NATIONAL HEALTH RESEARCH ETHICS COUNCIL

www.nhrec.org.za

# Application to register an AREC

*Application to register an Animal Research Ethics Committees (ARECs) with the National Health Research Ethics Council (NHREC)*

*Approved by the National Health Research Ethics Council: 2025-03-05*

*Version 4.01*

Please read the important background information on p. 2-5, and then complete all Sections of the application form from p. 6 onwards.

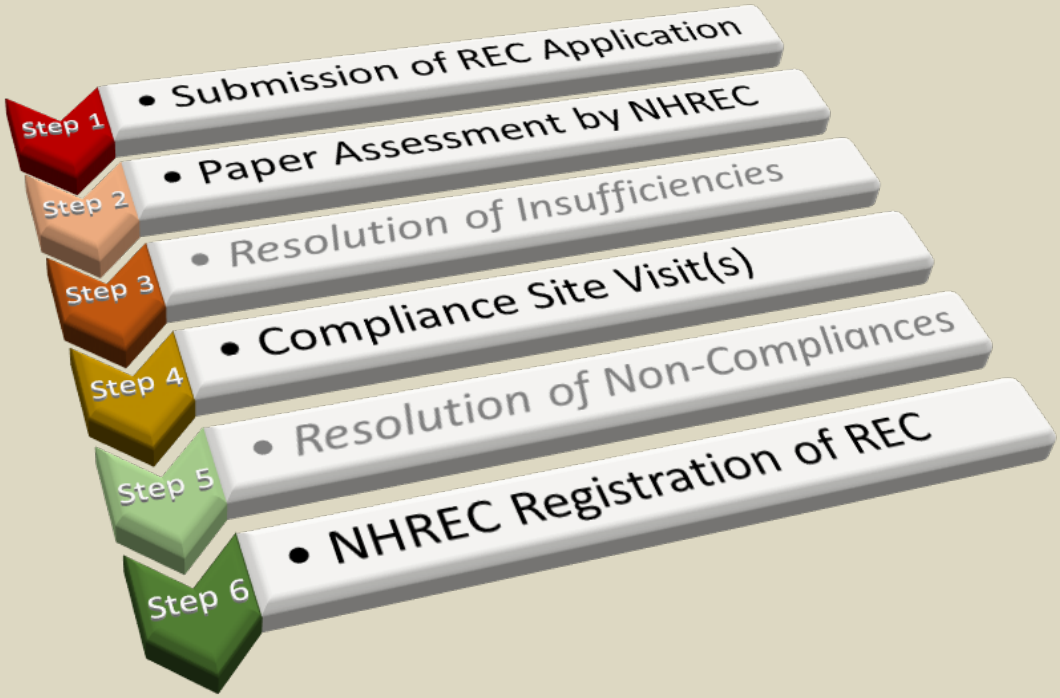
| | | |
|---|---|---|
| Date submitted by AREC | | *(in this form AREC implies applicant AREC)* |
| Date received by NHREC | | ← **this particular date is for office use only** |
| AREC full name | | |
| AREC acronym / short name | | **Note!** Please ensure that you use the CORRECT full name and acronym of your HREC, and in particular the EXACT provisional number if provided by the NHREC *(i.e., no omission of any letters, numbers, leading 0's or hyphens, and no addition of spaces in the number).* |
| AREC provisional no. | **AREC-** | **-** |
| Registration status | **Applicant AREC** | |
| Name of primary organisation/institution | | |

**Illustrative example**

Date submitted: 2025-02-28
Date received: *…leave open…* ***(office use only)***
Reporting date: 2024-01-01 to 2024-12-31 ***(01 Jan – 31 Dec of the reporting year)***
AREC full name: South Africa Dummy University Animal Research Ethics Committee 1 *(i.e., Institution's full name + REC's full name)*
AREC acronym: SADU-AREC1 *(i.e., institution's acronym hyphen REC acronym)*
AREC reg. no.: AREC-123456-078 ***(NB! exact number)***
Reg. status: Applicant AREC
Name of primary institution: South Africa Demo University

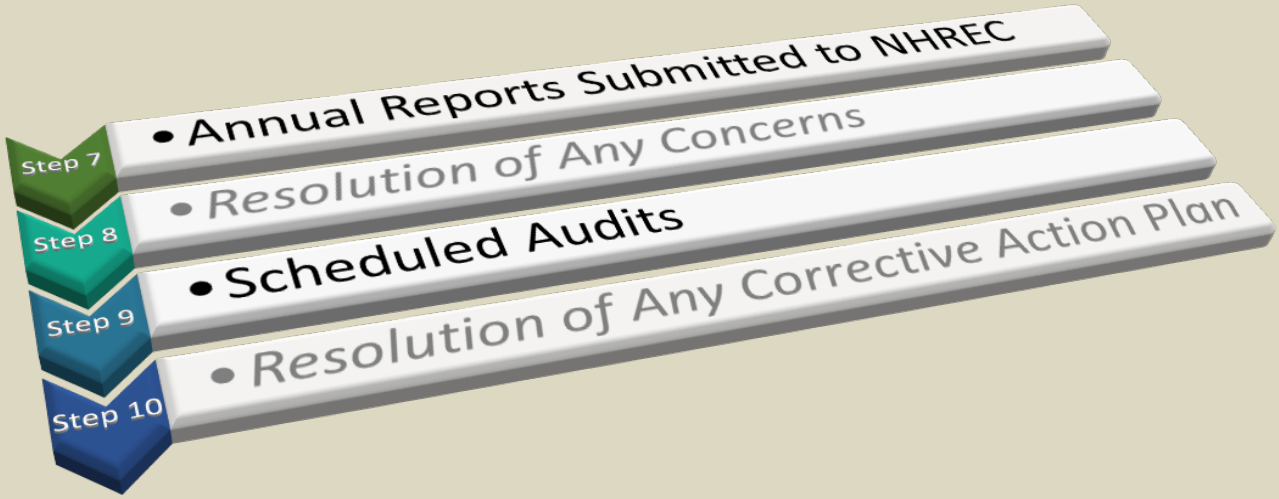
# Important Information

### Application and registration process




### Maintenance of registration

Continued compliance with registration requirements




## Applying for registration

An **Animal Research Ethics Committee (AREC)** of an organisation/institution or independent AREC may apply for registration with the **National Health Research Ethics Council (NHREC)**. To be eligible for registration, the organisation/institution and AREC must demonstrate compliance with Section 73 of the National Health Act, Act No 61 of 2003 (NHA 2003), and therefore, by implication, compliance with South African Ethics in Health Research Guidelines: Principles, Processes and Structures (NDoH 2024; 3rd ed. or latest version) and (2) the South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386:2021; 2st ed. latest version)..

All South African ARECs reviewing proposals for **health or health-related research** involving the use of animal for the purpose of human health (see NHA 2003), including testing (e.g. vaccines, drugs, medical devices, etc.) and health-related education and training (e.g. surgery, anatomy, physiology, pre-clinical and/or translation of clinical, dentistry, etc.), must register with the NHREC. Registration may contribute to promotion of higher standards and uniform application of ethics principles and thus to maintain public confidence.

This application must be signed by the **Authorised Institutional Official** (see full definition under "

" below) or, in the case of an independent HREC, by the highest authorised line manager or the Chairperson of the HREC. If the AREC serves more than one organisation or institution, the Authorised Institutional Official of each of these organisations and institutions must sign the form.

To prevent unnecessary delays in the registration process, please ensure that the information provided is complete and accurate. The applicant may be contacted if additional information is needed, and will be advised of the outcome.

