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: 2021-05-13

Version 2.21

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.

- Office Use Only –

Date received			
Reporting period - from		to	
AREC full name			
AREC acronym / short name			
AREC registration no.			
Registration status	- select -		
Name of primary organisation/institution			

This button for office use only to export data

Important Information

Purpose

In South Africa, **Animal Research Ethics Committees (ARECs)** must report annually to the **National Health Research Ethics Council (NHREC)** on their activities, as required by the guidelines, Ethics in Health Research: Principles, Processes and Structures, Department of Health (DoH 2015; 2nd ed. or latest version), Section 4.6 iii. 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) DoH 2015 and (2) the South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386; 1st ed. 2008 or latest version).

Reports are due by **28 February annually** on the 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.
- 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 2017 SAU-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) Ethics in Health Research: Principles, Processes and Structures, Department of Health (DoH 2015; 2nd ed. or latest version) and (2) the South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386:2008; 1st ed. 2008 or latest version).
- Maintain an updated and publically 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

http://www.health.gov.za/ and http://www.nhrec.org.za/

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	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 7 of this form below
NDoH	National Department of Health
DoH 2015	Ethics in Health Research: Principles, Processes and Structures, Department of Health, 2nd ed. 2015
NHA 2003	National Health Act, Act No 61 of 2003
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
NHREC	National Health Research Ethics 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
SANS 10386	South African National Standard: Care and Use of Animals for Scientific Purposes, 1st ed. 2008
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*		*until*	

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		Web Address	
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		Web Address	
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

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

Section 2: General Reporting Information

Requirements of an AREC

2.1 Guidelines and standards

As indicated in the Ethics in Health Research: Principles, Processes and Structures, Department of Health (**DoH 2015**; 2nd ed. or latest version), all ARECs must be familiar with and comply with the DoH 2015 guidelines and the South African National Standard: Care and Use of Animals for Scientific Purposes (**SANS 10386**, 1st ed. 2008 or latest version). Other guidelines may be used in addition, as long as they do not contradict DoH 2015 or SANS 10386.

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.*

Guideline:	**DoH 2015**		**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 guidelines or standards?	**Yes** ○	**No** ○
If "Yes", specify which and why *(500 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 DoH 2015 par 4.3.2 and the SANS 10386:2008 par 5.2.2. 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.). The organisation/institution and the AREC must have instructions in one or more SOPs explaining the following elements:

- Frequency of meetings
- Preparation of agendas and minute
- Distribution of documentation prior to meetings
- Review and approval of proposals/protocols (including expedited)
- How final decisions are reached
- Prompt notification of decisions
- Reporting of unanticipated problems/incidents/adverse events
- Reporting of allegations of misconduct/complaints
- Mechanisms for "whistle-blower" protection
- Post-approval passive monitoring[1] of proposals/protocols
- Post-approval active monitoring[1] of proposals/protocols
- Routine and regular oversight (inspection) of animal care and use facilities
- 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 and teachers
- Maintenance of records in accordance with the DoH 2015 & SANS 10386 guidelines
- Development and management (review, monitor, approve) of SOPs

- ***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
- 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 provide brief information (1 page max) of any updated policies over the last reporting period.

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.*

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 DoH 2015 par. 4.4.2i, 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. (***Note!*** AREC member categories A to D are defined in SANS 10386:2008 par. 5.2.3, whereas additional members *(optional)* may be appointed to complement expertise and roles of the AREC).

Name of member *(title, initials, surname) This column duplicates on the next page*		Position in AREC	Categories A to D or other *(see DoH-2015 §4.4.1.3)*	Years serving on AREC	Assessed animal ethics training in past 3 years	Relation to organisation / institution	Demo-graphics	Age group	Sex
							…see DoH 2015 § 4.4		
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 -

Name of member *(title, initials, surname)* *This column duplicates from the previous page*		AREC membership requirements *(see DoH-2015 §4.4.1.2)*	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; Exp. in quantitative	*e.g.* Pharmacist, Proff Scientists	*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".

NB! *If any comment in the question below requires more space than maximum provided (max 600 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

3.2 AREC composition and appointment

The composition of members must comply with the requirements set out in DoH 2015 par. 4.4.1.3 and SANS 10386:2008 par 5.2.3. 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. 3Rs 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 DoH 2015 par. 4.4).

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 DoH 2015 and SANS 10386:2008 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 ethics of the use of animals for scientific purposes, on the relevant South African legislation, national standards and guidelines, and on their respective roles as AREC members in the ethics review, approval and ethical oversight processes.

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.*

Have all AREC members undertaken **appropriate animal ethics training in the last 3 years**, with some form of assessment (i.e. not mere attendance) and a certificate of proof (mandatory)?	**Yes** ○	**No** ○
Do you have **induction training for new AREC members** in place?	**Yes** ○	**No** ○
Do you have **continuing training for existing AREC members** in place?	**Yes** ○	**No** ○

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[2] held during the reporting period?	…total scheduled		…total held	
	…total not quorate[2]		…total cancelled	
What are the main reasons for non-quorate[2]**?** *(max 250 char.)*				
Steps taken when non-quorate[2]**?** *(max 250 char.)*				
Number of other meetings held during the reporting period?	…by the Executive Committee			

Second opinions: List and provide details of any second opinions by experts (compare DoH 2015, par. 4.5.1.3 & SABS 10386, par. 5.2.3.3) 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 ○

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 ○

[2] 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 (DoH 2015, par. 4.4.1.3), plus that at least one member from each category (A, B C & D) be present (SANS 10386:2008, par. 5.2.5.1).

