NATIONAL HEALTH RESEARCH ETHICS COUNCIL

www.nhrec.org.za

AREC Annual Report Form

Annual report form for Animal Research Ethics Committees (ARECs) registered with the National Health Research Ethics Council (NHREC)

Approved by the National Health Research Ethics Council: 2023-11-01

Version 3.00

Please read the important background information on p. 2-3, and then complete Sections 1 to 7 of the report form from p. 4 onwards.

Date submitted by AREC			
Date received by NHREC		**…this date for office use only**	
Reporting period - from	2023-01-01	to	2023-12-31
AREC full name			
AREC acronym / short name		**Note!** Please ensure that you use the CORRECT full name and acronym of you AREC, and in particular the EXACT registration number as it appears on your registration certificate *(i.e., no omissions of any letters, numbers, 0's, or hyphens, or even addition of wrong spaces in the number).*	
AREC registration no.			
Registration status	- select -		
Name of primary organisation/institution			

Illustrative example

Date submitted: 2024-02-28
Date received: *…leave open…* ***(office use only)***
Reporting date: 2023-01-01 to 2023-12-31
AREC full name: South Africa Dummy University Animal Research Ethics Committee 1
AREC acronym: SADU-AREC1
AREC reg. no.: AREC-123456-078 ***(NB! exact number)***
Reg. status: Registered
Name of primary institution: South Africa Demo University

Important Information

Purpose

In South Africa, **Animal Research Ethics Committees (ARECs) that review health and health-related research** must report annually to the **National Health Research Ethics Council (NHREC)** on their activities, as required by the South African Guidelines on Ethics in Health Research Principles, Processes and Structures (**NDoH 2024**, 3rd ed. or latest version). For continued registration with the NHREC, 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 (1) NDoH 2024 and (2) the South African National Standard: Care and Use of Animals for Scientific Purposes (**SANS 10386:2021**, 2nd ed. or latest version).

Reports are due by **28 February annually** on this AREC annual reporting form (see NHREC website). To prevent unnecessary delays in the current annual reporting process, please ensure that the information provided is complete and accurate. The AREC may be contacted if additional information is needed, and will be advised of the outcome.

Instructions

Basic instructions

- Please complete the AREC annual report 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 Annual Report*" + "*reporting year*" + "*the acronym for your AREC name*", for example [AREC Annual Report 2023 SADU-AREC1.pdf]). Click on the "Submit" button (executes an e-mail action) in this original, fillable PDF report form, write a brief cover e-mail message and also attach all other supporting documentation. Save a copy for your own records.

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. **Please note!** It is understood that this document is still under revision after the 1st circulation for comment in 2023 *(i.e., not yet published)*.
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.

Reporting Period

The reporting period is typically one calendar year, since your last report, unless specified otherwise.

Dates for this report	*from*	2023-01-01	*until*	2023-12-31

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

1.1 AREC identification

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

1.2 Any changes during the reporting period?

	Yes	No
Have there been any changes since your last annual report to NHREC 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 has changed in the space below:
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.*

Details of any changes *(if applicable)*	

1.3 Any changes foreseen during the next year?

	Yes	No
Do you foresee any changes during the upcoming 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:
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.*

Details of any changes *(if applicable)*	

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.*

1.4 AREC contact person

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

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.*

1.5 AREC head of administrative functioning *(if applicable)*

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

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.*

1.6 AREC chairperson

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

1.7 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** 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***.

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	

1.8 Succession plan

	Yes	No
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)?	◉	○

If "No", then please explain any progress or obstacle in executing your succession plan in the past year	

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

Section 2: General Reporting Information

Requirements of an AREC

2.1 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 2023**		**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/research?	**Yes** ◉	**No** ○
If "Yes", specify which and why *(500 char. max)*:		