## Instructions

**Basic instructions**

- Please complete the AREC registration form electronically in this original, fillable PDF application form (*for ease of accurate data capturing purposes*). Therefore, please do NOT submit a scanned copy.
- ALL questions MUST be answered in the spaces provided. All information provided in this application must be accurate, to the best of your knowledge. Also note:
  - Useful instruction tips will appear when you move your mouse over the fields to be completed.
  - Ensure that ALL required fields have been completed *(note required field indicated by "red" borders)*, otherwise your form will not submit.
  - Some text boxes allow a specific maximum number of characters (e.g., *indicated as "250 char. max"*) and will truncate beyond the maximum, limiting how much you can type. If you have reached the limit and need to say more, or when supporting documentation is required to fully answer a particular question, summarise your answer in the text box, attach an additional document with your full answer and clearly reference this attached document in the space provided for your answer in this report form (e.g., *"See full answer in the document attached, named [Answers.docx], par 3.2"*).
- Have this original, completed PDF document signed electronically *(preferred)* by all indicated authorised signatories. Only when a printed version of the declaration *(see Section 3)* is signed by a signatory, scan a high quality copy of that page in PDF or JPG format for submission as a separate page, and refer to the name of the scanned document with the signed page in the space provided in this PDF form.
- When saving on your computer, give the completed annual report form an appropriate name (e.g., "*AREC Registration*" + "*application year*" + "*the acronym for your AREC name*", for example [AREC Register 2024 SADU-AREC1.pdf]).
- Write a brief cover e-mail message and also attach all other supporting documentation. E-mail the completed form to the NHREC secretariat as in the contact information below, with the e-mail subject "Application to register a new AREC".

**Contact information**


| | |
|---|---|
| E-mail: | nhrec@health.gov.za |
| Tel: | 012 395 8119/8125 |
| Fax: | 012 395 9249 |

## Use of information

Information about the registered AREC and its organisation/institution is used to confirm compliance with the requirements for continued registration. The requirements include scrutiny of compliance with best practice regarding ethical conduct of the use of animals for scientific purposes including research, testing and education.

Information collected during annual reporting will be used for the following purposes:

- Promote constructive communication between the AREC and NHREC.
- Update contact and other details to the NHREC's database of ARECs.
- Maintain a record of AREC activities, enquiries and complaints.
- Monitor and review AREC compliance with the National Health Act, Act No 61 of 2003 (**NHA 2003**), and, therefore, by implication, compliance with (1) South African Guidelines on Ethics in Health Research Principles, Processes and Structures (**NDoH 2024** 3rd ed. or latest version) and (2) the South African National Standard: Care and Use of Animals for Scientific Purposes (**SANS 10386:2021**; 2nd ed. or latest version).
- Maintain an updated and publicly accessible database of registered ARECs.

## Protection of disclosure of information

The Protection of Personal Information Act No 4 of 2013 and the ethical principles supporting confidentiality govern disclosure of information collected by the NHREC about ARECs and organisations/institutions.

## Additional information on the NHREC can be retrieved from

https://www.health.gov.za/nhrec-home/

## Abbreviations, terms & definitions

The following common abbreviations and terminology are used in this application:

| Abbreviation/Term | Definition |
|---|---|
| **Active monitoring** | Refers to active validation of compliance to the ethical aspects of the approved study, including an onsite inspection of the execution of a study. |
| **AREC** | Animal Research Ethics Committee |
| **Authorised institutional official (AIO)** | The authorised member of senior administration/management of the institution/organisation bearing ultimate responsibility and accountability for the animal care and use programme |
| **Authorised signatory** | The person taking responsibility for indicated functions related to the AREC, according to institutional policy – see also Section 1.7 & 8 of this form below |
| **BESEC** | Biological and Environmental Safety Ethics Committee |
| **DALRRD** | Department of Agriculture, Land Reform and Rural Development |
| **NDoH 2024** | South African Guidelines on Ethics in Health Research Principles, Processes and Structures, 3rd ed., 2024. |
| **GCP / VGCP** | Good Clinical Practice / Veterinary GCP |
| **IACUP** | Institutional animal care and use programme |
| **MoA** | Memorandum of Agreement *(i.e., a contractual agreement)* |
| **MoU** | Memorandum of Understanding |
| **MTA** | Material Transfer Agreement *(i.e., regarding animal biological material)* |
| **NDoH** | National Department of Health |
| **NHA 2003** | National Health Act, Act No 61 of 2003 |
| **NHREC** | National Health Research Ethics Council |
| **Organisation/institution** | The organisation/institution taking responsibility of the AREC |
| **Passive monitoring** | Refers to regular (typically annually) written reporting by the principal investigator about animal use, progress and problems with the study |
| **Policy** | High-level governance or operational principles formally adopted by an institution |
| **SAHPRA** | South African Health Products Regulatory Authority |
| **SANS 10386:2021** | South African National Standard: Care and Use of Animals for Scientific Purposes, 2nd ed., 2021 |
| **SAVC** | South African Veterinary Council |
| **Serious adverse event (SAE)** | Relates to an unforeseen harmful event related to the study (e.g., injury/death due to an experimental intervention) |
| **Serious incident (SI)** | Relates to an unforeseen harmful event unrelated to the study itself (e.g., facility failure/pathogen outbreak) |
| **SOP** | Standard Operating Procedure |
| **ToR** | Terms of Reference |
| **Unanticipated problem** | Relates to any obstacle that negatively affects a study and the possibility to achieve the outcomes, other than due to a SAE or SI defined above. |

Please complete all sections of the form below, and include all supporting documentation as indicated.

# Section 1: Details of the Animal Research Ethics Committee (AREC)

## 1.01 AREC identification

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| AREC's full name | | | | | | | |
| AREC's acronym or short name | | NHREC registration no. | **AREC-** | | **-** | | |
| Date of registration at NHREC | | Status of registration | - select - | | | | |

**Please note!** There is no 1.02 – this is intended and not a mistake.

## 1.03 Any changes foreseen during the next year?

| | Yes | No |
|---|---|---|
| The reporting period is typically one calendar year. Do you foresee any changes within the first reporting period (year) with regard to the below-mentioned (par 1.4 – 1.7) AREC contact person, head of administrative functioning, chairperson, responsible organisation and/or contact information? | ○ | ○ |

If "Yes", identify which information will change and when in the space below:

***Please note!***

- *Any changes need to be communicated with the NHREC as they are implemented. It is of particular importance that details of the contact person and chairperson are kept up-to-date with NHREC.*
- *If any comments in the question below require more space than maximum provided (max 500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

| | |
|---|---|
| Details of any changes *(if applicable)* | |

## 1.04 AREC contact person

***Please note!*** *All correspondence to the AREC, including to the chairperson, will be sent to the AREC contact information as indicated above. This should be an address that does not change when individuals of the secretariat, the AREC chairperson or other office bearers change.*

| | | | | |
|---|---|---|---|---|
| Contact person | | | | |
| | *title* | *first name* | *last name* | |
| E-mail | | REC Web URL1 | | |
| Telephone | | Fax: | | |
| Physical address | | Postal address | | |

### 1.05 AREC head of administrative functioning *(if applicable)*

***Please note!*** *Some ARECs may be supported by a central administrative office, and in some instances this office may have a senior manager. If this is the case, this manager's details may be provided here.*

| | | | | |
|---|---|---|---|---|
| Contact person | | | | |
| | *title* | *first name* | | *last name* |
| E-mail | | | REC Web URL2 | |
| Telephone | | | Fax: | |
| Physical address | | | Postal address | |

