health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Application to Register an HREC

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

Application form to register a Human Research Ethics Committee (HREC) with the National Health Research Ethics Council (NHREC)

Approved by the National Health Research Ethics Council: 2019-11-06

Version 2.20

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 –

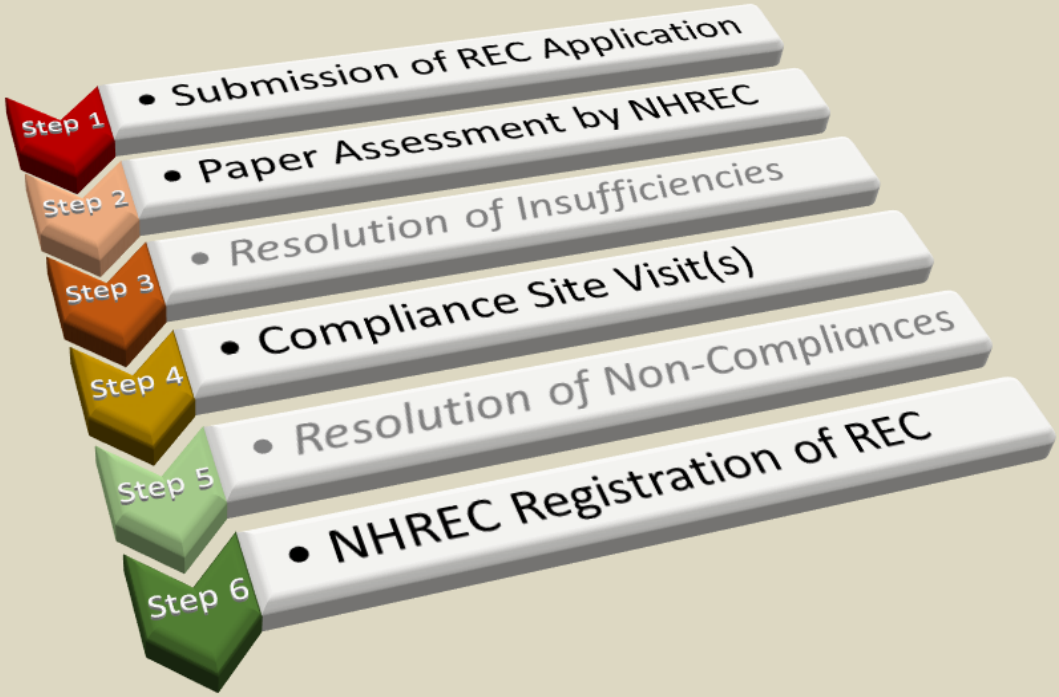
Date received	
HREC full name	
HREC acronym / short name	
HREC provisional no.	
Name of primary organisation/institution	

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 Human Research Ethics Committee", short name "SAFU-HREC"

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

A **Human Research Ethics Committee (HREC)** of an organisation/institution or independent HREC may apply for registration with the **National Health Research Ethics Council (NHREC)**. To be eligible for registration, the organisation/institution and HREC must demonstrate compliance with Section 73 of the National Health Act, Act No 61 of 2003 (NHA 2003), and therefore, by implication, compliance with Ethics in Health Research: Principles, Processes and Structures, Department of Health (DoH 2015; 2nd ed. or latest version).

All South African HRECs reviewing proposals for **health or health-related research** involving human participants (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, dentistry, etc.), must register with the NHREC. Registration may contribute to promotion of higher standards and uniform application of ethics principles and thus to maintain public confidence.

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

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

Instructions

Basic instructions

- Please complete the 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 specified 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 but need to say more, or supporting documentation is required to fully answer a particular question, summarise your answer in the text box, attach the 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. "*HREC application for…*" + "*the acronym for your HREC name*", e.g. [HREC application for SA-HREC.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 HREC 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 in the involvement of human participants including research, testing and education.

Information collected during registration will be used for the following purposes:

- Communicate with the HREC and its organisation/institution.
- Add contact and other details to the NHREC's database of HRECs.
- Maintain a record of correspondence, enquiries and complaints.
- Support and advise HRECs and research/testing/educational organisations/institutions.
- Monitor and review HREC compliance with the National Health Act, Act No 61 of 2003 (NHA 2003), and, therefore, by implication, compliance with Ethics in Health Research: Principles, Processes and Structures, Department of Health (DoH 2015; 2nd ed. or latest version).
- Consult with HRECs on relevant policy.