Does the AREC have appropriate institutional policies, SOPs and/or other processes in place 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/MoUs), as well as joint or reciprocal ethical review?	**Yes** ◯	**No** ◯	**n/a** ◯
requirements for national and international material transfer agreements (MTAs)?	**Yes** ◯	**No** ◯	**n/a** ◯
requirements of the South African Veterinary Council (SAVC)?	**Yes** ◯	**No** ◯	**n/a** ◯
the Veterinary Medicines operational unit of the South African Health Products Regulatory Authority (SAHPRA)?	**Yes** ◯	**No** ◯	**n/a** ◯
requirements for a Section 20 permit of the Department of Agriculture, land reform & rural Development (DALRRD)?	**Yes** ◯	**No** ◯	**n/a** ◯
the Guideline Document for Work with Genetically Modified Organisms, 2004 (or latest version) of DALRRD?	**Yes** ◯	**No** ◯	**n/a** ◯
Any comments of notes on the above that the AREC wishes to bring to the attention of the NHREC? *(1000 char. max)*:			

2.2 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** 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 AECs.
- 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.*

Are the AREC's ToR updated and operational?	**Yes** ○	**No** ○
Do the AREC's ToR include the abovementioned critical elements?	**Yes** ○	**No** ○
Can the AREC's ToR be accessed online?	**Yes** ○	**No** ○
If yes, provide the URL:		
If no, attach any newly developed ToR, or ToR with substantive updates (not necessary for minor updates)		
When last were the AREC's ToR updated?		
Any comments *(optional; 500 char. max)*:		

2.3 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** 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 guidelines and the SANS 10386:2021 standard (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[Error! Bookmark not defined.] of p roposals/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.*

Are the AREC's SOPs updated and operational?	Yes ○	No ○
Do the AREC's SOPs include the abovementioned elements?	Yes ○	No ○
Can the AREC's SOPs be accessed online?	Yes ○	No ○
If yes, provide the URL:		
If no, attach any newly developed SOPs, or SOPs with substantive updates (not necessary for minor updates)		
When last were the AREC's SOPs updated?		
Provide the name, date and one-sentence description for any new SOPs or substantive changes/updates to existing SOPs *(if applicable; 750 char. max)*:		

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

2.4 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.*

Are the AREC's forms/templates updated and operational?	**Yes** ○	**No** ○
Do the AREC's forms/templates include the abovementioned examples?	**Yes** ○	**No** ○
Can these forms/templates be accessed online?	**Yes** ○	**No** ○
If yes, provide the URL:		
When last were the AREC's forms/templates updated?		
Provide an action plan and/or explanation if any form is NOT available or insufficient *(750 char. max)*:		

2.5 Research Ethics Policy

Please answer below:

	Yes	No
Has the Research Ethics Policy *(or an overarching governance document that pertains to research conduct and research infrastructure of the institution)* been updated during the reporting period?	○	○

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

2.6 AREC administrative support

Please explain the nature, strengths and/or limitations of the administrative support available to the AREC during the reporting period (see **NDoH 2024** and **SANS 10386:2021** 5.3.3.4, Section 5.3.3.5.1, e.g., secretariat/human resources, office space, computers, printers, financial support).

NB! *If your 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.*

Section 3: AREC Composition

3.1 AREC member names and profile

Indicate how the membership of your present AREC is constituted, 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, whereas additional members *(optional)* may be appointed to complement expertise and roles of the AREC.
- Please complete the table below comprehensively, as the information is extracted and used to verify compliance with NDoH 2024 and SANS 10386:2021. Use additional note 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 Section 4.3.3.2.1)*	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 -
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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 -
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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 -
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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 -