### 1.06 AREC chairperson

***Please note!*** *Appointment date when the chairperson took office for the first time (compare NDoH 2024 Section 5.3.2).*

| | | | | |
|---|---|---|---|---|
| Chairperson's name | | | | |
| | *title* | *first name* | | *last name* |
| Appointment date* | | | E-mail | |
| Office phone | | | Mobile phone | |

### 1.07 Responsible organisation/institution and person

The institutional governance of the entire ***institutional animal care and use programme (IACUP)***, including institutional policies, the AREC(s) and research animal facility(ies), is overseen by the **Authorised Institutional Official (AIO)** (see **NDoH 2024** Section 5.6e and **SANS 10386:2021** Section 5.2.3.5.1). This individual represents senior administration/ management, and bears the mandate, authority and ultimate responsibility (and accountability) to align, allocate, enact and ensure all support and resources needed by all institutional stakeholders (including the AREC(s) to effectively fulfil their respective responsibilities within the ***IACUP***. The **AIO** must also work in close collaboration with applicable institutional line managers, AREC(s) and any relevant research facility managers, professional supervisor(s) and other supervisors and managers within the ***IACUP***.

***Please note!*** *Each institution appoints the AIO in line with its own policies. Without being prescriptive, this individual is typically a chief executive officer (CEO), or Deputy Vice Chancellor Research & Innovation.*

| | | | | |
|---|---|---|---|---|
| Name of responsible organisation/ institution | | | | |
| Name of the Authorised Institutional Official | | | | |
| | *title* | *first name* | | *last name* |
| Position | | | | |
| E-mail | | | Telephone | |
| Physical address | | | Postal address | |

### 1.08 Succession plan

Please describe the plan of the AREC for capacity building and development (succession planning), for example development plans and support by the organisation/institution, training initiatives, contact and support by other experienced persons or established ARECs, etc.

***Please note!*** *As per* the ***NDoH 2024****, AREC membership is limited to a maximum of two terms, with each term being a maximum of 4 years.*

| Do you have proper succession planning and/or capacity building in place, particularly for the future chairperson and senior positions in the secretariat (i.e., to ensure preparedness & competence for future appointments and to facilitate smooth processes during transition or unplanned absence)? | Yes ◯ | No ◯ |
|---|---|---|
| Please explain briefly your succession plan and the current status of implementation. If applicable, explain any remedial action plan, progress, and/or any related obstacles experienced in the past year | | |

### 1.09 Sector of the organisation/institution

Please indicate which category best describes the organisation/institution (***Please note!*** tick only one):

| | | | |
|---|---|---|---|
| ◯ | Public hospital/health service | ◯ | Private health laboratory |
| ◯ | Private hospital/health service | ◯ | Pharmaceutical / biotechnology company |
| ◯ | Public university/educational institution | ◯ | Institution for vaccine production or testing |
| ◯ | Private university/educational institution | ◯ | National Park |
| ◯ | Government Department | ◯ | Zoo |
| ◯ | Government statutory agency (e.g. HSRC, MRC, NRF, CSIR) | ◯ | Private Research Ethics Committee (non-profit) |
| ◯ | Public health laboratory | ◯ | Private Research Ethics Committee (for profit) |
| ◯ | Other *(specify; max 100 char.)* | | |

## Background Information

### *1.10 Applicants*

Please indicate for whom the AREC intends to evaluate applications (***Please note!*** select "Yes" or "No" for EACH item):

| Yes | No | Item |
|---|---|---|
| ◯ | ◯ | Application for ethics approval of projects internal to the organisation/institution |
| ◯ | ◯ | Application for ethics approval of projects external to the organisation/institution |
| ◯ | ◯ | Other (specify; *100 char. max*) |

### *1.11 Activity Levels*

| | Yes | No |
|---|---|---|
| Has the AREC approved ethics applications in the past? | ○ | ○ |

| | |
|---|---|
| How many research/testing/education proposals/protocols has the AREC reviewed in the last 12 months? | |
| How many research/testing/education proposals/protocols does the AREC anticipate reviewing per annum? | |
| How many meetings *(to review proposals/protocols)* has the AREC held in the last 12 months? | |
| How many meetings *(to review proposals/protocols)* does the AREC anticipate holding per annum? | |

### *1.12 Types of science*

Please indicate the types of science to be encountered during the review of proposals/protocols (***Please note!*** tick all that may be applicable):

| Yes | No | Item | Yes | No | Item |
|---|---|---|---|---|---|
| ○ | ○ | Agricultural sciences | ○ | ○ | Human health sciences |
| ○ | ○ | Conservational and wildlife sciences | ○ | ○ | Veterinary and para-veterinary sciences |
| ○ | ○ | Environmental sciences | ○ | ○ | Zoological sciences |
| ○ | ○ | Biological sciences | | | |
| ○ | ○ | Other (specify; *100 char. max*) | | | |

### *1.13 Types of animals*

Please indicate the types of animals to be used in the proposals/protocols that will evaluate (***Please note!*** tick all that may be applicable):

| Yes | No | Item | Yes | No | Item |
|---|---|---|---|---|---|
| ○ | ○ | Domestic animals | ○ | ○ | Lower invertebrates (including insects) |
| ○ | ○ | Farm or agricultural animals | ○ | ○ | Marine animals or aquaculture |
| ○ | ○ | Feral animals | ○ | ○ | Non-human primates |
| ○ | ○ | Higher invertebrates | ○ | ○ | Wildlife animals |
| ○ | ○ | Laboratory animals | ○ | ○ | Zoo animals |
| ○ | ○ | Other (specify; *100 char. max*) | | | |

# Section 2: General Reporting Information

## Requirements of an AREC

### *2.01 Legislation, guidelines and standards*

As indicated in the South African Guidelines on Ethics in Health Research Principles, Processes and Structures (**NDoH 2024**; 3rd ed. or latest version), all ARECs must be familiar with and comply with the **NDoH 2024** guidelines and the South African National Standard: Care and Use of Animals for Scientific Purposes (**SANS 10386:2021**, 2nd ed. or latest version). Other guidelines may be used in addition, as long as they do not contradict the **NDoH 2024** or the **SANS 10386:2021**.

| **Guideline:** | **NDoH 2024** | | **SANS 10386** | |
|---|---|---|---|---|
| Are electronic/printed copies of the indicated guidelines available to the AREC management? | **Yes** ◯ | **No** ◯ | **Yes** ◯ | **No** ◯ |
| Are electronic/printed copies of the indicated guidelines readily available to each AREC member? | **Yes** ◯ | **No** ◯ | **Yes** ◯ | **No** ◯ |
| Are electronic/printed copies of the indicated guidelines readily available to researchers using animals in research? | **Yes** ◯ | **No** ◯ | **Yes** ◯ | **No** ◯ |
| Does the AREC comply with the indicated guidelines, being knowledgeable about its requirements? | **Yes** ◯ | **No** ◯ | **Yes** ◯ | **No** ◯ |

| | | |
|---|---|---|
| Does the AREC comply with any other national or international guidelines or standards related to the care and use of animals for scientific purposes ***Note!*** *excluding South African legislation/Acts)* | **Yes** ◯ | **No** ◯ |
| If "Yes", specify which and why *(500 char. max)*: | | |

