APORG
AFRICAN PERIOPERATIVE RESEARCH GROUP

REGULATIONS

Vision, Mission & Aims

The African Perioperative Research Group (APORG) intends to be a world-leading network capable of developing, supporting and co-ordinating the efficient delivery of large-scale clinical studies and trials in Africa. The aim of the research and supporting structures of APORG are to improve the health outcomes of patients receiving perioperative and critical care in Africa.

The African Perioperative Research Group (APORG will achieve this objective by creating a community of researchers in hospitals across African countries, and by developing the skills and experience of these investigators to ensure they are ready, willing and able to recruit patients into clinical studies and trials adopted or initiated by the Group.

1. Preliminaries

1.1 **Citation**

This is Version 1.0 of the Regulations of the African Perioperative Research Group (APORG) and first came into force on 2 November 2024.

1.2 **Introduction and Background**

The African Perioperative Research Group (APORG) was launched on 17th November 2018 at the South African Perioperative Research Group Annual Meeting. The objective was to promote perioperative clinical research considered to positively impact on patient outcomes across Africa.

As of July 2024, APORG has led five large studies across Africa which include the African Surgical Outcomes Study (ASOS), the African Surgical OutcomeS-2 (ASOS-2) trial, the African Covid-19 Critical Care Outcomes Study (ACCCOS), the African Surgical Outcomes Study-Paediatrics (ASOS-Paeds), and the African Critical Illness Outcomes Study (ACIOS).

These studies have recruited over 70 000 patients, with representation from 43 African countries, 1 147 hospitals and over 1 800 clinician investigators.

2. Funding, Governance and Administration

2.1 The African Perioperative Research Group (APORG) is unfunded, and membership is free.

2.2 Matters of finance and governance will be approved by the Board of the African Perioperative Research Group (APORG).

- 2.2.1 APORG is not financial entity and does not have its own bank account.
- 2.2.2 Funding for projects coordinated by APORG will be the responsibility of the Chief Investigator of the study.
- 2.2.3 APORG will not provide remuneration to APORG members for work done in studies, or leadership.

2.3 The APORG Board will fulfil an advisory role to the APORG Director and facilitate communication between APORG and their respective organisations.

2.4 APORG Board meetings will take place at least twice a year.

2.5 The Director, or a nominated deputy, will give a short interim report at each APORG Board meeting.

2.6 The Director will complete an annual written report to the APORG Board, or more frequently if required to comply with the timescales set out in the respective funding agreements.

2.7 Administrative and data support

Safe Surgery South Africa (SSSA) has the mandate to provide the administrative and data repository support for APORG. Safe Surgery South Africa (SSSA) has the mandate to raise funds to fulfil these duties to APORG.

2.7.1 Safe Surgery South Africa (SSSA) will primarily provide administrative support for the APORG website, APORG membership platform (African Perioperative Network platform), and virtual Board and APORG Member meetings.

2.7.2 Safe Surgery South Africa (SSSA) will provide data support for large APORG projects. These projects will have to include funding for SSSA to fulfil this function.

2.7.3 Safe Surgery South Africa (SSSA) will manage the databases from previous APORG studies, and will ensure data access to APORG members for approved secondary analyses through accepted data governance procedures as determined by a data governance standard operating procedure.

3 Network Membership

3.1 Content of application

Any data or statement provided in support of any application for any category of Group membership that is found to be false or inaccurate will invalidate any membership awarded.

3.2 Eligibility criteria

Applicants for African Perioperative Research Group (APORG) membership will be asked to confirm that they are willing to 'develop, support and coordinate the efficient delivery of large-scale or scalable clinical studies or trials in Africa'.

3.3 Maintenance of membership

To maintain membership in the African Perioperative Research Group (APORG) members must:

3.3.1 Possess a valid Good Clinical Practice (GCP) certificate. If the member's GCP certificate expires during their term of membership, a new valid certificate must be obtained. Failure to maintain GCP will invalidate any membership awarded. Should a newly awarded GCP certificate not be obtained within the first year of APORG membership, membership will lapse before the opportunity for renewal of APORG membership presents itself.

3.3.2 Be able to provide evidence of an ongoing commitment to research activity through participation in at least one African Perioperative Research Group (APORG) clinical study or trial within a 3-year period.

3.3.3 If the member has not participated in an APORG study within the prior three years, they will have to submit a short summary of activities which have supported APORG within the prior 3 years in order to ensure membership renewal.

