Standard Operating Procedures (SOP) for APORG Data Repositories

Introduction

The research data collected by the African Perioperative Research Group (APORG) will be made available to all active members with as few restrictions as possible. This document serves to ensure secure, controlled, and compliant access to the APORG datasets; it outlines the procedures for requesting, granting, and managing access to data repositories.

Information on all available data repositories may be viewed on the website: https://safesurgery.co.za/data-repositories/ .

Scope

This SOP applies to all APORG members who are registered on the African Perioperative Network Platform (APON) and wish to apply for access to the data repositories.

Definitions

De-identified data	Data with no identifiable information regarding patients, hospitals and/or country.
Data repository	Refers to any dataset as collected for a APORG study or made available to the APORG group.
Data User	Any investigator that was granted access to one or more Repositories.

Data Use Agreements:

- The data and other materials provided will not be redistributed or sold to other individuals, institutions or organisations without the written agreement of the APORG Board.
- The data will be used for statistical, scientific research, or quality assurance purposes only.
- Only the reporting of aggregated information will be done; the data will not be used for the comparison between specific individuals, organisations or countries.
- The Data User will neither use nor permit the use of the data in any way other than that listed in the original, approved statistical analysis plan or study protocol.

- No attempt will be made to re-identify any countries, sites or individuals participating in the project. If the identity of any person, site or country was made accidentally this will be immediately reported to the APORG Board.
- The Data User will ensure that the data are kept in a secure environment and only authorised users will have access.
- Any books, articles, dissertations, theses, reports or other publications that use the data in the APORG repositories will cite the source of the data. All APORG investigators who contributed to the initial data collection will be listed in supplementary material and/or collaborators on PubMed in all publications arising from the data repositories.
- An electronic copy of all the reports and publications based on the requested data will be sent to the APORG Board upon completion.
- Progress reports and project completion reports will be submitted annually, or as requested by the APORG Board.
- Once the dataset has served its indicated purpose, it must be destroyed. If the same dataset is needed for a different purpose, the dataset must be re-requested and the new purposes indicated.

Access Request Procedures:

- **Who can apply for access?**
  All active APORG members registered on APON can apply for access to the data repositories. Active members are those that meet the requirements as outlined in the APORG regulations.

- **What information is required to apply?**
  The following information is required to process an access request:

    - User details (name, contact info, affiliations, and APORG membership details)
    - Level of access required (read-only, write, etc.)
    - Specific dataset(s) requested
    - Purpose and justification for access (i.e. protocol, statistical analysis plan, etc)
    - Ethics approval for the protocol (if applicable)
    - Letter from an Institution/Organisation supporting and/or approving the proposed project
    - Proposed funding sources and application deadlines
    - Project start and end dates

- **Application process**:
  Applications are submitted via REDCap and will be reviewed by the APORG Board. The Board may contact study leads or principal investigators (PIs) for input and further consideration before making a final decision.
- **Acceptance criteria**:
  - The requesting party must provide an ethics-approved protocol.
  - The requesting party must be an active APORG member as outlined in the regulations
  - Additional institutional or organisational support and/or approval may be required for some projects or datasets.
  - Only de-identified data will be made available.
  - Access will be granted based on the principle of least privilege (i.e. minimum amount of access will be granted to the dataset(s) as necessary to achieve the stated purpose).
- **Notification**:
  Applicants will be notified of the outcome of their request within one month of submission, via the email address provided in the application form. Where additional information is requested before a final decision can be made, final approval may take longer than one month.

Data Users:

The data users for the datasets are divided into:

Administrators – Safe Surgery South Africa NPC : have full read and write access to the entire repository. All data stored will be made available in accordance with the terms outlined in this document.

Data Users (analysts/statisticians/PIs): will be granted access to de-identified raw data exports and data dictionaries in the required format for further analysis.

External viewers: will be provided with read-only access to exports of data files and/or finished analyses upon request.

Permissions for Specific Datasets or Types of Data:
Permissions will be granted based on the following criteria:

- **Hospital-specific data**: Data may be requested for additional analysis by investigators at the hospital where the data was collected.
- **Country-specific data**: Investigators from the respective country may request data specific to their location.

- **Comparative data**: **Country-comparative data** may not be requested unless explicitly authorized for such a purpose.

Datasets originating outside of APORG projects:

Data repositories that are made available for use to APORG members, but originated outside of APORG projects may also be included. Requests to include these projects will be considered by both the APORG Board and be subject to the same procedures for access as outlined in this document. In the event of additional requirements from Principle Investigators not outlined here, these will be communicated on the website.

For data repositories to be included, they will be evaluated for:

Authentication:

Data download links will be provided as single-use access links, with two-factor authentication to protect the data security. These links will expire after a limited time period to ensure the data cannot be accessed outside the approved time frame.

All data access will be logged for auditing purposes. Logs will capture user ID, the dataset accessed, time of access, and any modifications made to the data.

Data security:

Data will be hosted through Safe Surgery South Africa and security will be applied as specified in Safe Surgery's data management and disaster recovery plans.

Public information on the data repositories will include background to the collected data and may include a data dictionary/list of variables that is available in the datasets. Actual study data will be stored securely on Figshare and/or REDCap with links to the datasets made available as outlined in this document.

Publications and authorships:

All investigators who contributed to the initial data collection will be acknowledged in any publications arising from the data repositories. This acknowledgement will take the form of inclusion in the study supplementary material and, where supported by the publishing journal and indexing systems, as collaborators on PubMed. Safe Surgery South Africa will maintain and provide the full list of contributing investigators to ensure appropriate and consistent recognition across all publications. An electronic copy of all the reports and planned publications based on the requested data will be sent to the APORG Board upon completion and before submission to the journals where applicable.