health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Application to Register an AREC

NATIONAL HEALTH RESEARCH ETHICS COUNCIL
www.nhrec.org.za

Application form to register an Animal Research Ethics Committee (AREC) with the National Health Research Ethics Council (NHREC)

Approved by the National Health Research Ethics Council: 2017-11-08
Version 2.00

Please read the important background information on p. 2-4, and then complete Sections 1 to 3 of the application form from p. 5 onwards.

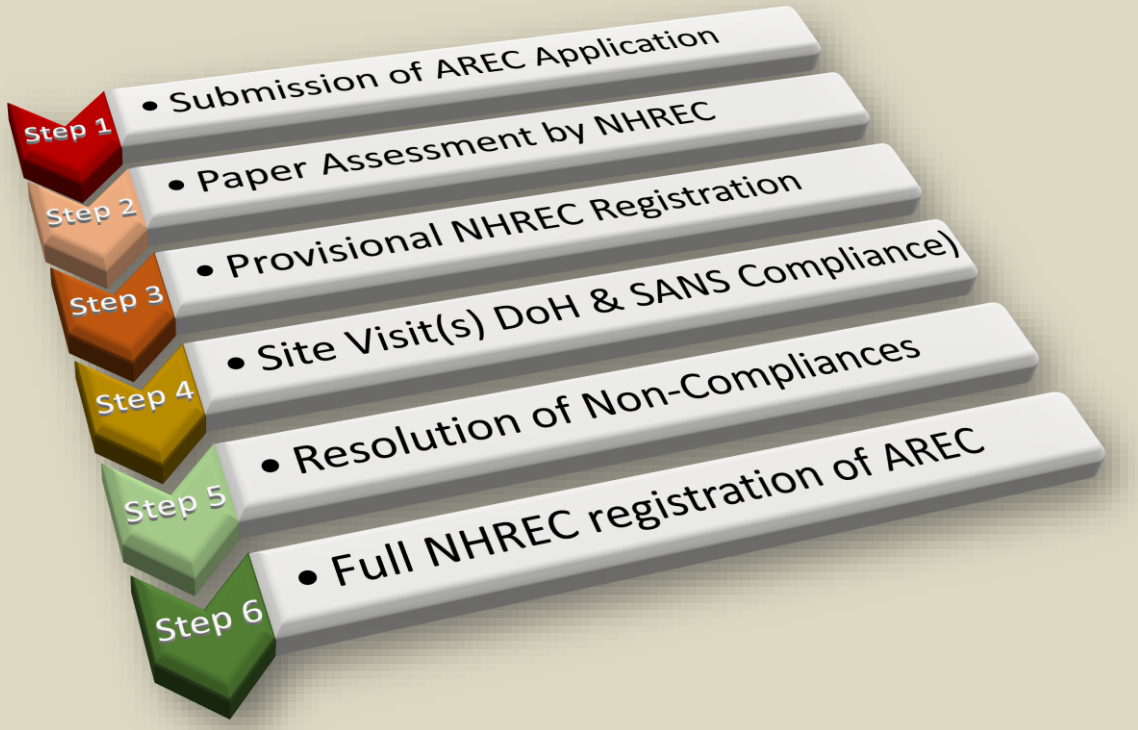
- Office Use Only –

Date received	
AREC full name	
AREC acronym / short name	
AREC provisional no.	
Name of primary organisation/institution	

