

CONSTITUTION

SOUTH AFRICAN CLINICAL RESEARCH ASSOCIATION

Version 7: Version 10: Version 11: Adopted by the members on 27 February 2015 Amended: March 2017 Amended: March 2021

1. NAME AND CONSTITUTION

- 1.1 The name of the association shall be SOUTH AFRICAN CLINICAL RESEARCH ASSOCIATION ("SACRA" or "the Association").
- 1.2 SACRA shall be a body corporate and shall be capable in law of suing and being sued and of acquiring, holding and alienating property movable and immovable, in its own name.
- 1.3 In any legal proceedings by or against SACRA, the members of the Executive Committee as provided for in clause 12 below shall in their capacity as such sue and be sued on behalf thereof.

2. ADDRESS

The address of SACRA shall be that of the Administrator, Treasurer or Accountant for the time being of SACRA.

3. OBJECTIVES

- 3.1 The objectives of SACRA shall be to:
- 3.1.1 research information on the most recent trends, challenges and gaps within the pharmaceutical, clinical, bio-ethical, and other related fields in the Republic of South Africa;
- 3.1.2 stimulate and promote discussion and interaction between the members of the association in order to promote greater professionalism in the field of pharmaceutical clinical, bio-ethical and other related research in South Africa;
- 3.1.3 establish and maintain contact between clinical research and other related research personnel employed in the pharmaceutical industry;
- 3.1.4 consider and act upon such professional matters as may be of concern to members of the association;
- 3.1.5 arrange informative meetings with speakers who are leaders in their field in order to promote the development of expertise in clinical research;
- 3.1.6 take such action as may be deemed necessary in matters affecting the legitimate interests of its members;
- 3.1.7 inform all members about new developments in industry.
- 3.2 The Association shall utilise substantially the whole of its funds towards achieving the aforementioned objects.

4. CONFLICT OF INTEREST – PRINCIPLES

- 4.1 **Conflict of Interest**. A conflict of interest is a situation where an individual, or the organization he or she represents or has an interest in, has a real, potential or perceived, direct or indirect competing interest with SACRA activities. This competing interest may result in the individual, or others related to them or entities in which they have an interest, being in a position to benefit from the situation or in SACRA not being able to achieve a result which would be in the best interest of SACRA. Conflict under this code shall be interpreted broadly.
- 4.2 **Conflicts**. Committee Members of SACRA must not have a business, commercial or financial interest in any transaction or initiative which would conflict with the conduct of their duties within SACRA, the best interests of SACRA or the carrying out of SACRA's objectives. This includes, without limit, interests in entities funding research or entities, which may have an interest in the outcome of SACRA activity.
- 4.3 **General Conflict Disclosure**. All activities involving business, commercial or financial interests, whether real, potential or apparent, which may conflict with the interest of SACRA or the duties of the individual, must be promptly disclosed to SACRA or the appropriate officer of SACRA committee member.
- 4.4 **Disclosure**. Disclosure of a conflict of interest, whether real, potential or apparent, must take place as soon as the individual becomes aware of the conflict. This may be, for example, in the case of a contract, grant, award, contribution or research project, at a meeting when an individual becomes aware that a contract, grant, award, contribution or research project is being proposed or considered, at the first opportunity after an individual becomes interested in an existing or proposed contract, grant, award, contribution or research project, or at the first possible moment when they become involved with SACRA and a contract, grant, award, contribution or research project pre-exists.
- 4.5 **Remedy** Where a disclosed interest is determined to be unacceptable by the SACRA, the contract, grant, award, contribution or research project or other conflict shall be amended to remove the offending provisions or be terminated, such determination has to be made by the Council or its delegate. Where a disclosed interest is determined to be a problem for the integrity of the decision of the Council, the member shall recuse him/herself from the decisional process. Should the conflict of interest be irremediable and be such that the member's continuing participation in the work of SACRA poses a significant threat to the integrity of the SACRA, the member will be asked to resign from the committee.