3.4 Membership fees

3.4.1 Membership is free of charge and must be renewed every 3 years.

3.5 Local Investigator scheme

3.5.1 This scheme is intended for individuals whose usual research contribution would be to undertake day to day trial activities in a research study site (hospital), but not as the local lead (which is the role of the Principal Investigator).

3.5.2 In the vast majority of cases, trainee doctors, nurses, and allied health professionals will join the Local Investigator scheme. This does not preclude local investigators from being appointed as Principal Investigator in any individual African Perioperative Research Group (APORG) study if they have suitable skills and experience. The final decision would be taken by the Chief Investigator of the trial or study concerned.

3.5.3 African Perioperative Research Group (APORG) will provide support and training specifically targeting the skills and knowledge required to act in the role of Local Investigator.

3.6 Principal Investigator scheme

3.6.1 This scheme is intended for individuals who will usually take overall responsibility for activities at a research study site (hospital).

3.6.2 The African Perioperative Research Group (APORG) will provide support and training specifically targeting the skills and knowledge required to act in the role of Principal Investigator.

3.6.3 Members of the Principal Investigator scheme may still contribute to African Perioperative Research Group (APORG) trials and studies at the level of Local Investigator.

3.7 Chief Investigator scheme

3.7.1 This scheme will be available to a very small number of investigators. Mentorship and training will be provided by an experienced Chief Investigator, tailored to the needs of the individual member concerned.

3.7.2 Members of the Chief Investigator scheme must already be members of the Principal Investigator scheme, and must remain compliant with the requirements of the Principal Investigator scheme for the duration of their membership of the Chief Investigator scheme.

3.7.3 Given the intensive mentoring requirements of this scheme, it is anticipated that there will be no more than five members of the Chief Investigator scheme at any one time.

3.7.4 Candidates for the Chief Investigator Scheme will be appointed through an open application process from members of the Principal Investigator scheme.

3.7.5 Membership of the Chief Investigator scheme may continue for 2 years and may be renewed on two occasions to a maximum total of 6 years, subject to the requirements of 3.7.2 above.

3.8 Associate Investigator scheme

3.8.1 This scheme is intended for individuals who may play an important role in the conduct of clinical trials, which does not involve patient related activities in a research study site. This may include but not be confined to statisticians, study co-ordinators, health economists, lay representatives etc.

3.8.2 Members of the Associate Investigator scheme are eligible to participate in African Perioperative Research Group (APORG) training for Local and Principal Investigators.

3.8.3 Associate Investigator membership must be renewed every 2 years.

3.8.4 Investigators from outside Africa who wish to build links with the African Perioperative Research Group (APORG) will be eligible to join the Associate Investigator scheme.

3.9 Rights and privileges

All African Perioperative Research Group (APORG) members shall have the following rights and privileges:

3.9.1 Eligibility to attend, speak and vote at African Perioperative Research Group (APORG) meetings.

3.9.2 Opportunity to organise, chair or present at African Perioperative Research Group (APORG) meetings, provided the programmes permit.

3.9.3 To be nominated for awards for investigator contributions (e.g. exceptional recruiters, team of the year, overcoming local difficulties).

3.9.4 To be nominated for appointment to the African Perioperative Research Group (APORG) Board.

4 Investigator roles for adopted clinical studies and trials

4.1 **Local Investigator**

4.1.1 The research contribution of local investigators is to undertake day to day study activities in a study site (hospital)

4.1.2 The local investigator role is defined in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines (www.ich.org).

4.1.3 For those wishing to be local investigators who do not already meet the person specification, African Perioperative Research Group (APORG) will provide support and training specifically targeting the skills and knowledge required to act in the role of Local Investigator.

4.2 **Principal Investigator**

4.2.1 The research contribution of principal investigators is to take overall responsibility for activities at a study site (hospital).

4.2.2 The principal investigator role is defined in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines (www.ich.org).

4.2.3 For those wishing to be principal investigators who do not already meet the person specification, the African Perioperative Research Group (APORG) will provide support and training specifically targeting the skills and knowledge required to act in the role of Principal Investigator.

4.3 **Chief Investigator**

4.3.1 The research contribution of a chief investigator is to take overall responsibility for a study or trial.

4.3.2 The chief investigator role is defined in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines (www.ich.org).

4.3.3 For those who have not previously acted as chief investigator for a successfully executed multicentre clinical study or trial, mentorship and training will be provided by an experienced Chief Investigator, tailored to the needs of the individual member concerned.