- Maintain an updated and publically accessible database of registered HRECs.

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 HRECs 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
HREC	Human Research Ethics Committee
Authorised institutional official	The authorised member of senior administration/management of the institution/organisation bearing ultimate responsibility and accountability for research practices
Authorised signatory	The person taking responsibility for indicated functions related to the HREC, 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 HREC
Passive monitoring	Refers to regular (typically annually) written reporting by the principal investigator about research involving human participants, 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. unexpected patient response)
SOP	Standard Operating Procedure
ToR	Terms of Reference
Unanticipated problem	Relates to any obstacle that negatively affects a study and the possibility to achieve the outcomes, other than due to a SAE or SI defined above

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

Section 1: Details of the Human Research Ethics Committee (HREC)

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

HREC's full name			HREC'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 HREC, including to the chairperson, will be sent to the HREC contact information as indicated above. This should be an address that does not change when individuals of the secretariat, the HREC chairperson or other office bearers change.*

1.1b HREC 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 HRECs 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 HREC 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 HREC ('Applicant'). Every organisation/institution, health agency and health establishment at which health research involving human participants is conducted, must establish or have access to an HREC, 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 HREC 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).

Please provide the name of the responsible organisation/institution in the table below. *(If there are more than one organisation/institution associated with the HREC, 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 HREC, 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	○	Public health laboratory
○	Private hospital/health service	○	Private health laboratory
○	Public university/educational institution	○	Pharmaceutical / biotechnology company
○	Private university/educational institution	○	Institution for vaccine production or testing
○	Government Department	○	Private Research Ethics Committee (non-profit)
○	Government statutory agency (e.g. HSRC, MRC, NRF, CSIR)	○	Private Research Ethics Committee (for profit)
○	Other *(specify; max 100 char.)*		

Background Information

1.5 Applicants

Please indicate for whom the HREC 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*)

1.8 Activity Levels

	Yes	No
Has the HREC approved ethics applications in the past?	◯	◯

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

Section 2: Registration Information

2.1 Requirements of an HREC

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 HRECs must be familiar with and comply with the DoH 2015 guidelines or latest version. Other guidelines may be used in addition, as long as they do not contradict DoH 2015.

NB! *If any comments in the question below require 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.*

	Yes	No
Are electronic/printed copies of the indicated guidelines available to the HREC (e.g. executive committee, authorised institutional official, ethics office, etc., as applicable)?	◯	◯
Are electronic/printed copies of the indicated guidelines freely available to each HREC member?	◯	◯
Has the HREC formally adopted the indicated guidelines?	◯	◯
Does the HREC comply with the requirements of the indicated guidelines?	◯	◯
Does the HREC use other guidelines or standards?	◯	◯

If "Yes" to this last question, 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 HREC, set out Policy and Terms of Reference (ToR) as specified in the DoH 2015 par 4.3.1. Note that the ToR serve a separate function from that of the SOPs . The HREC's ToR should contain the following **critical elements**:

- Formal description of the authority granted to the HREC, the nature and scope of the committee's mandate, and how it complies with organisational/institutional and statutory requirements, including the scope of authority, powers (including whether subcommittees and delegated authority are permitted), responsibilities, membership composition (in broad terms) and whether alternative quorum arrangements are permitted.
- Relationship to and communication lines within the organisation/institution and the accountability lines of reporting.
- Requirement for formal procedures and processes, including development of standard operating procedures (SOPs), including but not limited to SOPs that:
  - ensure compliance with national legislation and standards (name the applicable legislation and standards)
  - require general competence (e.g. regarding member selection, *ad hoc* inclusion of experts, training of HREC members)
  - promote appropriate reviewing, approval and monitoring of approved studies
  - manage potential conflicts of interest and how to maintain confidentiality
  - establish clear reporting lines and accountability channels for the HREC
  - guide how to deal with adverse events, non-compliance, misconduct, grievances, investigations, and withdrawal of approvals.
- Requirement have a secretariat (relating to admin, record keeping, minutes, etc.).
- Relationship to affiliated and non-affiliated researchers, as well as with other NHREC-registered HRECs.
- Whether financial compensation (remuneration) is permitted for external HREC members *(e.g. travel expenses, loss of income for any professionals, etc.)*.