5. ADMINISTRATION AND MANAGEMENT OF THE ASSOCIATION

- 5.1 The Association will be managed by the Executive Committee. The Executive Committee shall have the power and authority to undertake any activities that are necessary to achieve the Association's objectives as set out in clause 3 provided that such activities comply with all laws applicable to the Association.
- 5.2 The Association shall at all times be comprised of at least 3 (three) people who are not connected persons in relation to each other. No single person shall directly or indirectly control the decision-making powers of the Association.
- 5.3 At a meeting of the Executive Committee, a majority of the Executive Committee members shall constitute a quorum.
- 5.4 Subject to this Constitution, the Executive Committee shall have exclusive administration and control of the Association and of the income arising therefrom.
- 5.5 The Executive Committee may delegate its powers and duties to such sub-committees as it deems fit.
- 5.6 The financial year end of the Association will be the last day of December

6. **INCOME AND PROPERTY**

- 6.1 The assets of the Association shall consist of: -
- 6.1.1 subscriptions, contributions or donations payable to the Association in accordance with this Constitution;
- 6.1.2 income or gains derived from the investment of any moneys of the Association; and
- 6.1.3 any other assets to which the Association may become entitled.
- 6.2 Substantially the whole of the Association's funding shall be derived from its members and/or from any appropriation by the Government of the Republic of South Africa.
- 6.3 No contribution will be accepted by the Executive Committee which is revocable at the instance of the contributor for reasons other than a material failure to conform to the designated purposes and conditions of such contribution, including any misrepresentation with regard to the tax deductibility thereof in terms of section 18A of the Income Tax Act 52 of 1968 as amended ("the Income Tax Act"): provided that a contributor (other than a contributor which is an approved public benefit organisation or an institution, board or body which is exempt from tax in terms of section 10(1)(cA)(i) of the Income Tax Act, which has as its sole or principal object the carrying on of any public benefit activity) may not impose any conditions which could enable such contributor or any connected person in relation to such contributor to derive some direct or indirect benefit from the application of such contribution.
- 6.4 The Association shall not at any stage knowingly become a party or permit itself to be used as part of an impermissible avoidance arrangement contemplated in part IIA of chapter 3, or a transaction, operation or scheme contemplated in section 103(5) of the Income Tax Act or any similar provision.
- 6.5 Subject to the provisions of this Constitution, the Executive Committee may generate additional contributions from whatever source the Executive Committee may determine.
- 6.6 No activity of the Association will directly or indirectly promote the economic self-interest of any fiduciary or employee of the Association otherwise than by way of reasonable remuneration. Furthermore, no member of the Association may directly or indirectly have any personal or private interest in the Association.
- 6.7 Remuneration may be paid to an employee of the Association, office bearer, as determined by EXCO. Members of the Executive Committee shall endeavour to serve members at minimal cost to the Association, where necessary covering their own travel costs to and from meetings,
- 6.8 All income and property of the Association shall be applied solely towards the promotion of the Association's objectives as stated in this Constitution. Accordingly, the Association may not directly or indirectly distribute any of its funds or assets to any person other than in the course of furthering its objectives.
- 6.9 The Association will not carry on any business undertaking or trading activity unless specifically permitted in terms of section 30(3) (b) (iv) of the Income Tax Act
- 6.10 The Association shall not have any share or interest in any business, profession or occupation which is carried on by its members.

7. SUBSCRIPTION

- 7.1 The subscription shall consist of either an individual or company membership. The annual membership fees will be decided by the Executive Committee on an annual basis.
- 7.2 A reduced membership fee will be offered to full-time students.
- 7.3 Annual membership will start on the day the first membership fee is paid. Subsequent subscriptions must be paid no later than the seven days after the annual membership expires.

8. MEMBERSHIP

- 8.1 Any company involved in Clinical Research in any way may apply for membership.
- 8.2 Any person involved in Clinical Research in any way either through the Pharmaceutical Industry, Academia, Contract Research Organisations (CROs), Site Management Organisations (SMOs) any other organisation involved in any way in clinical research, or any student studying towards a career in clinical research may apply for membership. Persons involved in bio-ethical or other related fields of research shall also be considered for membership.

8.3 Full membership

- 8.3.1 Those members that are fully paid-up members shall be called "full members" and have the right to vote at meetings. Unless designated "full members", by the Association from time to time, no person shall have the right to vote at meetings of the Associations.
- 8.3.2 The Executive Committee will offer free membership to members of the medicine's regulatory authority.