4.4 **Associate Investigators**

4.4.1 Associate investigators will play an important role in the conduct of clinical research, which does not involve patient related activities in a research study site. This may include but not be confined to statisticians, trial co-ordinators, health economists, lay representatives etc.

5 African Perioperative Research Group (APORG) Board

5.1 **Board appointments**

5.1.1 The APORG Board will be constituted of seven board members: one Board member per African region (Northern Africa, Central Africa, Southern Africa, Eastern Africa, and Western Africa), a current or previous Chief Investigator, and a patient representative or patient advocate.

5.1.2 The African Perioperative Research Group (APORG) Board will consist only of active researchers in the field of clinical perioperative and/ or critical care research in Africa, with the exception of the community representative.

5.1.3 African Perioperative Research Group (APORG) Board members must be current members of APORG.

5.1.4 Board appointments will be nominated, and voted onto the Board. The nomination needs to be made by an APORG member, and seconded by an APORG member. The nomination must include a short curriculum vitae of the proposed candidate, and a candidate statement of skills and proposed contributions to the vision for APORG if elected. Election will be determined by a major vote by APORG members to the specified Board position.

5.1.5 When appointing members to the Board, APORG members need to consider maintaining, where possible, representation of the specialties of anaesthesia, surgery and medicine, as well as trainees, nurses and allied health professionals.

5.1.6 Removal of a Board member from office, in the unlikely event of their performance or conduct giving serious cause for concern, must be put as a motion supported by a voting majority of the African Perioperative Research Group (APORG) Board. It is expected that such concerns would initially be addressed by the Director via informal methods.

5.2 **Terms of office**

The term of office for Board members is two years, renewable for a further two terms to a maximum of six years.

5.3 **Co-opted members**

The African Perioperative Research Group (APORG) Board is able to co-opt up to three short-term, non-voting members at any one time to assist with specific tasks or projects. This period of membership would not usually exceed 24 months.

5.4 **Voting rights**

5.4.1 All members officially appointed to the African Perioperative Research Group (APORG) Board are eligible to vote on any issue under discussion.

5.4.2 Co-opted members do not have voting rights.

5.5 **Board member responsibilities**

5.5.1 *Meeting attendance:* Members are expected to attend all meetings. Members who consistently fail to attend meetings without prior leave may be removed from the Board. Members will also be expected to attend major functions of the African Perioperative Research Group (APORG).

5.5.2 *Delegates:* Board members may not send delegates to attend in their place.

5.5.3 *Confidentiality:* Members of the Board should observe total confidentiality with respect to any discussions or papers considered confidential or sensitive, except where disclosure has been formally permitted.

5.5.4 *Disclosure of interest:* All Board members should disclose to the Director any relevant conflicting interest of any kind (financial, industry, academic or otherwise) arising in relation to any item on the agenda. Where a relevant interest has been disclosed, the member may, subject to the DIrector's agreement, remain present during and participate in any debate on the item concerned, but must not vote.

5.5.5 It is recommended that Board members discuss their appointment with colleagues and managers in their affiliations and workplace.

5.6 **Board meetings**

5.6.1 The African Perioperative Research Group (APORG) Board will meet at least twice a year. This does not necessarily have to be in person meetings.

5.6.2 Meetings will be chaired by the Director or, in his or her absence, the Deputy Director, or the longest serving member of the Board present.

5.6.3 The quorum will be four voting members. If at any time the number of members is less than a quorum, the Board may meet only for discussion purposes.

5.6.4 Questions arising at a meeting of the Board (either in person, by teleconference or webinar) are decided by a majority of votes of voting members present and voting, with abstentions not being counted in the total number of votes. The Director has a casting vote in addition to a deliberative vote where there is an equality of votes.

6 Director and Deputy Director

6.1 The APORG Director will be appointed by the Board of APORG.

6.2 The APORG Deputy Director will be appointed by the Board of APORG.

6.3 The APORG Deputy Director will become the next Director following the 2-year term of the Director, at which point the Board will appoint a new Deputy Director.

6.4 **Terms of office**

6.4.1 The terms of office for the Director and Deputy Director roles will be 2 years.

6.4.2 The Director will be expected to serve another 2-year term on the Board following vacating the role of Director.

6.4.3 The maximum term on the Board is a total of 6 years.

6.5 **Reimbursement**

6.5.1 There will be no direct payment for Board Members.

7 Adoption of African Perioperative Research Group (APORG) trials and studies

7.1 The African Perioperative Research Group (APORG) Board will oversee an open and transparent process to select multicentre clinical trials (and studies) for African Perioperative Research Group (APORG) adoption.