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

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

2.3 Nomination, selection and appointment of HREC members

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

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

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

2.4 Appointment and indemnification of HREC members

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

Indicate below how HREC members are informed about their appointment:

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

Do members receive formal written notification about their appointment?	**Yes** ◯	**No** ◯
Does the notice specify the term of appointment?	**Yes** ◯	**No** ◯
Does the notice specify indemnification against liability that may arise in the course of *bona fide* conduct of their duties as committee members?	**Yes** ◯	**No** ◯
Any comments *(optional)*		

2.5 Training of HREC members

HREC members are required have appropriate and up-to-date training in the ethics of research involving human participants, on the relevant South African legislation, national standards and guidelines, and on their respective roles as HREC members in the ethics review, approval and ethical oversight processes.

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

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

2.6 HREC member details

Indicate how the membership of your present HREC is constituted, by completing the text fields or selecting from the drop-down boxes in the two linked tables on the two consecutive pages below.

	Name of member *(title, initials, surname) This column duplicates on the next page*	Position in HREC	Years serving on HREC	Assessed human ethics training in past 3 years	Relation to organisation/ institution	Demo-graphics	Age group	Sex
0	Prof XX Example	*e.g.* Vice-Chairperson	*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 -
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 -
9.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
10.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
11.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
12.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
13.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
14.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
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 -
19.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
20.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
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22.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
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24.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
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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 -

Name of member (title, initials, surname) This column duplicates from the previous page		HREC membership requirements (see DoH-2015 §4.4.1.2)	HREC-relevant discipline and expertise	HREC-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	Prof XX Example	*e.g.* Biostatistician; Exp. in qualitative	*e.g.* Nurse; Psychologist	*e.g.* Clinical trial research	*e.g.* HPCSA
1.		- select -	- select -		- select -
		- select -	- select -		
2.		- select -	- select -		- select -
		- select -	- select -		
3.		- select -	- select -		- select -
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7.		- select -	- select -		- select -
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8.		- select -	- select -		- select -
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9.		- select -	- select -		- select -
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10.		- select -	- select -		- select -
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11.		- select -	- select -		- select -
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12.		- select -	- select -		- select -
		- select -	- select -		
13.		- select -	- select -		- select -
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14.		- select -	- select -		- select -
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15.		- select -	- select -		- select -
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16.		- select -	- select -		- select -
		- select -	- select -		
17.		- select -	- select -		- select -
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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 -
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24.		- select -	- select -		- select -
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25.		- select -	- select -		- select -
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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 "Members expertise" or "position in HREC", 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 comments in the question below require 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 HREC composition

The composition of members must comply with the requirements set out in DoH 2015 par. 4.4.1.2. In principle, collectively, they must have the necessary qualifications, knowledge and experience to review and evaluate the science, protection of human participants and ethics of the proposed involvement of human participants in research. In complying with the requirements, HRECs should be independent, multi-disciplinary, multi-sectoral and pluralistic. Diversity of HREC membership refers mostly to ethnicity, culture and gender of members (compare DoH par. 4.4).

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

Is the HREC membership constituted in accordance with the requirements specified in the DoH 2015 guidelines?	Yes	No
Comment if "No"		

2.8 HREC procedures

Organisations/Institutions and their HRECs 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 (e.g. for SOPs NOT available as specified) below require 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 HREC have instructions in one or more SOPs describing the **frequency of meetings**[1]?	Yes	No
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.