8.4 Honorary Life Membership

The full members present at a properly constituted meeting of the Association may by a majority vote of at least two-thirds of the members present and provided such a proposal was included in the agenda of the meeting issued to members, elect anyone to honorary membership.

9. TERMINATION OF MEMBERSHIP

- 9.1 Membership shall be lost by a member in the following circumstances: -
- 9.1.1 resignation from the Association; or
- 9.1.2 if a member's status changes so as to make him/her ineligible for continued membership; or
- 9.1.3 after a decision by the Executive Committee to that effect adopted by majority vote at general meeting; or
- 9.1.4 being in arrears in payment of membership fees for more than one month after fees become due; or
- 9.1.5 being found guilty in a South African court of law, applicable governing council or pharmaceutical company of unethical/negligent conduct during the performance of their duties.

9.2 Register of members

The name, address and relevant contact information of every member shall be entered in a register to be called the "Register of Members". Each member is obliged to inform the Association of any change of particulars.

9.3 Rights of members

- 9.3.1 Members shall have the right to participate in any discussion on any matter affecting their interests at any meetings (except Executive Committee meetings) of the Association. Members will always retain the right to communicate directly with the Chairman, Executive Committee members or employees of the Association regarding problem areas experienced with clinical research. This right refers to general problems and no confidential information of any company in the pharmaceutical industry may be revealed.
- 9.3.2 The members of the Association will have the right to dismiss all members of the Executive Committee, provided a Special General Meeting has been convened in terms of clause 11.5 for this purpose. On presentation of a ballot of all full members taken prior to the meeting, gathered by a credible electoral officer selected for this purpose and which shows that at least 60% of all full members are in favour of the dismissal, the motion will be carried. It is understood that all full members have the right to be fully informed of all events that may have led up to such an unusual ballot before they are asked to cast their vote. This will be the duty of the electoral officer must arrange a new election within 14 days from date of the dismissal of the Executive Committee.

9.4 Duration of membership

The duration of membership shall run for the full financial year unless membership is terminated in terms of this clause 9. The Association shall continue to exist notwithstanding changes in the composition of its membership or office-bearers.

10. ALTERATIONS TO THE CONSTITUTION

- 10.1 The Constitution shall be reviewed on an annual basis by the Executive Committee. In the event that the Executive Committee propose amendments to the Constitution, the proposed amendments shall be made available to all the members to review during a SACRA meeting and via the website for at least 6 weeks. Amendments to the Constitution will be accepted provided two thirds of the votes are cast by all the members in favour of the changes. If required by any applicable constitution, a copy of all amendments to the Constitution will be submitted to all the relevant statutory bodies that the Association is registered with.
- 10.2 Notwithstanding any contrary provision contained herein and specifically clause 10.1, the Executive Committee is authorised to take all necessary steps (including but not limited to amending this Constitution) to register the Association as a non-profit organisation in terms of the Non-profit Organisations Act and as a Public Benefit Organisation in terms of section 30 of the Income Tax Act.
- 10.3 For so long as the Association is registered with the South African Revenue Service:

- 10.3.1 any amendment to the Constitution shall be submitted to the Commissioner for the South African Revenue Service ("the Commissioner") within 30 (thirty) days from the date on which the amendment was effected, by the Executive Committee; and
- 10.3.2 the Association shall comply with such reporting requirements as may be determined by the Commissioner from time to time.
- 10.4 The latest version of this Constitution (incorporating any latest amendments) shall supersede all previous constitutions of the Association from the date on which any amendments are accepted by the members of the Association in terms of this clause 10.

11. MEETINGS

- 11.1 The EXCO will determine the appropriate mode of meeting to ensure sufficient engagement with stakeholders. At least three meetings will be held each year, including the Annual General Meeting and two or more others.
- 11.2 The Association may conduct a meeting of the members by electronic communication.
- 11.3 Financial Statements are to be presented at the Association's first meeting after the financial year end.