Name of member *(title, initials, surname)* *This column duplicates from the previous page*		AREC membership requirements *(see NDoH 2024)*	AREC-relevant discipline and expertise	AREC-relevant experience	Professional registration / authorisation
		Note! *Select one or two requirements, and one or two disciplines/expertise per member from the drop-down lists below.*			
0	*e.g.,* Prof XX Example	*e.g.,* Biostatistics; Expert in quantitative	*e.g.,* Pharmacist; Professional scientist	*e.g.,* Experimental use of rodents	*e.g.,* SAVC, HPCSA
1.		- select - / - select -	- select - / - select -		- select -
2.		- select - / - select -	- select - / - select -		- select -
3.		- select - / - select -	- select - / - select -		- select -
4.		- select - / - select -	- select - / - select -		- select -
5.		- select - / - select -	- select - / - select -		- select -
6.		- select - / - select -	- select - / - select -		- select -
7.		- select - / - select -	- select - / - select -		- select -
8.		- select - / - select -	- select - / - select -		- select -
9.		- select - / - select -	- select - / - select -		- select -
10.		- select - / - select -	- select - / - select -		- select -
11.		- select - / - select -	- select - / - select -		- select -
12.		- select - / - select -	- select - / - select -		- select -
13.		- select - / - select -	- select - / - select -		- select -
14.		- select - / - select -	- select - / - select -		- select -
15.		- select - / - select -	- select - / - select -		- select -
16.		- select - / - select -	- select - / - select -		- select -
17.		- select - / - select -	- select - / - select -		- select -
18.		- select - / - select -	- select - / - select -		- select -
19.		- select - / - select -	- select - / - select -		- select -
20.		- select - / - select -	- select - / - select -		- select -
21.		- select - / - select -	- select - / - select -		- select -
22.		- select - / - select -	- select - / - select -		- select -
23.		- select - / - select -	- select - / - select -		- select -
24.		- select - / - select -	- select - / - select -		- select -
25.		- select - / - select -	- select - / - select -		- select -
26.		- select - / - select -	- select - / - select -		- select -
27.		- select - / - select -	- select - / - select -		- select -
28.		- select - / - select -	- select - / - select -		- select -
29.		- select - / - select -	- select - / - select -		- select -
30.		- select - / - select -	- select - / - select -		- select -

If you indicated "other (specify below)" in the table above for any member under the "category of membership" or "position in AREC", please indicate in the text box below the name(s) of the member(s) you refer to and then specify the "other".

Please note!

- *Use additional notes ONLY 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.*

3.2 AREC composition and appointment

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**).

NB! *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)*:		

3.3 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.

NB! *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** & **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.

NB! *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[2]		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 ◯

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

Briefly describe the typical training your AREC provided during the reporting period, and/or that your members participated in (attended or completed online). Also indicate how you will ensure compliance in cases of any insufficiencies.

NB! *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.*

Section 5: Functions and Operations of the AREC

5.01 AREC meetings

Number of AREC meetings[3] held during the reporting period?	…total scheduled		…total held	
	…total not quorate[3]		…total cancelled	
What are the main reasons for non-quorate[3]? *(max 1000 char.)*				
Steps taken when non-quorate[3]? *(max 1000 char.)*				
Number of other meetings held during the reporting period?		…by the Executive Committee		

[3] Here "meetings" imply an interactive (i.e., physical / face-to-face / teleconferencing / videoconferencing) discussion of applications (including project overview, reviewer feedback, deliberation, consensus decision, etc.) by a quorum of members present in term of number and representation. "Quorum/quorate" is defined by the guidelines, including that >50% of members be present when ≤15 members, or 33% when >15 members (**NDoH 2024**), plus that at least one member from each category (A, B C & D) be present (**SANS 10386:2021**, Section 5.3.3.2).

Second opinions: List and provide details of any second opinions by experts (compare **NDoH 2024** & **SANS 10386:2021**, Section 5.3.3.2.2, Section 5.4.3.1.2j) sought / provided during the reporting period.

NB! *If any comment in the question above 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.*

Agendas, Minutes and other meeting documents		
Were agendas, minutes and other meeting documents made available before AREC meetings during the reporting period?	**Yes** ◯	**No** ◯
How many days prior to meetings are agendas, minutes and other meeting documents made available to AREC members?		
Were minutes approved at the next meeting during the reporting period?	**Yes** ◯	**No** ◯
How are conflicts of interests recorded and managed?		

Approval of applications		
Is it a requirement of the AREC that applications can only be approved following deliberation at interactive (face-to-face or technology-based) AREC meetings?	**Yes** ◯	**No** ◯
Can you confirm that the abovementioned requirement of interactive meetings for ethics approval is indeed implemented by the AREC?	**Yes** ◯	**No** ◯

Review of Applications

5.02 General statistics

Provide the information below as accurately as possible.