Does the AREC have appropriate institutional policies, SOPs and/or other guidance/processes in place and operational to ensure compliance with:

| | | | |
|---|---|---|---|
| the Protection of Personal Information Act 4 of 2013 (POPIA)? | Yes ◯ | No ◯ | |
| good practice for national and international and multi-institutional collaborative research (MoUs/MoAs), as well as joint or reciprocal ethical review? | Yes ◯ | No ◯ | n/a ◯ |
| requirements for a Section 20 permit under as per the Animal Diseases Act, 1984 (Act 35 of 1984), as issued by the Department of Agriculture? | Yes ◯ | No ◯ | n/a ◯ |
| requirements for national and international material transfer agreements (MTAs), exports and imports of animals or animal biological materials, and/or biodiversity collections, as applicable? | Yes ◯ | No ◯ | n/a ◯ |
| requirements of the South African Veterinary Council (SAVC) regarding registration or authorisation, any veterinary or para-veterinary procedures, or other requirements? | Yes ◯ | No ◯ | n/a ◯ |
| the Veterinary Medicines operational unit of the South African Health Products Regulatory Authority (SAHPRA) regarding pre-clinical animal studies investigating health products for human health purposes, or animal veterinary trials, as applicable? | Yes ◯ | No ◯ | n/a ◯ |
| the Guideline Document for Work with Genetically Modified Organisms, 2004 (or latest version) of the Department of Agriculture? | Yes ◯ | No ◯ | n/a ◯ |
| requirements of using certifiable, protected and threatened animal species, for example CITES, SANBI, SANBI Red Lists, Mammal Red List, Wildlfe Act, National Environmental Management; Biodiversity Act, 2004 (Act 10 Of 2004)? | Yes ◯ | No ◯ | n/a ◯ |
| responsible management of information and research data (i.e. any relevant policy, plan, procedures & best practices) | Yes ◯ | No ◯ | |
| Any comments of notes on the above that the AREC wishes to bring to the attention of the NHREC? *(1000 char. max)*: | | | |

### *2.02 Terms of reference (ToR)*

The organisation(s)/institution(s) must, when establishing an AREC, set out Terms of Reference (ToR) as specified in the **NDoH 2024** Section 5.2.2 and the **SANS 10386:2021** Section 5.3.3.3. The AREC's ToR should contain the following **critical elements**:

- Formal character of the committee, and how it complies with organisation/institutional and statutory requirements, including scope of authority, powers, and responsibilities, membership and quorum rules.
- Relationship and communication with the organisation/institution and accountability responsibilities.
- Requirement for formal procedures and processes, including the development of standard operating procedures (SOPs), including but not limited to:
  - ensure compliance with national legislation and standards (referring to the applicable legislation and standards), and the requirement of general competence (e.g., member selection, *ad hoc* inclusion of experts, training of AREC members);
  - promote proper reviewing, approval and monitoring of approved studies and animal welfare;
  - manage potential conflicts of interest and to maintain confidentiality;
  - establish clear reporting lines and accountability channels for the AREC, as well as to report of adverse events, non-compliance, misconduct, grievances, investigations, reporting to organisation/institution for disciplinary action, and withdrawal of approvals.
- Functions and responsibilities of the secretariat functions (e.g., relating to admin, record keeping, minutes, etc.).
- Relationship to affiliated and non-affiliated researchers, as well as with other NHREC-registered ARECs.
- Financial compensation (remuneration), if any, for non-affiliated members *(e.g., travel expenses, loss of income for veterinarian or other professionals, etc.)*.

***NB!*** *If your comments in the question below require more space than maximum provided (max 500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

| | | |
|---|---|---|
| Have the AREC's ToR been developed? | **Yes** ○ | **No** ○ |
| Do the AREC's ToR include the abovementioned critical elements? | **Yes** ○ | **No** ○ |
| Have the AREC's ToR been formally approved by your institution? | **Yes** ○ | **No** ○ |
| Any comments *(optional; 500 char. max)*: | | |

## *2.03 Standard operating procedures (SOPs)*

Organisations/Institutions and their ARECs must have **Standard Operating Procedures (SOPs)**, defined here as formally approved and implemented instruction documents in the appropriate format (including document number/code, SOP title & description, version & date, purpose, scope, responsibilities, instruction(s), authorised signatures, etc. – see **NDoH 2024** Section 5.2.2 and **SANS 10386:2021** Section 5.3.3.5.11). The organisation/institution and the AREC must have instructions in one or more SOPs explaining the following elements:

- Development and management (review, monitor, approve) of SOPs
- Frequency of meetings
- Preparation of agendas and minutes
- Distribution of documentation prior to meetings
- Review and approval of proposals/protocols (including expedited)
- How final decisions are reached
- Prompt notification of decisions
- How to address conflicts of interest and conflict of commitment for AREC members
- How to address conflicts of interest and conflicts of commitment for researchers
- Informed consent for animal owners
- Reporting of unanticipated problems/incidents/adverse events
- Protocol amendment procedures
- Protocol deviations and protocol violations
- Maintenance of records in accordance with the NDoH 2024 Section 5.5.1.8 and the SANS 10386:2021 (e.g., Section 5.2.3.1.2j, Section 5.3.3.5.9, Section 5.4.3.3.6)
- Reporting of allegations of misconduct/non-compliance
- Mechanisms for "whistle-blower" protection
- Complaints procedures
- Post-approval passive monitoring[1] of proposals/protocols
- Post-approval active monitoring of proposals/protocols
- Routine and regular oversight (inspection) of animal care and use facilities
- Continuing review and recertification procedures
- Suspension and termination
- Biological materials collection and storage
- Data bases, registries and repositories
- Developing memoranda of understanding/agreement (MoUs/MoAs) between institutional ARECs, as well as material transfer agreements (MTAs), for national and international multi-institutional research collaboration
- …and others as appropriate and added from time to time

***NB!*** *If your comments in the question below require more space than maximum provided (max 500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

**Whereas all of the above elements must be included in one more of the SOPs, indicate whether the following specific elements have been properly addressed:**

| | Yes | No |
|---|---|---|
| 1. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining the **frequency of meetings**[2]? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 2. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining the **preparation of agendas and minutes**? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 3. Do the organisation/institution and the AREC have instructions in one or more SOPs describing the **distribution of documentation prior to meetings?** | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 4. Do the AREC have instructions in one or more SOPs describing the process for **review and approval of proposals/protocols (including expedited), and how final decisions are reached**? | ◯ | ◯ |
| Comment if "No" | | |

[1] Refer to the table on p. 3 for a definition of passive and active monitoring, respectively.

[2] **NB!** Here "meetings" implies an interactive *(i.e. physical / face-to-face / teleconferencing / videoconferencing)* discussion of applications *(including project overview, reviewer feedback, deliberation, harms-benefit assessment, etc.)* by a quorum of members present, as well as by representation of categories A, B, C & D members present (compare SANS 10386:2008 par. 5.2.5.1).

| | Yes | No |
|---|---|---|
| 5. Do the organisation/institution and the AREC have instructions in one or more SOPs that explains how **prompt notification of decisions are made**? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 6. Do the organisation/institution and the AREC have instructions in one or more SOPs outlining guiding timelines for REC operational efficiency of application review and approval processes, and do these include that records will be kept of actual time spent on various administrative, review, feedback and response processes, thereby to effectively manage efficiency? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 7. Do the organisation/institution and the AREC have instructions in one or more SOPs describing how **reporting of unanticipated problems/incidents/adverse events must be done**? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 8. Do the organisation/institution and the AREC have instructions in one or more SOPs that explains the process for **reporting of allegations of non-compliance or violation of good research practice, or complaints**? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 9. Do the organisation/institution and the AREC have instructions in one or more SOPs describing **mechanisms for "whistle-blowing" and "whistle-blower" protection**? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 10. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining the process for **post-approval passive monitoring[3] of proposals/protocols**? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 11. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining the process for **post-approval active monitoring[3] of proposals/protocols**? | ◯ | ◯ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 12. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining how to handle **routine and regular oversight (inspection) of animal care and use facilities**? | ◯ | ◯ |
| Comment if "No" | | |