7.2 The final decision to adopt a trial or study will be taken by the African Perioperative Research Group (APORG) Board, after the proposal has been reviewed in accordance with the trial or study adoption standard operating procedure. The decision must be supported by a majority vote of the Board members.

7.3 The Director will identify two or more individuals to review each proposal, at least one of whom will be a member of the Board. The over-riding considerations in selecting new studies or trials will be quality and relevance to global research. Global research in this context will be aimed at creating knowledge that can inform policy-making on access to surgery, healthcare resource use and quality (safe, effective, patient-centred) perioperative and critical care in low to middle income countries. The primary focus will be on large clinical studies and trials (500+ patients) but some smaller studies will be appropriate for support, especially if these are likely to translate into subsequent larger studies or trials (i.e. scalable projects). Whilst it may be appropriate to accept preliminary or feasibility studies with some limitations, full study proposals will be expected to meet very high methodological standards such as those required by major public funders.

7.4 In reviewing new study proposals, the Board will also give particular consideration to the current and potential future contributions to the African Perioperative Research Group (APORG) of the proposing individual or group. The culture of the Group will be that every member should contribute more to the activities of the organisation, than they receive in terms of support.

7.5 The African Perioperative Research Group (APORG) does not expect to take responsibility for the conduct or leadership of adopted trials, but will instead focus on providing effective infrastructure to facilitate patient recruitment, and study completion. It is recognised that in many cases, a group may seek the involvement of a member of the African Perioperative Research Group (APORG) Board in the leadership of a new study or trial, but this is **not a requirement of adoption**. As active clinical researchers, members of the Board are encouraged to submit their new study or trial proposals for adoption by the African Perioperative Research Group (APORG). In accordance with the study and trial adoption standard operating procedure, such cases will be considered on the same criteria as any other new proposal. However, the proposal must be reviewed in detail by members of the Board who are not involved in the trial leadership. The management group of the study or trial in question has the responsibility to obtain funding if not already secured and to conduct the trial in accordance with African Perioperative Research Group (APORG) regulations and standard operating procedures.

7.6 Notwithstanding point 7.5, the Board will scrutinise the design, conduct, analysis and reporting of adopted studies or trials to satisfy themselves that the highest standards of quality, rigour and participant care are adhered to at all times. All studies and trials must comply with codes of research conduct (*Good Clinical Practice*).

7.7 All adopted studies must be presented to the membership at an African Perioperative Research Group (APORG) meeting on at least one occasion prior to launch of recruitment. The African Perioperative Research Group (APORG) must receive a written report once a year on the anniversary of adoption, or more frequently if requested. Adopted studies will be listed on the APORG website along with a brief summary of key points of relevance. Completed studies must also be presented at an African Perioperative Research Group (APORG) meeting.

7.8 **Appeals/Reviews**
Applicants may seek a review in the event of a decision not to adopt a study. The Board has the discretion to invite applicants to re-submit a modified application after an agreed duration of no less than 6 months.

7.9 **Withdrawal of support**
The Board reserves the right to withdraw adoption of a study or trial which fails to comply with African Perioperative Research Group (APORG) policies, or conflicts of interest are identified which make continued African Perioperative Research Group (APORG) support impractical or undesirable.

8 Making, Amending and Repealing Regulations

8.1 Any requests for amendments to, or repeals of, Regulations or requests for new Regulations must be brought by voting members of the Board and discussed with the members of the Board in the first instance. At the Board meeting, the Board may agree by consensus or vote (by a simple majority) to either repeal or amend the Regulation.

8.2 The Board may postpone a decision on the resolution whilst further advice or information is sought about related matters.

8.3 All formal changes to the Regulations must be noted in a table in the main Regulations document, indicating the nature of the change and where the change was approved.

8.4 The Director and Board should review the Regulations of the African Perioperative Research Group (APORG) on an annual basis.

Appendix: Glossary of terms and abbreviations

APORG	African Perioperative Research Group (APORG)
Board	The Board of the African Perioperative Research Group (APORG), unless otherwise stated
Director	The Director of the African Perioperative Research Group (APORG)
GCP	Good Clinical Practice
Group	Means the African Perioperative Research Group (APORG) unless otherwise stated
SSSA	Safe Surgery South Africa