2. Do the HREC have instructions in one or more SOPs describing the **preparation of agendas and minutes**?	Yes ◯	No ◯
Comment if "No"		

3. Do the HREC have instructions in one or more SOPs describing **distribution of documentation prior to meetings?**	Yes ◯	No ◯
Comment if "No"		

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

5. Do the HREC have instructions in one or more SOPs that explains how **prompt notification of decisions is sent to applicants**?	Yes ◯	No ◯
Comment if "No"		

6. Do the HREC have instructions in one or more SOPs describing how to **report unanticipated problems/incidents/adverse events**?	Yes ◯	No ◯
Comment if "No"		

7. Do the HREC have instructions in one or more SOPs describing how to **report allegations of misconduct/complaints**?	Yes ◯	No ◯
Comment if "No"		

8. Do the HREC have instructions in one or more SOPs describing **mechanisms for "whistle-blowing" and "whistle-blower" protection**?	Yes ◯	No ◯
Comment if "No"		

9. Do the HREC have instructions in one or more SOPs describing the process for **post-approval *passive* monitoring[2] of proposals/protocols**?	Yes ◯	No ◯
Comment if "No"		

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

10. Do the HREC have instructions in one or more SOPs describing the process for **post-approval *active* monitoring[2] of proposals/protocols**?	Yes ◯	No ◯
Comment if "No"		

11. Do the HREC have instructions in one or more SOPs describing how to manage **conflicts of interest and conflicts of commitment for HREC members**?	Yes ◯	No ◯
Comment if "No"		

12. Do the HREC have instructions in one or more SOPs describing how to manage **conflicts of interest and conflicts of commitment for researchers and teachers**?	Yes ◯	No ◯
Comment if "No"		

13. Do the HREC have instructions in one or more SOPs describing how to maintain **records in accordance with the DoH 2015 guidelines**?	Yes ◯	No ◯
Comment if "No"		

14. Do the HREC have instructions in one or more SOPs describing how to **develop and manage (i.e. review and approve) SOPs?**	Yes ◯	No ◯
Comment if "No"		

NB! *If any comments (e.g. for SOPs NOT available as specified) above require 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.*

2.9 Supporting documentation to be attached

Please attach the following HREC-supporting documentation to your application, and then indicate below (Yes/No) which have indeed been attached or not:
(Please provide explanatory comments below if any document is not attached)
NB! *If any comments (for documents NOT attached) below require 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. Is the template of the HREC membership appointment letter (that includes term of office and indemnification of members) attached?	Yes ◯	No ◯
Comment if "No"		

2. Are the Terms of Reference (ToR) document of the HREC attached?	Yes ◯	No ◯
Comment if "No"		

3. Are all Standard Operating Procedure documents (SOPs) of the HREC attached?	Yes ◯	No ◯
Comment if "No"		

4. Are the application forms/templates for ethics review of new proposals/protocols (including checklist for applications) attached?	Yes ◯	No ◯
Comment if "No"		

5. Are the application forms for amendments to approved proposals/protocols attached?	Yes ◯	No ◯
Comment if "No"		

6. Are the Serious Adverse Events SOP (as in par. 3 above), and where available the accompanying report form/template (as will be used by researchers and teachers) attached?	Yes ◯	No ◯
Comment if "No"		

7. Is the confidentiality agreement form for HREC members and reviewers attached?	Yes ◯	No ◯
Comment if "No"		

8. Is the conflict of interest declaration template for HREC members and reviewers attached?	Yes ◯	No ◯
Comment if "No"		

9. Is the template of the HREC ethics approval letter for a study attached?	Yes ◯	No ◯
Comment if "No"		

10. Is the post-approval passive monitoring[2] form (e.g. annual report by researchers or teachers) attached?	Yes ◯	No ◯
Comment if "No"		

11. Is the post-approval active monitoring[2] forms (e.g. onsite inspection of active studies) attached?	Yes ◯	No ◯
Comment if "No"		

12. Other *(specify)*	Yes ◯	No ◯

NB! *If any comments (for documents NOT attached) above require 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 Description of the HREC's capacity building and succession planning

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

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

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

Section 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 HREC, 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 HREC, and takes responsibility for the HREC as stipulated in Ethics in Health Research: Principles, Processes and Structures, Department of Health (**DoH 2015**; 2nd 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 HREC**	
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 HREC has only one responsible organisation/institution)*	**Yes** ○	**No** ○

Name of org./institution			**Name of HREC**	
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 HREC has only one or two responsible organisation/institution)*	Yes	No

Name of org./institution			**Name of HREC**	
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 *(HREC Chairperson)*

Affiliated org./institution			**Name of HREC**	
Name of signatory	*title*	*first name*		*last name*
Position	HREC 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