11.4 The Annual General Meeting ("the final AGM")

- 11.4.1 This shall be held no later than December of each year. The time and place of the meeting shall be determined by the Executive Committee. The purpose shall be to carry out business as may appear on the agenda of such a meeting and in particular the following:
- 11.4.2 To read and confirm the minutes of the previous Annual General Meeting and of any Special General Meetings which may have been held during the year under review.
- 11.4.3 To receive the report of the Executive Committee covering the activities of the Executive Committee for the same period.
- 11.4.4 To meet the Executive Committee members for the following year. Names, addresses and telephone numbers of the Executive Committee members will be circulated to members via the SACRA website.
- 11.4.5 To consider any other business.

11.5 Special General Meetings

The chairperson may at any time convene a Special General Meeting and shall call a Special General Meeting if petitioned to do so by not less than two thirds of the members who are in good standing.

11.6 Notice of Meetings

The Administrator or any Executive Committee Member shall issue notice of meetings at least 14 days prior to a meeting. This will be announced via the SACRA website. In the case of a Special General Meeting, the secretary will contact and inform members directly of the date and venue of such a meeting as soon as possible.

11.7 **Quorum**

Twenty percent (20%) of the full members shall constitute a quorum. The act of the majority of the members present at any such meeting shall be the act of the membership at large.

Twenty r

11.8 Voting 11.8.1 Whether at a meeting of the members or via the SACRA website, each full member shall have the right to cast one vote, also when electing the Executive Committee.

- 11.8.2 In the event of equality of votes the Chairperson shall have the casting vote.
- 11.8.3 Any resolution involving alteration, amendment or addition to this Constitution shall be carried by the vote as provided in clause 10 of this Constitution.
- 11.8.4 Each member is entitled to one vote either at a meeting by a show of hands or by ballot, or via the SACRA website. No proxy votes may be cast.

12. ELECTION AND COMPOSITION OF THE EXECUTIVE COMMITTEE

12.1 The Executive Committee

- 12.1.1 The Executive Committee shall be composed of 5 (five) or more members. The Executive Committee shall have the power to co-opt additional members, and to increase the number of Executive Committee members.
- 12.1.2 The Chairperson, Vice-Chairperson and Treasurer will be elected by the Executive Committee.
- 12.1.3 The members of the Executive Committee will be representative of the different disciplines, interest or working groups within the clinical research industry.
- 12.1.4 The executive should preferably consist of members from varied companies. There should not be more than 2 (two) members of a company forming part of the Executive Committee.
- 12.1.5 Every member of the Executive Committee shall be indemnified by the Association against, and it shall be the duty of the Executive Committee from the funds of the Association to pay, all liabilities, costs, losses and expenses which any such member of the Executive Committee may incur or become liable to in respect of any matter or thing bona fide done by him/her in the execution, or purported execution of his duties, or of any powers, authorities or discretions vested in him whether in his capacity as a member of the Executive Committee, including all liabilities, costs, losses or expenses consequent on any mistake, oversight or omission on the part of such member of the Executive Committee.

12.2 Election

12.2.1 Full members will elect the members of the Executive Committee prior to the final AGM as contemplated in clause 11.4. Nominations should occur during the end of the third quarter of that year so that a full handover can be conducted at the final AGM. Available members will be nominated in writing. Nominations are to reach the secretary 30 days prior to voting and will be posted on the SACRA website.