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	
Average number of <u>days</u> spent on an AREC application, e.g. from the date of closure of the agenda (i.e. deadline for submission) to communication of approval to the researcher?				

5.03 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*)			

5.04 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*)			

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

Provide the information below as accurately as possible, relating to the number of animals used per species, per severity category. Here severity category refers to the impact on animal wellbeing, discerned as "none" (or non-invasive), "mild", "moderate", and "severe". Please complete the following:

- Tick "not applicable" when no animals of this species were used, OR
- Tick "Yes" or "No" regarding availability of data on numbers used
  - If this data is available, type the number of animals used under each severity category + total
  - If this data is NOT currently available, implement strategies to have it available for next year

Species [3] *(in alphabetical order)*	**Not applicable**	**Animals used**							**Number of animals euthanised due to over-breeding or NOT used**
		Data on numbers used available?		**TOTAL number of animals used**	**Of the total number of animals used, indicate the number of animals, where the impact on animal wellbeing (severity category) was as indicated below**				
		Yes	**No**		**None**	**Mild**	**Moderate**	**Severe**	
Amphibians	○	○	○						
Birds	○	○	○						
Cats (domestic)	○	○	○						
Cattle	○	○	○						
Cephalopods	○	○	○						
Decapods	○	○	○						
Dogs (domestic)	○	○	○						
Embryonated eggs	○	○	○						
Fish	○	○	○						
Guinea pigs	○	○	○						
Goats	○	○	○						
Horses	○	○	○						
Lower invertebrates[4]	○	○	○						
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)*								

[3] These also include eggs, foetuses and embryos.

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

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

Provide the information below as accurately as possible, relating to the number of wildlife or other animals (not in the table above) used per species, per severity category. Again, severity category refers to the impact on animal wellbeing, discerned as "none" (or non-invasive), "mild", "moderate", and "severe". Now leave the table open if you have nothing to report on here, or define (specify) each species you wish to report on in the left column, and then:

- Tick "Yes" or "No" regarding availability of data on numbers used
  - If this data is available, type the number of animals used under each severity category + total
  - If this data is NOT currently available, implement strategies to have it available for next year

Wildlife or other species … define below *(e.g. antelope (specify species), large cats, wild dogs, wild boar, wildebeest, giraffe, rhinoceros, elephant, etc.)*	**Animals used**						
	Data on numbers used available?		**TOTAL number of animals used**	**Number of animals where the impact on animal wellbeing (risk category) was as indicated below**			
	Yes	**No**		**None**	**Mild**	**Moderate**	**Severe**
	○	○					
	○	○					
	○	○					
	○	○					
	○	○					
	○	○					
	○	○					
	○	○					
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	○	○					
	○	○					
	○	○					
	○	○					
	○	○					

5.07 Other sensitive issues in studies approved

Please indicate the other of issues encountered during the review of proposals/protocols during the reporting period:

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.*

Yes	No	Item	Describe briefly
◯	◯	Studies with environmental impact	
◯	◯	Studies with endangered species	

Monitoring

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

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	
Are the abovementioned facilities registered with the South African Veterinary Council (SAVC)?			**Yes** ◯	**No** ◯
Were the abovementioned facilities inspected by an animal welfare organisation during the reporting period?			**Yes** ◯	**No** ◯

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.*

5.09 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.

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 active monitoring of proposals/protocols by AREC members

Post-approval active monitoring (during the reporting period)	…required by the AREC?	**Yes** ○	**No** ○	…total number of studies inspected	
	…number of studies found compliant			…number of studies found non-compliant	

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

Describe the general status 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.

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 Unanticipated problems, serious incident or adverse event reports

Are there mechanisms for the reporting of **unanticipated problems**, **serious incidents (SIs)** and **Serious adverse events (SAEs)** 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?

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.*

5.12 Amendments (changes to proposals/protocols)

Is approval of **amendments**[5] required by the AREC?	Yes ◯	No ◯
Was there proper record keeping of **amendments**[5] by the AREC during the reporting period?	Yes ◯	No ◯

[5] Here *"amendment"* refers to any change in the research/teaching team, study design, animal number/type/procedure that requires permission by the AREC.

Briefly describe the requirements and process for application of amendments at the AREC.

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.*

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

5.13 Number of cases received/handled

Please indicate the number of cases ("0" for none) submitted to the AREC during the reporting period.

Number of whistle blowing cases		**Complaints**		**Alleged non-compliance or violation of good research practice**	
…about conduct in an approved study		…about conduct in an approved study		…about conduct in an approved study	
…from scientists about the outcome of ethics approval		…from scientists about the outcome of ethics approval		…from scientists about the outcome of ethics approval	
…about the AREC in general		…about the AREC in general		…about the AREC in general	
Any comments *(optional)*:					

5.14 Types of whistle blowing, 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)*:					

5.15 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: Other Issues

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.*

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 7: 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

Submit Form via E-mail