[3] Refer to the table on p. 3 for a definition of passive and active monitoring, respectively.

| 13. Do the organisation/institution and the AREC have instructions in one or more SOPs explain how **conflicts of interest and conflicts of commitment for AREC members should be addressed**? | **Yes** ◯ | **No** ◯ |
|---|---|---|
| Comment if "No" | | |

| 14. Do the organisation/institution and the AREC have instructions in one or more SOPs that explains how **conflicts of interest and conflicts of commitment for researchers and teachers should be addressed**? | **Yes** ◯ | **No** ◯ |
|---|---|---|
| Comment if "No" | | |

| 15. Do the organisation/institution and the AREC have instructions in one or more SOPs that indicate how **records in accordance with the NDoH 2024 & SANS 10386 guidelines should be maintained**? | **Yes** ◯ | **No** ◯ |
|---|---|---|
| Comment if "No" | | |

| 16. Do the organisation/institution and the AREC have instructions in one or more SOPs to **develop and manage (review, monitor, approve) SOPs?** | **Yes** ◯ | **No** ◯ |
|---|---|---|
| Comment if "No" | | |

| **Are the developed SOPs in an appropriate and official SOP format?** (including document number/code, SOP title & description, version & date, purpose, scope, responsibilities, instruction(s), authorised signatures, etc.). | **Yes** ◯ | **No** ◯ | **n/a** ◯ |
|---|---|---|---|
| Which of the SOPs still need to be developed so that the collection contains all of the critical elements? | | | |

### *2.04 AREC forms/templates*

ARECs develop forms to support their function, in line with its SOPs, including to facilitate application, notification, reporting, monitoring, inspection and queries. These forms are used by applicants and researchers when applying for approval or when reporting on any matter related to approved projects. Typical examples of forms may include the following:

- Ethics application form for approval of a study
- Reviewer report forms for study applications
- Ethics application for approval of sub-studies under a larger/umbrella/parent study
- Ethics application form for approval of a SOP related to animal care and procedures
- Notification form for studies not requiring ethical approval (e.g., lower invertebrates)
- Application form to amend an approved study
- Form for annual passive monitoring of an approved study
- Form for active monitoring of an approved study in progress
- Form for the inspection of animal holding facilities by AREC member
- Report form for serious adverse events or incidents
- Form for raising a query or complaint

- ***NB!*** *If your comments in the question below require more space than maximum provided (max 500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

| | Yes | No |
|---|---|---|
| Have some of the AREC's forms/templates been developed? | ○ | ○ |
| Which of the forms/templates still need to be developed so that the collection contains all of the critical elements? | | |

## 2.05 Research Ethics Policy

Please answer below:

| | Yes | No |
|---|---|---|
| Has the Research Ethics Policy *(or an overarching governance document that pertains to research conduct research infrastructure and research ethics of the institution)* been developed and approved? | ○ | ○ |

***NB!*** *Provide a brief summary of any changes here and provide a URL link to this document.*

## 2.06 Processes for the nomination, selection and appointment of AREC members

Please describe the respective processes of nomination, selection and formal appointment of AREC chairperson and members, as well any documentation (e.g. *curriculum vitae*) of the nominees required to be submitted for appointment?

***NB!*** *If any comments in the question below require more space than maximum provided (max 500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

| | |
|---|---|
| Nomination *(500 char. max)* | |
| Selection *(500 char. max)* | |
| Appointment *(500 char. max)* | |
| Required Documentation *(500 char. max)* | |

## 2.07 Documentation for the appointment, indemnification of AREC members and code of conduct

Members must receive formal written notification (electronic or printed) of their appointment, the term of office and the assurance that the organisation/institution provides indemnification against liability that may arise in the course of *bona fide* conduct of their duties as committee members.

Indicate below how AREC members are informed about their appointment:

***NB!*** *If any comments in the question below require more space than maximum provided (max 500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

| | | |
|---|---|---|
| Do members receive formal written notification about their appointment? | **Yes** ◯ | **No** ◯ |
| Does the notice specify the term of appointment? | **Yes** ◯ | **No** ◯ |
| Does the notice specify indemnification against liability that may arise in the course of *bona fide* conduct of their duties as committee members? | **Yes** ◯ | **No** ◯ |
| Members should sign a code of conduct when appointed. Does the AREC have a code of conduct for its members? | **Yes** ◯ | **No** ◯ |
| Any comments | | |

## 2.08 AREC management/administrative support

Please explain the nature, strengths and/or limitations of the management/administrative support available to the AREC during the reporting period (see **NDoH 2024**, e.g., secretariat/human resources, office space, computers, printers, financial support).

***NB!*** *If any comments in the question below require more space than maximum provided (max 1,500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

## 2.09 Supporting documentation to be attached

**Please attach the following AREC-supporting documentation to your application:**
*(Please provide explanatory comments below if any document is not attached)*
***NB!*** *If any comments (for documents NOT attached) below requires more space than maximum provided (max 200 char.), provide a brief summary in the comment box and refer to the name of your attached document containing the full details.*

| | Yes | No |
|---|---|---|
| 1. Policies/procedures of the AREC and the organisation/institution on animal care and use attached? | ○ | ○ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 2. Template of the AREC membership appointment letter (that includes term of office and indemnification of members) attached? | ○ | ○ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 3. All Standard Operating Procedure documents (SOPs) of the AREC attached? | ○ | ○ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 4. Application forms for ethical review of new proposals/protocols (including checklist for applications) attached? | ○ | ○ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 5. Application forms for amendments to approved proposals/protocols attached? | ○ | ○ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 6. Serious Adverse Events report form (or SOP, as will be used by researchers and teachers) attached? | ○ | ○ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 7. Confidentiality agreement form for AREC members and reviewers attached? | ○ | ○ |
| Comment if "No" | | |

| | Yes | No |
|---|---|---|
| 8. Conflict of interest declaration for AREC members and reviewers attached? | ○ | ○ |
| Comment if "No" | | |

| 9. Template of the AREC approval letter for a study attached? | Yes ○ | No ○ |
|---|---|---|
| Comment if "No" | | |

| 10. Post-approval passive monitoring[3] form (e.g. annual reporting by researchers or teachers) | Yes ○ | No ○ |
|---|---|---|
| Comment if "No" | | |

| 11. Post-approval active monitoring[3] forms (e.g. onsite inspection of active studies) | Yes ○ | No ○ |
|---|---|---|
| Comment if "No" | | |

| 12. The code of conduct form for AREC members | Yes ○ | No ○ |
|---|---|---|
| Comment if "No" | | |

| 13. Animal facility inspection form | Yes ○ | No ○ |
|---|---|---|
| Comment if "No" | | |

| 14. Other *(specify)* | | Yes ○ | No ○ |
|---|---|---|---|

***NB!*** *If any comments (for documents NOT attached) above requires more space than maximum provided (max 200 char.), provide a brief summary in the comment box and refer to the name of your attached document containing the full details.*

# Section 3: AREC Composition

## 3.1 AREC member names and profiles

Indicate how the membership of your AREC was constituted during the reporting period, by completing the text fields or selecting from the drop-down boxes in the table below.