12.2.2 The outgoing Executive Committee shall determine what proportion of incoming Executive Committee must be representatives from the various regions in which SACRA has a presence, to ensure that the constitutional obligations can be met in all areas. 12.3 Term Each elected member of the Executive Committee shall hold office for a term of four years. Members of the Executive Committee may be re-elected save that no member of the Executive shall serve more than two consecutive terms of office in a single portfolio. 12.4 Chairperson For the purpose of continuity, it shall be customary, although not mandatory for an incoming Chairperson to have served as an Executive member in a preceding term of office. 12.5 Duties and powers of the executive The duties and powers of the Executive Committee shall be to: 12.5.1 preside at each member and Executive Committee meetings (at least 3 Executive Committee members must be present at each Executive Committee meeting); 12.5.2 arrange and convene meetings; 12.5.3 issue notices of meetings in due time; 12.5.4 keep an accurate record of the minutes of the meetings; have in safe-keeping all the general written records of the Association; 12.5.5 12.5.6 receive all monies payable to the Association and to pay the same into the banking account of the Association as soon as possible thereafter. In this regard, the Executive Committee shall procure that a bank account/s is opened with a bank as defined in the Banks Act 1990 (Act No. 94 of 1990) in the name of the Association into which account all moneys received on account of the Association shall be paid and shall, by resolution, from time to time authorise cheques, bills or other documents appertaining to the Association to be signed or endorsed by such person or persons as they may authorise; 12.5.7 keep a proper record of the financial transactions of the Association, and to issue and obtain proper documents for the payment and receipt of monies respectively. The Executive Committee and employees of the Association shall administer the funds of the Association according to standard accounting practices; 12.5.8 keep an up to date record of full and honorary members also reflecting subscriptions paid; 12.5.9 prepare an annual financial statement; 12.5.10 ensure that all financial obligations are met; keep members informed of new developments; 12.5.11 12.5.12 create appropriate sub-committee(s) and co-opt members to serve on the sub-committee(s).

12.6 Filling vacancies

- 12.6.1 Should an Executive Committee Member cease to serve on the Executive Committee before their term of office expires, the Executive Committee shall have the power to co-opt or elect another Executive Committee Member for the remaining term of office, should this be considered necessary by the remaining Executive Committee members.
- 12.6.2 Should any Executive member be absent from any three (3) consecutive Executive Committee Meetings without reasonable excuse, the Executive Committee shall be empowered to declare the position vacant. Due notice will be sent to the member so removed from office.

13. **WEBSITE**

- 13.1 Unless advised otherwise by the Executive Committee, the official website address for the Association will be <u>www.sacraza.com</u>
- 13.2 The website will contain all information relevant to the Association, its functions, meetings, executive as well as information related to research. The website will be maintained by a webmaster, appointed by the Executive Committee.

14. DISSOLUTION

- 14.1 The Association may be dissolved if at least 75% (seventy five percent) of the members of the Association present and voting at a meeting convened for the purpose of dissolving the Association, are in favour of dissolving the Association.
- 14.2 In the event of dissolution of the Association, the Executive Committee shall pay all the liabilities of the Association and the remaining assets of the Association (if any) shall be transferred to a similar public benefit organisation(s) as selected by the Executive Committee, provided that such organisation(s) is an association recognised by the pharmaceutical industry and approved by the Commissioner or approved in terms of section 30 of the Income Tax Act or exempt from tax under section 10(1)(cA)(i) of the Income Tax Act.

15. **GENERAL**

Reference to any act or section in this Constitution shall be deemed to include any amendments to the Act or section or to the corresponding provisions of any replacing Act.

I declare that I have read and agreed to the amendments of the attached SACRA Constitution (Version 11) and confirm that these were duly discussed and agreed upon as EXCO 2021 - 24

EXCO MEMBERS' SIGNATURES	
NAME	SIGNATURE & DATE
1. Bicky Nyeleti Mthombeni	Nyeleti Mthombeni 02 Sep 2021
2. Gerben van den Hoogen	Gerben van den Hoogen
3. Elandrè Kok	Elandre Kok
4. Leonard Lazarus	L.N.Lazarus
5. Nyeleti Rikhotso	Nyeleti Rikhotso
6. Dr Precious Garnett	Precious Garnett
7. Raphala Seima	
8. Rob van den Bergh	
9. Sorika van Niekerk	

10. Dr Tienie Stander

11. Victor Kgothatso Rameetse

Dated: March 2021 SACRA Constitution Version 11.

Sorika van Niekerk

Signature: Gerben van den Hoogen

Email: gerben@task.org.za

Signature: Len Lazarus Len Lazarus (Sep 6, 2021 10:49 GMT+2) Email: leonard.lazarus@biocair.com

Signature: Elandre Kok Elandre Kok (Sep 6, 2021 10:57 GMT+2) Email: elandre.kok@ppdi.com

Signature:

Email: precious.garnett@cipla.com

Signature: 2021 15:23 GMT+2) Email: nyeleti.sacra@gmail.com

Signature: Sita von Nübert

Email: sorika.vanniekerk@cytespacelabs.com