This button for office use only to export data

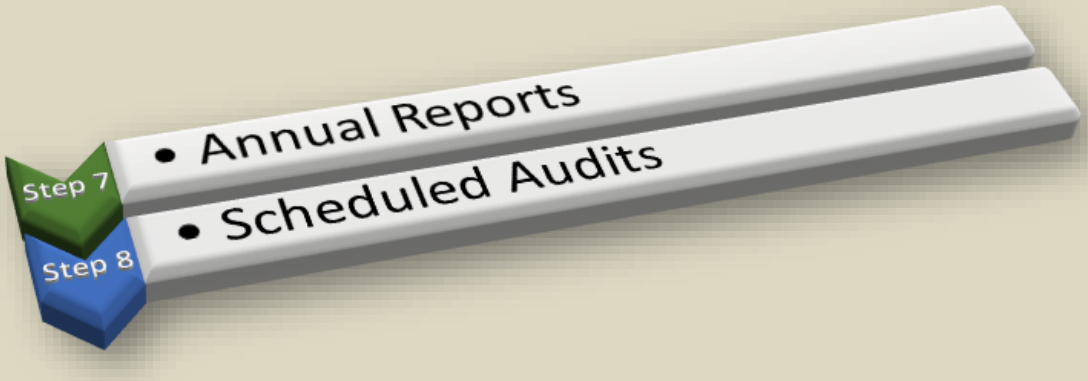
Important Information

Application and registration process



Maintenance of registration

Continued compliance with registration requirements



Applying for registration

An **Animal Research Ethics Committee (AREC)** of an organisation/institution or independent AREC may apply for registration with the **National Health Research Ethics Council (NHREC)**. To be eligible for registration, the organisation/institution and AREC must demonstrate compliance with Section 73 of the National Health Act, Act No 61 of 2003 (NHA 2003), and therefore, by implication, compliance with (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; 1st ed. 2008 or latest version).

All South African ARECs reviewing proposals for **health or health-related research** (see NHA 2003), including testing (e.g. vaccines, drugs, medical devices, etc.) and health-related education and training (e.g. surgery, anatomy, physiology, clinical skills, etc.), using animals are obligated to register with the NHREC. In addition, the NHREC accepts voluntary registration of other types of ARECs in the country (e.g. research, testing or education performed with

domestic/farm/zoo/wildlife animals for purposes other than health or health-related research). This is particularly important, since no other statutory body currently registers ARECs in South Africa. However, the ethical principles and considerations remain the same for other types of scientific uses of animals. Registration may contribute to promotion of higher standards and uniform application of ethics principles in the country and maintaining public confidence.

This application must be signed by the **Authorised Institutional Official** (see full definition under "Abbreviations, terms & definitions", p. 4 below) or, in the case of an independent AREC by the highest authorised line manager or the Chairperson of the AREC. If the AREC serves more than one organisation or institution, the Authorised Institutional Official of each of these organisations and institutions must sign the form.

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

Instructions

Basic instructions

- Please complete the application 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 application form (e.g. *"See full answer in the document attached, named [Long 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 application form an appropriate name (e.g. "*AREC application for…*" + "*the acronym for your AREC name*", e.g. [AREC application for SA-AREC.pdf]). Click on the "Submit" button (executes an e-mail action) in this original, fillable PDF application 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 applicant AREC and its organisation/institution is used to determine compliance with the requirements for 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 registration will be used for the following purposes:

- Communicate with the AREC and its organisation/institution.
- Add contact and other details to the NHREC's database of ARECs.
- Maintain a record of correspondence, enquiries and complaints.
- Support and advise ARECs and research/testing/educational organisations/institutions.
- 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).

- Consult with ARECs on relevant policy.
- 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.

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

1.1a AREC contact person (e.g. administrative support or secretariat)

AREC's full name			AREC's acronym or short name	
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.*

1.1b 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.*

1.2 AREC chairperson

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

1.3 Responsible organisation/institution and person

This section relates to the organisation/institution with primary responsibility for the AREC ('Applicant'). Every organisation/institution, health agency and health establishment at which health research using animals is conducted, must establish or have access to an AREC, which is registered with the National Health Research Ethics Council (Section 73 of the National Health Act, Act No 61 of 2003) and the latter mandated under section 72 (6) (c) to set norms and standards for conducting research on humans and animals. The organisation/institution, represented by its Authorised Institutional Official, must take responsibility to provide resources for the AREC and must accept all responsibilities specified in the Ethics in Health Research: Principles, Processes and Structures, Department of Health (DoH 2015; 2nd ed. or latest version), and the South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386:2008; 1st ed. 2008 or latest version).