Number of applications during the reporting period?	…considered		…in process	
	…approved		…not approved	
Number of SOPs relating to animal care and procedures during the reporting period?	…considered		…in process	
	…approved		…not approved	

5.03 Operational efficiency & record keeping

Operational efficiency of application review and approval processes is essential for RECs, in particular to manage timelines optimally to avoid undue delays, while also allowing sufficient time for administrative processes and proper ethical review.

Notes: *Ethical approval processes have often been criticised for delaying the commencement of research for postgraduate students (i.e., long turn-around times). Whereas such processes may play a role, delays may also relate to insufficient planning by investigators, time spent on rebuttals (e.g., slow response/procrastination) and delays to obtain external approvals and permits. Having the information below at hand would greatly assist the HREC to assess its administrative and review time efficiency, and to address any issues accurately and/or determine (even defend) to which extent the HREC and its processes are truly responsible for the delays.*

It is hence important that your SOP guides on, and you keep record of how many days…

- before a scheduled meeting the agenda closes for the submission of new applications, as per deadline communicated to all stakeholders?
- are afforded to reviewers to review an ordinary *(i.e., not expedited/rapid)* applications (i.e., from the date of receipt until submission of the review report to secretariat)?
- are typically spent on an ordinary AREC application from the date of closure of the agenda to first communication to the researcher (i.e., feedback on the ARECs decision at the meeting)?
- are afforded to investigators (i.e., applicants) to address comments (e.g., 60 days) in a rebuttal to AREC comments, after receipt of the first decision letter (i.e., not within the control of the AREC or secretariat)?
- are afforded to reviewers to review an expedited/rapid AREC application (i.e., from the date of receipt until submission of the review report to secretariat)?
- are typically spent on an expedited/rapid AREC application from the date of closure of the agenda to first communication to the researcher (i.e., feedback on the ARECs decision at the meeting)?

Does your SOP outline guiding timelines for REC operational efficiency of application review and approval processes, as indicated above?	**Yes** ◯	**No** ◯
Does your REC keep record of actual time spent on various administrative, review, feedback and response processes, thereby to effectively manage efficiency?	**Yes** ◯	**No** ◯

Briefly comment on any challenges you experience with the above (SOP and record keeping), or mention any accolades of any newly implemented, successful strategies that others may learn from.

5.04 Types of science

Please indicate the types of science encountered during the review of proposals/protocols during the reporting period (***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*)			

5.05 Types of animals

Please indicate the types of animals to be used in the proposals/protocols that the AREC received to evaluate during the reporting period (***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*)			

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

Provide in the table below the information per species as accurately as possible, relating to the number of animals used and number of studies applicable, per severity category of studies approved and overseen by the AREC during the reporting period. Over time this may be a useful indicator of effective implementation of the 4Rs. The RECs are reminded to assess implementation of the 12Rs Framework when assessing applications (see **NDoH 2024**).

Notes: *ARECs may have their own system for severity classification of animal studies/interventions. One illustrative example is provided in the* ***SANS 10386:2021****, Annex R: The AEC Templates, H. Type of Research. From this informative example, cat. A1, excluding cephalopods and decapods, would refer to* ***'None'****, cat. A1 with cephalopods and decapods, cat. A2 & cat. B would refer to* ***'Mild'****, cat. C would refer to* ***'Moderate****, and cat. D & cat. E would refer to* ***'Severe'*** *in the table below.*

Species [4] *(in alphabetical order)*	**Indicate per severity category[5] of the study (i.e., none, mild, moderate, severe) the total number of animals used (*N*), and number of studies applicable (*S*)**								**Number of animals…**	
	None		**Mild**		**Moderate**		**Severe**		**…bred**	**…sur-plus[6]**
	N	***S***	***N***	***S***	***N***	***S***	***N***	***S***	***N***	***N***
Amphibians										
Birds										
Cats (domestic)										
Cattle										
Cephalopods										
Decapods										
Dogs (domestic)										
Embryonated eggs										
Fish										
Guinea pigs										
Goats										
Horses										
Lower invertebrates[7]										
Marine mammals										
Mice										
Non-human primates										
Pigs										
Rabbits										
Rats										
Reptiles										
Sheep										
Wildlife animals or other	…specify in the table on the next page *(see par. 5.06)*									

Note! If this data is NOT currently available, implement strategies to have it available for next year.