***Please note!***

- AREC member categories A to D are defined in **SANS 10386**:2021 Section 5.3.3.2.1.2, whereas additional members *(optional)* may be appointed to complement expertise and roles of the AREC. The chairperson does not hold a category.
- Please complete the table below meticulously, as the information is extracted and used to verify compliance with **NDoH 2024** Sections 5.3.1 & 5.2.4 and **SANS 10386:2021**. Additional notes for when "*other (specify below)*" is selected in the table, is on the next page below the table. Use this only when the table does not accommodate the information you wish to share.

| | Name of member *(title, initials, surname) This column duplicates on the next page* | Position in AREC | Categories A to D or other *(see SANS 10386 5.3.3.2.1.2)* | Years serving on AREC | Assessed animal ethics training in past 3 years | Relation to organisation / institution | Demo-graphics | Age group | Sex |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | …see NDoH 2024 | | |
| 0 | *e.g.,* Prof XX Example | *e.g.,* Vice-Chairperson | *e.g.,* Cat B | *e.g.,* 4-6 | *e.g.,* Yes | *e.g.,* Affiliated | *e.g.,* Black | *e.g.,* 50-59 | *e.g.,* Female |
| 1. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 2. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 3. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 4. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 5. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 6. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 7. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 8. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 9. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 10. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 11. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 12. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 13. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 14. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 15. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 16. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 17. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 18. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 19. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 20. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 21. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 22. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 23. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 24. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 25. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 26. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 27. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 28. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 29. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 30. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 31. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 32. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 33. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 34. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 35. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 36. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 37. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 38. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 39. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |
| 40. | | - select - | - select - | - select - | - select - | - select - | - select - | - select - | - select - |

## 3.2 Required expertise of full members

Indicate the represented expertise discipline & profession of full AREC members *(i.e., excluding non-voting members)* by completing the fields in the table below.

***Please note!***

- At least one full member (or more) must represent the expertise listed below and must be qualified and experienced to serve in that capacity.
- One person may represent more than one category of expertise, and more than one person represent a particular category of expertise.

| **Required expertise** | | |
|---|---|---|
| **Expertise** | **#** | **Name(s)** |
| Expertise and experience in quantitative research methodologies | | |
| Translational *(basic to applied sciences or practice)* | | |
| Layperson *(see NDoH section 5.3.1, footnote 84)* | | |
| Entirely independent of the institution | | |
| Animal caretaker | | |
| Expertise in biostatistics | | |
| Expertise in animal research ethics | | |
| Legally qualified | | |
| Other (specify below) | | |
| Specify "Other" | | |

For notes on any member and descriptions above or below that may require further explanation, please indicate in the text box below the name(s) of the member(s) you refer to and then specify.

***Please note!***

- *These additional notes are optional. Please use this ONLY when necessary, when the table does not accommodate the information you wish to share.*
- *If any comment in the question below requires more space than maximum provided, provide a brief summary here and refer to the name of your attached document (ONLY when necessary) containing the full details.*

## 3.3 Membership categories

Indicate the categories of AREC members by completing the fields in the table below.

***Please note!***

- Each full member must be formally appointed in one category (i.e., A. B C or D), may not serve on more than one category, and may not switch between categories from one REC meeting to the next.
- The total number of full (voting) members must be at least 9, as per NDoH 2024. The alternate and non-voting members do not count towards the minimum of 9 full members required for a REC.
- The EXCO and Adverse Event/Incident committees must include the chairperson plus one representative of cat A, B, C & D. The EXCO may also serve as Adverse Event/Incident committee.

| | | | | |
|---|---|---|---|---|
| Total number of full members<br>- excluding nonvoting | | Is it expected that full members attend meetings regularly? | Yes ◯ | No ◯ |
| **Category** | **#** | **Category** | | **#** |
| Chairperson<br>- full member, one person without a category | | Vice-chairperson(s)<br>- from full members below, also holding a category | | |
| Cat A: veterinarian | | Cat B: research animal scientist | | |
| Cat C: animal welfarist | | Cat D: no research animal experience | | |
| Additional member<br>- full (voting) member adding value, but not fulfilling the criteria for cat A to D, e.g., animal caretaker | | Alternate member<br>- stands in for category when another is not available | | |
| Cat C + D | 0 | % Cat C + D<br>- must be ≥33% | NaN | **%** |
| Ad hoc member (expertise)<br>– nonvoting | | Advisory member<br>– nonvoting | | |
| Secretariat<br>(e.g., meeting support) – nonvoting | | Capacity building member<br>– nonvoting | | |
| EXCO members<br>- must represent chair, cat A, B, C & D | | Adverse event/incident committee<br>- must represent chair, cat A, B, C & D | | |
| Names of EXCO members | | Names of adverse event/incident committee members | | |
| | | | | |

For notes on any member and descriptions above or below that may require further explanation, please indicate in the text box below the name(s) of the member(s) you refer to and then specify.

***Please note!***

- *These additional notes are optional. Please use this ONLY when necessary, when the table does not accommodate the information you wish to share.*
- *If any comment in the question below requires more space than maximum provided, provide a brief summary here and refer to the name of your attached document (ONLY when necessary) containing the full details.*

## 3.4 Diversity and representation of full members

Indicate the diversity and representation of full AREC members *(i.e., excluding non-voting members)* by completing the fields in the table below.

**Demographics** *(...for equity and representation purposes)*

| | # | % | | # | % | | # | % |
|---|---|---|---|---|---|---|---|---|
| Black | | NaN % | Coloured | | NaN % | Indian | | NaN % |
| B + C + I | 0 | NaN % | White | | NaN % | Other *(specify)* | | NaN % |
| Specify if "Other" | | | | | | | | |

**Sex** *(...for equity and representation purposes)*

| | # | % | | # | % | | # | % |
|---|---|---|---|---|---|---|---|---|
| Male | | NaN % | Female | | NaN % | Other | | NaN % |

**Years serving on the REC**

| Yrs | # | % | Yrs | # | % | Yrs | # | % |
|---|---|---|---|---|---|---|---|---|
| <1 | | NaN % | 1-3 | | NaN % | 4-6 | | NaN % |
| 7-9 | | NaN % | >9 | | NaN % | | | |

**Age group distribution** *(...for equity and representation purposes)*

| Yrs | # | % | Yrs | # | % | Yrs | # | % |
|---|---|---|---|---|---|---|---|---|
| 20-29 | | NaN % | 30-39 | | NaN % | 40-49 | | NaN % |
| 50-59 | | NaN % | ≥60 | | NaN % | | | |

**Professional body registration**

| | # | | # | | # | | # |
|---|---|---|---|---|---|---|---|
| HPCSA | | SACNASP candidate | | SACNASP certificated | | SACNASP professional | | |
| SALPC | | SANC | | SAPC | | SAVC registered | | SAVC authorised | |
| Other | | Specify if "Other" | | | | | | |

**Note!** HPCSA = Health Professions Council of South Africa ; SACNASP = South African Council for Natural Scientific Professions ; SALPC = South African Legal Practice Council ; SANC = South African Nursing Council ; SAPC = South African Pharmacy Council ; SAVC = South African Veterinary Council

For notes on any member and descriptions above or below that may require further explanation, please indicate in the text box below the name(s) of the member(s) you refer to and then specify.

