



**NATIONAL HEALTH  
RESEARCH ETHICS COUNCIL**

[www.nhrec.org.za](http://www.nhrec.org.za)

## **Application to Register an AREC**

*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: 2021-05-13*

**Version 2.21**

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.

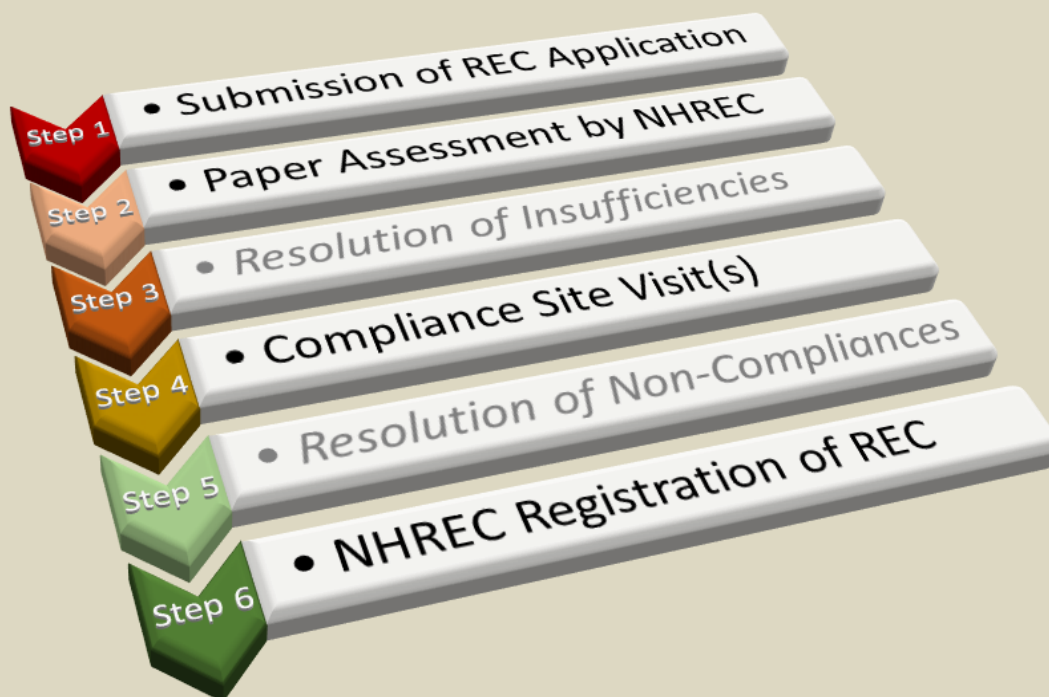
**- Office Use Only -**

Date received	<input type="text"/>
AREC full name	<input type="text"/>
AREC acronym / short name	<input type="text"/>
AREC provisional no.	<input type="text"/>
Name of primary organisation/institution	<input type="text"/>

**Please note!** When naming the REC (*see par. 1.1a below, and as it will appear above*), use the Institution's name as the first part of the name, e.g. full name "South African Fictitious University Animal Research Ethics Committee", short name "SAFU-AREC".

## 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; 2<sup>nd</sup> ed. or latest version) and (2) the South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386; 1<sup>st</sup> 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](mailto: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; 2<sup>nd</sup> ed. or latest version) and (2) the South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386:2008; 1<sup>st</sup> 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
<b>Active monitoring</b>	Refers to active validation of compliance to the ethical aspects of the approved study, including an onsite inspection of the execution of a study.
<b>AREC</b>	Animal Research Ethics Committee
<b>Authorised institutional official</b>	The authorised member of senior administration/management of the institution/organisation bearing ultimate responsibility and accountability for the animal care and use programme
<b>Authorised signatory</b>	The person taking responsibility for indicated functions related to the AREC, according to institutional policy – see also Section 7 of this form below
<b>NDoH</b>	National Department of Health
<b>DoH 2015</b>	Ethics in Health Research: Principles, Processes and Structures, Department of Health, 2 <sup>nd</sup> ed. 2015
<b>NHA 2003</b>	National Health Act, Act No 61 of 2003
<b>Organisation/institution</b>	The organisation/institution taking responsibility of the AREC
<b>Passive monitoring</b>	Refers to regular (typically annually) written reporting by the principal investigator about animal use, progress and problems with the study
<b>NHREC</b>	National Health Research Ethics Council
<b>Serious adverse event (SAE)</b>	Relates to an unforeseen harmful event related to the study (e.g. injury/death due to an experimental intervention)
<b>Serious incident (SI)</b>	Relates to an unforeseen harmful event unrelated to the study itself (e.g. facility failure/pathogen outbreak)
<b>SOP</b>	Standard Operating Procedure
<b>SANS 10386</b>	South African National Standard: Care and Use of Animals for Scientific Purposes, 1 <sup>st</sup> ed. 2008
<b>ToR</b>	Terms of Reference
<b>Unanticipated problem</b>	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					
	<i>title</i>	<i>first name</i>	<i>last name</i>		
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					
	<i>title</i>	<i>first name</i>	<i>last name</i>		
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					
	<i>title</i>	<i>first name</i>	<i>last name</i>		
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; 2<sup>nd</sup> ed. or latest version), and the South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386:2008; 1<sup>st</sup> 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 2<sup>nd</sup> and 3<sup>rd</sup> organisations/institution in Section 3 at the end of this document.)