[4] These also include eggs, foetuses and embryos.
[5] Severity category refers to the impact of the study interventions on animal well-being.
[6] Here "surplus" refers to animals that were euthanised due to over-breeding or otherwise NOT used.

5.07 Wildlife animals' numbers (and other species not specified above) used per severity category

Provide in the table below the information per wildlife species *(or other animals not in the table above)* as accurately as possible, relating to the number of animals used and number of studies applicable, per severity category of studies approved and overseen by the AREC during the reporting period. Define *(specify)* each species you wish to report on in the left column, of leave the table open if you have nothing to report on here:

Wildlife or other species … define below *(e.g., antelope (specify species), large cats, wild dogs, wild boar, wildebeest, giraffe, rhinoceros, elephant, etc.)*	**Indicate per severity category of the study (i.e., none, mild, moderate, severe) the total number of animals used (N), and number of studies applicable (S)**							
	None		**Mild**		**Moderate**		**Severe**	
	N	***S***	***N***	***S***	***N***	***S***	***N***	***S***

Note! If this data is NOT currently available, implement strategies to have it available for next year.

[7] Lower invertebrates include insects, arachnids and worms, but exclude the advanced members from the *Cephalopoda* and *Decapoda*.

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. Please indicate the following matters as encountered during the review of proposals/protocols during the reporting period *(indicate 'not applicable' animals if not if not)*:

NB! *If any comment in the question below requires 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.*

5.08.01 AREC's have ethical oversight over any studies with environmental impact

Note: *Compare the* ***Environmental Impact Assessment (EIA) Regulations 2006*** *of the Department of Environmental Affairs.*

Animal species involved	Number of animals	Number of studies	Was an impact analysis done?	Brief description & notes on environmental impact
			[select]	
			[select]	
			[select]	

5.08.02 AREC's ethical oversight over any studies using threatened/endangered species

Note: *Compare the* ***National Environmental Management: Biodiversity Act 10 of 2004****.*

Animal species involved	Number of animals	Number of studies	Names and description of the applicable animal facilities / sites.	Brief description & notes on threatened/endangered species

5.08.03 AREC ethical oversight over any studies or facilities producing, breeding of, and/or studies using genetically modified animals

Note: *Compare also the* ***SANS 10386:2021*** *(several stipulations) and the* ***Guideline Document for Work with Genetically Modified Organisms, 2004*** *(or latest version) of DALRRD.*

Animal species involved	**Number of animals**	**Number of studies**	**Names and description of the applicable animal facilities / sites**	**Were the animals produced, bred and/or used? Brief description & notes on genetically modified animals**

5.08.04 Does the AREC have ethical oversight over any studies using animal models, or special types of studies

Note: *Compare the* ***SANS 10386:2021*** *Section 5.3.3.6.3.*

Animal species involved	**Number of animals**	**Number of studies**	**Names and description of the applicable animal facilities / sites.**	**Brief description & notes on the models** *(e.g., diabetes, cancer, neuropsychological)* **or types of studies** *(e.g., efficacy, toxicology, safety)*

5.08.05 Animal pre-clinical studies on health products for use in humans

Note: *Compare the* ***SAHPRA*** *website - https://www.sahpra.org.za/veterinary-medicines-guidelnes/.*

Animal species involved	Number of animals	Number of studies	Names and description of the applicable animal facilities / sites.	Brief description & notes on the health products involved

Were all relevant studies registered with SAHPRA?	Yes ◯	No ◯
Comments *(optional)*:		

5.08.06 Veterinary clinical trials

Note: *Compare the* ***SAHPRA Veterinary Medicines Clinical Guideline 2022*** *(or latest version) and website - https://www.sahpra.org.za/document/veterinary-medicines-clinical-guideline/.*

Animal species involved	Number of animals	Number of studies	Names and description of the applicable animal facilities / sites.	Brief description & notes on the veterinary products involved

Were all of the studies registered with SAHPRA?	Yes ◯	No ◯	Did you follow any veterinary GCP guidelines?	Yes ◯	No ◯
Comments *(optional)*:					

5.08.07 Transport of animals

Transport of animals between facilities and sites is strictly regulated and requires a permit.