Please provide the name of the responsible organisation/institution in the table below. *(If there are more than one organisation/institution associated with the AREC, provide details of the primary (hosting) organisation/institution here, and then add the details and signature of the 2nd and 3rd organisations/institution in Section 3 at the end of this document.)*

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

Please note! *Usually communication is sent to the AREC, but there may instances of national relevance that may be communicated also to the organisation/institution. All correspondence to the Authorised Institutional Official of the organisation/institution will be sent to this address provided above. Please provide the address exactly as it should appear on a mailing label.*

1.4 Sector of the organisation/institution

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

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

Background Information

1.5 Applicants

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

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

1.6 Types of science

Please indicate the types of science that the AREC intends to evaluate in applications (***Please note!*** select "Yes" or "No" for EACH item):

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

1.7 Types of animals

Please indicate the types of animals that the AREC intends to evaluate in applications (***Please note!*** select "Yes" or "No" for EACH item):

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*)			

1.8 Activity Levels

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

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

Section 2: Registration Information

2.1 Requirements of an AREC

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 requires more space than maximum provided (max 150/500 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 freely available to each AREC member?	**Yes** ○	**No** ○	**Yes** ○	**No** ○
Did the AREC formally adopt the indicated guidelines, complying with its requirements?	**Yes** ○	**No** ○	**Yes** ○	**No** ○

Does the AREC comply with any other guidelines or standards?	**Yes** ○	**No** ○
If "Yes", specify which and why *(200 char. max)*:		
Any comments *(optional; 500 char. max)*:		

2.2 Terms of reference

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 ARECs.
- Financial compensation (remuneration), if any, for non-affiliated members *(e.g. travel expenses, loss of income for veterinarian or other professionals, etc.)*.

NB! *If your comments in the question below 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.*

Is the Terms of Reference developed and available?	Yes ○	No ○
Does the Terms of Reference contain all the above mentioned **critical elements** as required *(see list in bullet paragraphs above)*?	Yes ○	No ○
Is the Terms of Reference formally approved and implemented by the AREC?	Yes ○	No ○
Is the Terms of Reference developed and formally approved by the organisation/institution?	Yes ○	No ○
Any comments *(optional; 500 char. max)*:		

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

2.3 Nomination, selection and appointment of AREC members

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

NB! *If your comments 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.*

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

2.4 Appointment and indemnification of AREC members

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

Indicate below how AREC members are informed about their appointment:

NB! *If your comments 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.*

Do members 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** ◯
Any comments *(optional)*		

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

2.5 Training of AREC members

AREC members are required have appropriate and up-to-date training in the ethics of the use of animal 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 your 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.*

Have all AREC members undertaken **appropriate animal ethics training in the last 3 years, with certificate of proof (mandatory)?**	**Yes** ◯	**No** ◯
Comment if "No:		

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

2.6 AREC member details

Indicate how the membership of your 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)*	Categories A to D or Additional	Position in AREC	Years on AREC	Hours of animal ethics training in past 3 years	AREC-relevant experience	AREC-relevant expertise	AREC-relevant qualifications	Relation to organisation / institution	Demo-graphics	Age group	Sex
0	Prof XX Example	Cat B	Vice-Chairperson	4-6	10	Experimental use of rodents	Health scientist, medicines	BPharm, PhD	Independent	Black	50-59	Female
1.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
2.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
3.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
4.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
5.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
6.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
7.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
8.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
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11.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
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15.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
16.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
17.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
18.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
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20.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
21.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
22.		- select -	- select -	- select -					- select -	- select -	<20	- select -
23.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
24.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
25.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
26.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
27.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
28.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
29.		- select -	- select -	- select -					- select -	- select -	- select -	- select -
30.		- select -	- select -	- select -					- select -	- select -	- select -	- select -

If you indicated "other (specify below)" for any member under the "category of membership" or "position in AREC" in the table above, 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.*

2.7 AREC composition

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 par. 4.4).