***Please note!***

- *These additional notes are optional. Please use this ONLY when necessary, when the table does not accommodate the information you wish to share.*
- *If any comment in the question below requires more space than maximum provided (max 1000 char.), provide a brief summary here and refer to the name of your attached document (ONLY when necessary) containing the full details.*

## 3.5 Disciplines & professions of full members

Indicate the represented disciplines and professions of full AREC members *(i.e., excluding non-voting members)* by completing the fields in the table below.

| Discipline and profession | | | | | |
|---|---|---|---|---|---|
| **Discipline/profession** | **#** | **Name(s)** | | | |
| Legal Professional | | Nat Sci Professional - animal | | Nat Sci Professional - aquatic | |
| Nat Sci Professional - biological | | Nat Sci Professional - conservation | | Nat Sci Professional - ecological | |
| Nat Sci Professional - environmental | | Nat Sci Professional - toxicological | | Nat Sci Professional - zoological | |
| Medical practitioner | | Pharmacist | | Pharmacologist | |
| Veterinarian | | Para-veterinarian | | Statistician | |
| Other (specify below) | | | | | |
| Specify "Other" | | | | | |

For notes on any member and descriptions above or below that may require further explanation, please indicate in the text box below the name(s) of the member(s) you refer to and then specify.

***Please note!***

- *These additional notes are optional. Please use this ONLY when necessary, when the table does not accommodate the information you wish to share.*
- *If any comment in the question below requires more space than maximum provided, provide a brief summary here and refer to the name of your attached document (ONLY when necessary) containing the full details.*

## 3.6 AREC appointment requirements

The composition of members must comply with the requirements set out in **NDoH 2024** and **SANS 10386:2021** Section 5.3.3.2. In principle, collectively, they must have the necessary qualifications, knowledge and experience to review and evaluate the science, welfare of animals and ethics (e.g., 4Rs and harms-benefit assessment) of the proposed scientific use of animals. In complying with the requirements, ARECs should be independent, multi-disciplinary, multi-sectoral and pluralistic. Diversity of AREC membership refers mostly to ethnicity, culture and gender of members (compare **NDoH 2024**).

***Please note!*** *If any comment in the question below requires more space than maximum provided (max 1,000 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

| | | |
|---|---|---|
| Is the AREC membership at present constituted in accordance with the requirements specified in the **NDoH 2024** and **SANS 10386:2021** guidelines? | **Yes** ◯ | **No** ◯ |
| Have all AREC members received receive a formal written notification about their appointment? | **Yes** ◯ | **No** ◯ |
| Does the notice specify the term of appointment? | **Yes** ◯ | **No** ◯ |
| Does the notice specify provision of legal protection in respect of liability that may arise in the course of *bona fide* conduct of their duties as committee members? | **Yes** ◯ | **No** ◯ |
| Members should sign a code of conduct when appointed. Does the AREC have a code of conduct for its members and has this been signed by all members? | **Yes** ◯ | **No** ◯ |
| Any comments *(optional)*: | | |

## 3.7 Challenges with membership

List any challenges encountered in meeting the membership requirements as stipulated in national guidelines, in the AREC's own ToR/SOP and in additional organisational/institutional policies. Also clearly indicate you action plan to address any sub-optimal matters or inadequacies identified.

***Please note!*** *If any comment in the question below requires more space than maximum provided (max 1,500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

## Section 4: Research Ethics Training, Resources & Capacity

AREC members are required to have appropriate and up-to-date training in the research ethics of the use of animals for scientific purposes (see **NDoH 2024** Section 5.4 & **SANS 10386:2021** Section 5.10). These guidelines require specified topics for training (see **NDoH 2024** & **SANS 10386:2021**), refresher training every 3 years, that training be assessed (i.e., not mere attendance), and that a certificate of proof of training be available.

***Please note!*** *Animal research ethics training, as required, is different from human research ethics training, and is over and above any professional/clinical ethics training, such as for continuing professional development (CPD).*

| Target group | Required Topics[4] | | Last 3 years? | | Assessed? | | Certificate of proof? | |
|---|---|---|---|---|---|---|---|---|
| Induction training for all AREC members | Yes ◯ | No ◯ | | | | | | |
| Animal research ethics training for **all AREC members** | Yes ◯ | No ◯ | Yes ◯ | No ◯ | Yes ◯ | No ◯ | Yes ◯ | No ◯ |
| Animal research ethics education/training for **support staff** *(i.e., admin/secretariat)* of ARECs | Yes ◯ | No ◯ | Yes ◯ | No ◯ | Yes ◯ | No ◯ | Yes ◯ | No ◯ |

When an AREC reviews a particular application, the following must be required and verified. Is this indeed done when and as applicable to a particular study?

| Target group | Verified? | |
|---|---|---|
| Animal research ethics training for all **investigators and collaborators** (i.e., researchers & postgraduate students) | Yes ◯ | No ◯ |
| Animal research ethics training specifically for all **international collaborators** | Yes ◯ | No ◯ |
| Animal research ethics education/training for **professional and other supervisors**, e.g., the attending veterinarian, pharmacist, LAT, etc. *(over and above continuing professional development)* | Yes ◯ | No ◯ |

Briefly describe you action plan to ensure compliance in cases of any insufficiencies.

***Please note!*** *If any comment in the question below requires more space than maximum provided (max 2,000 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

[4] Required topics refer to NDoH 2024 Section 5.4 and SANS 10386:2021 Section 5.10.3

# Section 5: Functions and Operations of the AREC

***Please note!*** *There is no 5.01 to 5.05 in this application form. This is intended and not an error.*

### *5.06 Animal numbers used per species and severity category (as defined in the SANS 10386:2021)*

Records must be kept by the AREC regarding the use of animals accurately as possible. Answer the following questions:

| | | |
|---|---|---|
| Do you have procedures and systems in place to report annually regarding approved studies on the number of various animal species used? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually regarding approved studies on the number of studies per animal species used? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually regarding approved studies on the number of animals and studies per severity category? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually regarding approved studies on the number of various animal species bred? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually regarding approved studies on the number of surplus animals (i.e., animals that were euthanised due to over-breeding or otherwise NOT used, reintroduced or rehomed? | Yes ◯ | No ◯ |

***Please note!*** *There is no 5.07 in this application form. This is intended and not an error.*

### *5.08 Other sensitive issues in studies approved*

The **SANS 10386:2021**, as adopted by the **NDoH 2024**, requires an annual independent external review of the operations of the AREC (**SANS 10386:2021** Section 5.3.3.6). Some of the questions below, and elsewhere in this annual report form, may assist the AREC to comply with the requirements for this annual review. Answer the following questions:

| | | |
|---|---|---|
| Do you have procedures and systems in place to report annually on basic information regarding approved studies on animal pre-clinical studies on health products for use in humans? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually on basic information regarding approved studies on veterinary clinical trials? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually on basic information regarding approved studies on the AREC's ethical oversight over any studies using threatened/endangered species? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually on basic information regarding approved studies on the AREC's have ethical oversight over any studies with environmental impact? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually on basic information regarding approved studies on the AREC ethical oversight over any studies or facilities producing, breeding of, and/or studies using genetically modified animals? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually on basic information regarding approved studies on the transport of animals? | Yes ◯ | No ◯ |
| Do you have procedures and systems in place to report annually on basic information regarding approved studies on the use of animal biological materials? | Yes ◯ | No ◯ |
| Will you confirm that RAF personnel that are certified or authorized by the relevant national council by annually obtaining an updated list from the RAF management? | Yes ◯ | No ◯ |

***Please note!*** *There is no 5.08.01 to 5.08.09 in this report form. This is intended and not an error.*

### *5.08.09 Biosafety Committee & Officer(s)*

The Biosafety Committee is sometimes referred to as a Biological and Environmental Safety Ethics Committee (BESEC) which may hold international accreditation/registration), or some would resort this function under the occupational health and safety committee. Importantly this committee must be appropriately competent and authorised.

