terminate the participation of any practitioner, should the practitioner violate any of the terms and conditions contained herein.
 - c. 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.