Name of responsible organisation/ institution			
Name of Authorised Institutional Official	<i>title</i>	<i>first name</i>	<i>last name</i>
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):

<input type="checkbox"/>	Public hospital/health service	<input type="checkbox"/>	Private health laboratory
<input type="checkbox"/>	Private hospital/health service	<input type="checkbox"/>	Pharmaceutical / biotechnology company
<input type="checkbox"/>	Public university/educational institution	<input type="checkbox"/>	Institution for vaccine production or testing
<input type="checkbox"/>	Private university/educational institution	<input type="checkbox"/>	National Park
<input type="checkbox"/>	Government Department	<input type="checkbox"/>	Zoo
<input type="checkbox"/>	Government statutory agency (e.g. HSRC, MRC, NRF, CSIR)	<input type="checkbox"/>	Private Research Ethics Committee (non-profit)
<input type="checkbox"/>	Public health laboratory	<input type="checkbox"/>	Private Research Ethics Committee (for profit)
<input type="checkbox"/>	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
<input type="checkbox"/>	<input type="checkbox"/>	Application for ethics approval of projects internal to the organisation/institution
<input type="checkbox"/>	<input type="checkbox"/>	Application for ethics approval of projects external to the organisation/institution
<input type="checkbox"/>	<input type="checkbox"/>	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
		Agricultural sciences
		Conservational and wildlife sciences
		Environmental sciences
		Biological sciences
		Other (specify; 100 char. max)

Yes	No	Item
		Human health sciences
		Veterinary and para-veterinary sciences
		Zoological sciences

### 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
		Domestic animals
		Farm or agricultural animals
		Feral animals
		Higher invertebrates
		Laboratory animals
		Other (specify; 100 char. max)

Yes	No	Item
		Lower invertebrates (including insects)
		Marine animals or aquaculture
		Non-human primates
		Wildlife animals
		Zoo animals

### 1.8 Activity Levels

	Yes	No
Has the AREC approved ethics applications in the past?		
How many research/testing/education proposals/protocols has the AREC reviewed in the last 12 months?		
How many research/testing/education proposals/protocols does the AREC anticipate 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

### 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**; 2<sup>nd</sup> 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**, 1<sup>st</sup> 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 Policy and Terms of Reference

The organisation(s)/institution(s) must, when establishing an AREC, set out a Policy and 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 Policy and Terms of Reference developed and available?	Yes	No
Does the Terms of Reference contain all the above-mentioned <b>critical elements</b> as required ( <i>see list in bullet paragraphs above</i> )?	Yes	No
Is the Terms of Reference developed, formally approved and implemented by the AREC?	Yes	No
Is the Policy developed, formally approved and implemented 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 chairperson and 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, indemnification of AREC members and code of conduct

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 <i>bona fide</i> conduct of their duties as committee members?	Yes	No
Members should sign a code of conduct when appointed. Does the AREC have a code of conduct for its members?	Yes	No
Any comments (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 any 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.

Have <b>all</b> AREC members undertaken <b>appropriate animal ethics training in the last 3 years, with certificate of proof (mandatory)</b> ?	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).

0	Name of member (title, initials, surname) <i>This column duplicates on the next page</i>	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						e.g. Black	e.g. 50-59	e.g. Female
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Name of member (title, initials, surname) <i>This column duplicates from the previous page</i>	AREC membership requirements (see DoH-2015 §4.4.1.2)	AREC-relevant discipline and expertise	AREC-relevant experience	Professional registration / authorisation
	<b>Note!</b> 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
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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.

Is the AREC membership constituted in accordance with the requirements specified in the DoH 2015 and SANS 10386:2008 guidelines?	Yes	No
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.

1. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> explaining the <b>frequency of meetings</b> <sup>1</sup> ?	Yes	No
Comment if “No”		

<sup>1</sup> **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 <u>SOPs</u> explaining the <b>preparation of agendas and minutes</b> ?	Yes	No
Comment if "No"		
3. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> describing the <b>distribution of documentation prior to meetings</b> ?	Yes	No
Comment if "No"		
4. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> that describes the process for <b>review and approval of proposals/protocols (including expedited)</b> ?	Yes	No
Comment if "No"		
5. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> explaining <b>how final decisions are reached</b> ?	Yes	No
Comment if "No"		
6. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> that explains how <b>prompt notification of decisions are made</b> ?	Yes	No
Comment if "No"		
7. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> describing how <b>reporting of unanticipated problems/incidents/adverse events must be done</b> ?	Yes	No
Comment if "No"		
8. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> that explains the process for <b>reporting of allegations of non-compliance or violation of good research practice, or complaints</b> ?	Yes	No
Comment if "No"		
9. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> describing <b>mechanisms for "whistle-blowing" and "whistle-blower" protection</b> ?	Yes	No
Comment if "No"		

10. Do the organisation/institution and the AREC have instructions in one or more SOPs explaining the process for <b>post-approval passive monitoring<sup>2</sup> of proposals/protocols?</b>	Yes	No
Comment if "No"		
11. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> explaining the process for <b>post-approval active monitoring<sup>2</sup> of proposals/protocols?</b>	Yes	No
Comment if "No"		
12. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> explaining how to handle <b>routine and regular oversight (inspection) of animal care and use facilities?</b>	Yes	No
Comment if "No"		
13. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> explain how <b>conflicts of interest and conflicts of commitment for AREC members should be addressed?</b>	Yes	No
Comment if "No"		
14. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> that explains how <b>conflicts of interest and conflicts of commitment for researchers and teachers should be addressed?</b>	Yes	No
Comment if "No"		
15. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> that indicate how <b>records in accordance with the DoH 2015 &amp; SANS 10386 guidelines should be maintained?</b>	Yes	No
Comment if "No"		
16. Do the organisation/institution and the AREC have instructions in one or more <u>SOPs</u> to <b>develop and manage (review, monitor, approve) SOPs?</b>	Yes	No
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.

<sup>2</sup> 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.

1. Policies/procedures of the AREC and the organisation/institution on animal care and use attached?	Yes	No
Comment if "No"		
2. Template of the AREC membership appointment letter (that includes term of office and indemnification of members) attached?	Yes	No
Comment if "No"		
3. All Standard Operating Procedure documents (SOPs) of the AREC attached?	Yes	No
Comment if "No"		
4. Application forms for ethical review of new proposals/protocols (including checklist for applications) attached?	Yes	No
Comment if "No"		
5. Application forms for amendments to approved proposals/protocols attached?	Yes	No
Comment if "No"		
6. Serious Adverse Events report form (or SOP, as will be used by researchers and teachers) attached?	Yes	No
Comment if "No"		
7. Confidentiality agreement form for AREC members and reviewers attached?	Yes	No
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 <sup>2</sup> form (e.g. annual reporting by researchers or teachers)	Yes	No
Comment if "No"		
11. Post-approval active monitoring <sup>2</sup> forms (e.g. onsite inspection of active studies)	Yes	No
Comment if "No"		
12. The code of conduct form for AREC members	Yes	No
Comment if "No"		
13. Animal facility inspection form	Yes	No
Comment if "No"		
14. Other (specify)	Yes	No

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

## 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 2<sup>nd</sup> and 3<sup>rd</sup> 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; 2<sup>nd</sup> ed. or latest version) and in the South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386:2008; 1<sup>st</sup> ed. or latest version).

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

<b>Name of org./institution</b>				<b>Name of AREC</b>	
<b>Name of signatory</b>	<i>title</i>	<i>first name</i>		<i>last name</i>	
<b>Position</b>				<b>E-mail</b>	
<b>How does this signatory sign?</b>	<i>Digital</i>	<i>Hard copy</i>	<b>Signature</b>		
If a hard copy was signed, what is the name of the scanned copy of the signed document (attached)?					
				<b>Date</b>	

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

Do you want to add a second signatory on behalf of a 2 <sup>nd</sup> organisation/institution? (not applicable if the AREC has only one responsible organisation/institution)					<b>Yes</b>	<b>No</b>
<b>Name of org./institution</b>				<b>Name of AREC</b>		
<b>Name of signatory</b>	<i>title</i>	<i>first name</i>		<i>last name</i>		
<b>Position</b>				<b>E-mail</b>		
<b>How does this signatory sign?</b>	<i>Digital</i>	<i>Hard copy</i>	<b>Signature</b>			
If a hard copy was signed, what is the name of the scanned copy of the signed document (attached)?						
				<b>Date</b>		

### 3.3 Third signatory: Authorised Institutional Official for 3<sup>rd</sup> organisation/institution, (if applicable)

Do you want to add a third signatory on behalf of a 3 <sup>rd</sup> organisation/institution? (not applicable if the AREC has only one or two responsible organisation/institution)	Yes	No
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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](mailto:nhrec@health.gov.za)