***Please note!*** *Compare the **SANS 10386:2021** Section 5.2.3.1.2 f, Section 5.4.3.1.2 j and Section 5.5.3.1.5 j. An AREC should NOT assume this responsibility without the necessary expertise and authorisation.*

| | | | |
|---|---|---|---|
| Does the AREC have access to a Biosafety Committee and/or officer(s)? | **Yes** ◯ | **No** ◯ | **n/a** ◯ |
| If applicable, where/how is this committee(s) accredited or registered? | | | |
| Is there a formal process of review and approval of relevant studies and/or facilities with biosafety issues, with evidence of such approval, prior to submission for ethical review? | **Yes** ◯ | **No** ◯ | |
| Comments (accolades or concerns) about this committee/officers and functioning? | | | |

### *5.08.10 Prior scientific review*

Any study must undergo scientific review prior to ethical review. However, this does not preclude the AREC from commenting on and being satisfied with the scientific integrity of the study. Ethical integrity is inseparable from scientific integrity, and the REC has a responsibility to ensure the latter as well. Even a negligible risk of harm, or actual harm to an animal is unlikely to be justifiable if the research lacks scientific merit.

***Please note!*** *Compare the **NDoH 2024** Section 3.1.1 and **SANS 10386:2021** Section 4.6.*

| | | |
|---|---|---|
| Is there a formal process of scientific review and approval of studies prior to ethical review, with evidence of such approval? | **Yes** ◯ | **No** ◯ |
| Does the AREC require such evidence to be submitted with the ethics application? | **Yes** ◯ | **No** ◯ |

### *5.08.11 National and/or international multi-institutional collaborative research*

When doing multi-institutional collaborative projects, national and/or international, there are matters relating to onsite ethical oversight at research animal facilities/sites (e.g., national legislative requirements, supervision, training, active monitoring and adverse event/incident reporting, facility/site inspection, etc.). In this regard, answer the following:

***Please note!*** *Compare the **NDoH 2024** and **SANS 10386:2021** Section 5.5.3.2.4 and Section 5.7.4.2.*

| | | |
|---|---|---|
| Is there a formal process (and SOP) to set up memoranda of understanding/agreement (MoUs/MoAs) between institutional ARECs? | **Yes** ◯ | **No** ◯ |
| Is there a formal process (and SOP) to set up material transfer agreements (MTAs) between institutions, when transferring any animal or proprietary materials between labs? | **Yes** ◯ | **No** ◯ |

### *5.08.12 Independent external review*

Please answer the following:

***Please note!*** As per the **SANS 10386:2021** 2nd ed. Section 9 there are requirements of an independent external review of the operations of the AREC every year, as well as every four years of the operations of the institution regarding its animal care and use programme (ACUP). This NHREC annual report and review may assist the AREC to fulfil the requirements for the annual independent external review. However, the NHREC's 5-yearly audit of the AREC may not fully meet the requirement of the four yearly independent external review of the institution's ACUP. Nevertheless, the NHREC's audit report may be useful in this regard.

| | | | | | |
|---|---|---|---|---|---|
| Is there provision for annual reporting of the operations of the AREC in your ToR and/or SOP? *(e.g., reporting to the NHREC and institution)* | **Yes** ◯ | **No** ◯ | Is there provision for a 4-yearly independent external review of the operations of the institution's animal care and use programme? | **Yes** ◯ | **No** ◯ |
| Describe your actual progress so far (what has already been done), any stumbling blocks and concerns with the progress and implementation, as well as any accolades | | | | | |

## Monitoring

### *5.09 Oversight (inspection) of animal care and use facilities by AREC members in the reporting period*

| | |
|---|---|
| How many animal care and use facilities (research animal facilities - RAFs) will be overseen by the AREC? | |

| | | |
|---|---|---|
| Will you ensure that these RAFs are inspected annually? | **Yes** ◯ | **No** ◯ |
| Will you verify whether these RAFs are SAVC-registered if and as necessary? | **Yes** ◯ | **No** ◯ |
| Will you verify whether these RAFs have Section 20 permits if and as necessary? | **Yes** ◯ | **No** ◯ |
| Will you verify whether these RAFs have permits to house certifiable animals if and as necessary? | **Yes** ◯ | **No** ◯ |
| Will you ensure that these RAFs report to the AREC regularly at official AREC meetings? | **Yes** ◯ | **No** ◯ |

***Please note!*** *There is no section 6 in this report form. This is intended and not an error.*

# Section 7: Other matters

Please describe below any other information relevant to this application that may assist the NHREC in its assessment for registration.

***NB!*** *If any comments below require more space than maximum provided, provide a brief summary in the comment box and refer to the name of your attached document containing the full details.*

## Section 8: Declaration

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| AREC's full name | | | | | | | |
| AREC's acronym or short name | | NHREC provisional no. | **AREC-** | | **-** | | |
| Name of responsible organisation/ institution | | | | | | | |

This declaration must be completed and signed electronically in this original, fillable MSWord document (i.e., not a scanned copy) by the chair. Signatures by others indicated are optional.

***Please note!*** Only when electronic signing by a particular signatory is not possible and a printed version is signed by that person, scan a high-quality copy of that page in PDF or JPG format for submission as a separate page, refer to the signed page in this original MSWord form, and attach the scanned page in addition to this completed original MSWord form.

I, the undersigned, declare and undertake for the organisation/institution that:

- I am duly authorised to sign this approval,
- information supplied on this form and any attachment is correct to the best of my knowledge.

### First signatory: *AREC Chairperson*

| | | | | | |
|---|---|---|---|---|---|
| Name of signatory | *title* | *first name* | | *last name* | |
| Position | AREC Chairperson | | E-mail | | |
| **How does this signatory sign?** | *Digitally* ◯ | *Hard copy* ◯ | Signature | | |
| If a hard copy was signed, what is the name of the scanned copy of the signed document (attached)? | | | Date | | |

| | | |
|---|---|---|
| Do you confirm that the Authorised Institutional Official indeed received a copy of this annual report? | **Yes** ◯ | **No** ◯ |

***Please note!*** *It is required that the Authorised Institutional Official receives a copy and remains updated on all important matters related to the animal care and use programme.*

### Second signatory: *Head of Ethics Office or Authorised Institutional Official of the organisation/institution (optional)*

| | | |
|---|---|---|
| Do you want to add a second signatory? | **Yes** ◯ | **No** ◯ |

| | | | | | |
|---|---|---|---|---|---|
| Name of signatory | *title* | *first name* | | *last name* | |
| Position | | | E-mail | | |
| **How does this signatory sign?** | *Digitally* ◯ | *Hard copy* ◯ | Signature | | |
| If a hard copy was signed, what is the name of the scanned copy of the signed document (attached)? | | | Date | | |

**Third signatory:** *Head of Ethics Office or Authorised Institutional Official of the organisation/institution (optional)*

| Do you want to add a third signatory? | Yes ○ | No ○ |
|---|---|---|

| | | | | |
|---|---|---|---|---|
| Name of signatory | *title* | *first name* | | *last name* |
| Position | | | E-mail | |
| **How does this signatory sign?** | *Digitally* ◉ | *Hard copy* ○ | Signature | |
| If a hard copy was signed, what is the name of the scanned copy of the signed document (attached)? | | | Date | |

## Submission

After completion and signing, submit this original, fillable PDF form *(i.e., not a scanned copy)* plus any supporting documentation as attachment(s) to the **NHREC Secretariat** at:

nhrec@health.gov.za