Note: *Compare the* ***NDoH 2024*** *Section ??* *and* ***SANS 10386:2021*** *Section 10.2. Also see* ***SANS 1488:2014*** *on the Humane transportation of livestock by road.*

Do any of your research studies involve the transport of animals between facilities/sites?	**Yes** ◯	**No** ◯	**Does the AREC/facilities/sites have SOPs for the transport of animals in place?**	**Yes** ◯	**No** ◯

Animal species involved	**Number of animals**	**Number of studies**	**Names and description of the applicable animal facilities / sites.**	**Brief description & notes on the transport of animals**

5.08.08 Use of animal biological materials

The sharing and/or use of excess animal biological materials (i.e., prior sourced, and transferred or stored,) is encouraged and even required. In such cases the is responsible, safe, legal and ethical use of these animal biological materials is required. As such, this must be verified upon ethical review by the AREC.

Note: *Compare the* ***SANS 10386:2021*** *Section 4.7.2.6 and* ***NDoH 2024.***

Does the AREC verify compliance of relevant applications with the **NDOH 2024** and **SANS 10386:2021** for ethical approval or clearance?	**Yes** ◯	**No** ◯	**n/a** ◯

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.

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.

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:

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** ◯
How many multi-institutional collaborative projects did the AREC oversee during the reporting period?		
Comments (accolades or concerns) about this process at your institution?		

5.08.12 Independent external review

As per the **SANS 10386:2021** 2nd ed. there is a requirement of annual independent external review of the operations of the AREC, as well as every four years of the operations of the institution regarding its animal care and use programme. This NHREC annual report and review may assist the AREC to fulfil the requirements for an annual independent external review. Answer the following:

Note: *Compare the NDoH 2024 and SANS 10386:2021 Section 5.3.3.6 & Section 9.*

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** ◯
Comments (accolades or concerns) about this process at your institution?					

Monitoring

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

Official animal care and use facilities (during the reporting period)	…total number being overseen by the AREC		…number of facilities inspected	
	…number requiring follow-up (post-inspection) visits		… number of facilities NOT inspected	

	Official animal care and use facility's name/description (excluding other *ad hoc* sites)	Facility SAVC registered?		Facility Section 20 permit?		Facility Staff certified / authorised?		Animals certified / permits?		Facility inspected by AREC?		Facility reports regularly to AREC	
1		Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
	Special facility accreditation		Types of animals in facility				Any comments or issues						
2		Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
	Special accreditation		Types of animals in facility				Any comments or issues						
3		Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
	Special accreditation		Types of animals in facility				Any comments or issues						
4		Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
	Special accreditation		Types of animals in facility				Any comments or issues						
5		Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
	Special accreditation		Types of animals in facility				Any comments or issues						
6		Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
	Special accreditation		Types of animals in facility				Any comments or issues						
7		Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
	Special accreditation		Types of animals in facility				Any comments or issues						
8		Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
	Special accreditation		Types of animals in facility				Any comments or issues						

Describe the general status of the AREC's oversight of animal care and use facilities during the reporting period. Also describe any serious problems, deviations or non-compliance.

NB! *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.*

5.10 Post-approval passive monitoring of proposals/protocols

Post-approval passive monitoring (during the reporting period)	Is reporting (at least annual) required by the AREC?	**Yes** ◯	**No** ◯	…total number of studies overseen (reports required)	
	…number of monitoring reports received			… number of monitoring reports NOT received	
	…number of studies that could continue			…number of studies suspended/terminated	

Please note! *Refer to the table on p. 3 for a definition of passive monitoring.*

Describe the general status of post-approval passive monitoring (e.g., annual written reports) by researchers/teachers on their approved use of animals for scientific purposes during the reporting period. Also describe any deviations or non-compliance. Provide the reason(s) for any studies that were stopped.

