APORG
AFRICAN PERIOPERATIVE RESEARCH GROUP

REGULATIONS

Vision, Mission & Aims

The African Perioperative Research Group (APORG) is intended to become a world-leading network capable of developing, supporting and co-ordinating the efficient delivery of large-scale clinical studies and trials in the Africa with the aim of improving the health outcomes of patients receiving perioperative care. This network will achieve this 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 11th November 2019.

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 to promote important perioperative clinical research across Africa considered likely to positively impact on patient outcomes.

2. Funding, Governance and Administration

2.1 The African Perioperative Research Group (APORG) is currently 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).

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

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

2.5 The Director or representative will attend meetings of the APORG Board as requested.

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

2.7 **Administrative support**

Administrative support will be provided by Safe Surgery South Africa (SSSA). This will primarily focus on support for the website, membership, board meetings, and members' meetings. SSSA will develop and maintain a membership database to facilitate interaction between APORG members. The South African Perioperative Research Group (constituted separately from APORG) members will be included in this database.

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 demonstrate any engagement in 'developing, supporting and coordinating the efficient delivery of large-scale or scalable clinical studies or trials in Africa'. Those without previous relevant experience will be able to access online APORG training material.

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 Submit a short summary of research activity every 2 years to coincide with membership renewal.

3.3.3 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 2-year period.

3.4 **Local Investigator scheme**

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

3.4.2 In the great 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.

3.4.3 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.

3.4.4 Local Investigator membership is free of charge and must be renewed every 2 years.

3.5 **Principal Investigator scheme**

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

3.5.2 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.

3.5.3 Members of the Principal Investigator scheme may still make a contribution to African Perioperative Research Group (APORG) trials and studies at the level of Local Investigator.

3.5.4 Principal Investigator membership is free of charge and must be renewed every 2 years.

3.6 **Chief Investigator scheme**

3.6.1 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.

3.6.2 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.

3.6.3 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.

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

3.6.5 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 3.6.2 above.

3.7 **Associate Investigator scheme**

3.7.1 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 trial site. This may include but not be confined to statisticians, trial co-ordinators, health economists, lay representatives etc.

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

3.7.3 Associate Investigator membership must be renewed every 2 years.

3.7.4 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.

3.8 **Rights and privileges**

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

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

3.8.2 Opportunity to organise, chair or present at African Perioperative Research Group (APORG) meetings, as programmes permit.

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

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

4. Investigator roles for adopted clinical trials

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4.1 **Local Investigator**

4.1.1 The research contribution of local investigators is to undertake day to day trial activities in a trial 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 trial 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 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 trials, which does not involve patient related activities in a trial 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

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5.1 **Board appointments**

5.1.1 The APORG Board will be constituted of three board members; the Director of Safe Surgery South Africa, the Head of the University of Cape Town Global Surgery Consortium, and a third member who must currently or previously been part of the Chief Investigator scheme (3.6). The third member will be nominated and voted to the Board by APORG members everythree years.

5.1.2 The African Perioperative Research Group (APORG) Board will consist only of active researchers in the field of clinical perioperative outcomes in Africa. African Perioperative Research Group (APORG) Board members must be current and eligible members of APORG.

5.1.3 In appointing the third member of the Board, consideration will be given to maintaining where possible to representation of the specialties of anaesthesia, surgery and medicine, as well as trainees, nurses and allied health professionals, and geographical location throughout Africa.

5.1.4 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, with that

proposal then ratified by the University of Cape Town Global Surgery 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 3 years, renewable for a further two terms to a maximum of 9 years, notwithstanding item 6.2, below.

5.3 **Co-opted members**

The African Perioperative Research Group (APORG) Board is able, without ratification by the University of Cape Town Global Surgery Board, 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 36 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:* 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 Members should disclose to the Chairman 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 Chair'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 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 longest serving member of the Board present.

5.6.3 The quorum will be three 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 chair 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 the appointed Research Director of the University of Cape Town Global Surgery Consortium.

6.2 The APORG Director must to be unanimously endorsed by the Board of APORG. In the event that the appointed Director is not endorsed by the Board, then a Director will be appointed via advertisement to the APORG members and competition.

6.3 **Terms of office**

6.3.1 The terms of office for the Director roles will be 3 years, subject to annual performance review, and renewable for two further terms to a maximum total of 9 years.

6.4 **Reimbursement**

6.4.1 There will be no direct payment for the role of Director.

6.4.2 The post will be supported by the cost of two full time equivalents of professional activity (PA) per week, back-filled to the post-holder's employer, in order to enable the post-holder to dedicate a minimum of 8 hours per week to the work. It is anticipated that the workload of the project will fluctuate and the post-holder will need to be able to be flexible enough to dedicate considerably greater amounts of time to the African Perioperative Research Group (APORG) when this is required.

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 unanimous between the 3 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 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-centered) of perioperative 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 trials (scalable). Whilst it may be appropriate to accept preliminary or feasibility studies with some limitations, full trial proposals will be expected to meet very high methodological standards such as those required by major public funders.

7.4 In reviewing new trial proposals, the Board will also give particular consideration to the current and future contributions made to the African Perioperative Research Group (APORG) by the nominating 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. 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 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 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) policies to be developed.

7.6 Notwithstanding point 7.5, the Board will scrutinise the design, conduct, analysis and reporting of adopted trials to satisfy themselves that the highest standards of quality, rigour and participant care are adhered to at all times. All 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.

7.8 **Appeals/Reviews**
Applicants may seek a review in the event of a decision not to adopt. 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 but such changes must be approved by the University of Cape Town Global Surgery Board before they can come into effect.

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)
Founding Partner	The two founding partners of the African Perioperative Research Group (APORG): Safe Surgery South Africa (SSSA), and the South African Society of Anaesthesiologists.
Funding Partners	All other funding partners of the African Perioperative Research Group (APORG)
GCP	Good Clinical Practice
Group	Means the African Perioperative Research Group (APORG) unless otherwise stated
SASA	South African Society of Anaesthesiologists