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
Is the AREC membership constituted in accordance with the requirements specified in the DoH 2015 and SANS 10386:2008 guidelines?	◯	◯
Any comments *(optional)*:		

2.8 AREC procedures

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 following **elements** (i.e. clear and uniform standards for the following) should be included in one or more of the SOPs:

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

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

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

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

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

4. Do the organisation/institution and the AREC have instructions in one or more SOPs that describes the process for **review and approval of proposals/protocols (including expedited)**?	Yes ○	No ○
Comment if "No"		

5. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining **how final decisions are reached**?	Yes ○	No ○
Comment if "No"		

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

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

8. Do the organisation/institution and the AREC have instructions in one or more SOPs that explains the process for **reporting of allegations of misconduct/complaints**?	Yes ○	No ○
Comment if "No"		

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

	Yes	No
10. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining the process for **post-approval passive monitoring**[2] **of proposals/protocols**?	○	○
Comment if "No"		

	Yes	No
11. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining the process for **post-approval active monitoring**[2] **of proposals/protocols**?	○	○
Comment if "No"		

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

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

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

	Yes	No
15. Do the organisation/institution and the AREC have instructions in one or more SOPs that indicate how **records in accordance with the DoH 2015 & SANS 10386 guidelines should be maintained**?	○	○
Comment if "No"		

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

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

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

2.9 Supporting documentation to be attached

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

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

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

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

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

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

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

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

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

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

10. Post-approval passive monitoring[2] form (e.g. annual reporting by researchers or teachers)	Yes ◯	No ◯
Comment if "No"		

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

12. Animal facility inspection form	Yes ◯	No ◯
Comment if "No"		

13. Other *(specify)*		Yes ◯	No ◯

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

2.10 AREC growth plan

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

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

2.11 Other information

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

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

Section 3: Declaration

This declaration must be completed and signed electronically in this original, fillable PDF document (i.e. not a scanned copy) by all indicated, authorised signatories (i.e. the Authorised Institutional Official, as referred to in Section 1 and defined under "Abbreviations, terms & definitions", p. 4 above).

Please note!

- If more than one organisation/institution is responsible for this AREC, you MUST ensure that the Authorised Institutional Official of each organisation/institution signs (see 2nd and 3rd signatories if applicable).
- 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 fillable PDF form, and attach the scanned page in addition to this completed original form.

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

- I am duly authorised to sign this declaration,
- information supplied on this form and any attachment is correct to the best of my knowledge, and
- the organisation/institution has authorised the AREC, and takes responsibility for the AREC as stipulated in Ethics in Health Research: Principles, Processes and Structures, Department of Health (**DoH 2015**; 2nd ed. or latest version) and in the South African National Standard: Care and Use of Animals for Scientific Purposes (**SANS 10386:2008**; 1st ed. or latest version).

3.1 First signatory: *Authorised Institutional Official for the exclusive (solely) responsible organisation/institution or for the 1st (i.e. primary/hosting) responsible organisation/institution.*

Name of org./institution			**Name of AREC**	
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**	

3.2 Second signatory: *Authorised Institutional Official for 2nd organisation/institution, (if applicable)*

Do you want to add a second signatory on behalf of a 2nd organisation/institution? *(not applicable if the AREC has only one responsible organisation/institution)*	**Yes** ◯	**No** ◯

Name of org./institution			**Name of AREC**	
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**	

3.3 Third signatory: *Authorised Institutional Official for 3rd organisation/institution, (if applicable)*

Do you want to add a third signatory on behalf of a 3rd organisation/institution? *(not applicable if the AREC has only one or two responsible organisation/institution)*	Yes ○	No ○

Name of org./institution			**Name of AREC**	
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**	

3.4 Co-signatory *(AREC Chairperson)*

Affiliated org./institution			**Name of AREC**	
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**	

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