NB! *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.*

5.11 Post-approval active monitoring of proposals/protocols by AREC members

It is not necessary to actively monitor each approved study. However, active monitoring should be done for high-risk studies, or a study following multiple SAE/SI reports.

Post-approval active monitoring (during the reporting period)	…conducted by the AREC?	**Yes** ◯	**No** ◯	…total number of studies inspected	

Please note! *Refer to the table on p. 3 for a definition of active monitoring.*

Describe the strategies implemented, general status and significant outcomes/findings of post-approval active monitoring (e.g., onsite inspection) of researchers regarding their approved use of animals for scientific purposes during the reporting period. Also describe any deviations or non-compliance. Provide the reason(s) for any studies that were stopped.

NB! *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.*

5.12 Unanticipated problems, serious incident, or serious adverse event reports

Are there mechanisms for the reporting of **unanticipated problems**, **serious incidents (SIs)** and **serious adverse events (SAEs –** *viz. "unscheduled event"***)** to the AREC?	Yes ◯	No ◯
Is immediate reporting of **SIs** and **SAEs** required by the AREC?	Yes ◯	No ◯
Is there a mechanism in place to resolve **SIs** and **SAEs**?	Yes ◯	No ◯

Total number of **SIs** reported during the reporting period		Total number of **SAEs** reported during the reporting period	

Please note! *Refer to the table on p. 3 for a definition of unanticipated problem, serious incident and serious adverse event, respectively.*

Describe how you handle unanticipated problems, serious incidents or adverse events? Provide the reason(s) for any studies that were stopped.

NB! *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.*

5.13 Amendments (changes to proposals/protocols)

Is approval of amendments[8] required by the HREC?	Yes ◯	No ◯
Is there an SOP for major and minor amendments in place?	Yes ◯	No ◯
Was there proper record keeping of amendments[8] by the HREC during the reporting period?	Yes ◯	No ◯

[8] Here *"amendment"* refers to any change in the research team, study design and/or animal numbers that requires permission by the AREC.

Whistle blowing, complaints or alleged non-compliance or violation of good research practice

5.14 Number of cases received/handled

Please indicate the number of whistle blowing cases or complaints ("0" for none) submitted to the HREC during the reporting period…

…about misconduct in an approved study	
…from scientists about the outcome of ethics approval	
…about the HREC in general	
Any comments *(optional)*:	

5.15 Types of whistleblowing, complaints or alleged non-compliance or violation of good research practice

Please tick the types of concerns in cases dealt with. Briefly explain what the cases were and how it was dealt with.

Authorship		Conduct of a researcher		Conflict of interest	
Animal care / wellbeing / monitoring		Discrimination		Data security	
General AREC processes		Inappropriate communication, etc.			
Other (specify)					
Any comments *(optional)*:					

5.16 Status or outcome of cases

Please indicate the number of cases that were resolved, referred or escalated in the categories indicated below. If some cases were channelled elsewhere than to the AREC, please explain.

Status/outcomes of cases (during the reporting period)	…resolved by the AREC		…still under consideration	
	…resolved by the responsible organisation/institution		…referred to the NHREC	
	…resulting in disciplinary action against a scientist		…resulting in legal action (in court)	
Any comments *(optional)*:				

Section 6: AREC response to previous reports

Have you addressed all matters related to your AREC's latest NHREC audit report?	Yes ◯	No ◯
Any ongoing matters you wish the NHREC to take note of *(optional)*		

Have you addressed all matters related to the feedback from the NHREC regarding your ARECs previous annual report(s)?	Yes ◯	No ◯
Any ongoing matters you wish the NHREC to take note of *(optional)*		

Section 7: Other matters

Are there any other matters that received attention of the AREC that you wish to report to the NHREC?	Yes ◯	No ◯
Are there any issues for which further advice is needed?	Yes ◯	No ◯
If "YES" to either, please provide details here.		

Section 8: AREC Report Approved and Supported

AREC's full name			
AREC's acronym or short name		NHREC registration no.	
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?	*Digital* ○	*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?	*Digital* ○	*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?	*Digital* ○	*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