NATIONAL HEALTH RESEARCH ETHICS COUNCIL

www.nhrec.org.za

Application to register an HREC

Application to register a Human Research Ethics Committees (HRECs) with the National Health Research Ethics Council (NHREC)

Approved by the National Health Research Ethics Council: 2025-11-05

Version 4.03

Please read the important background information on p. 2-4, and then complete Sections 1 to 7 of the application form from p. 5 onwards.

Date submitted by HREC		*(in this form HREC implies applicant HREC)*
Date received by NHREC		← **this particular date is for office use only**
HREC full name		
HREC acronym / short name		
Name of primary organisation/institution		

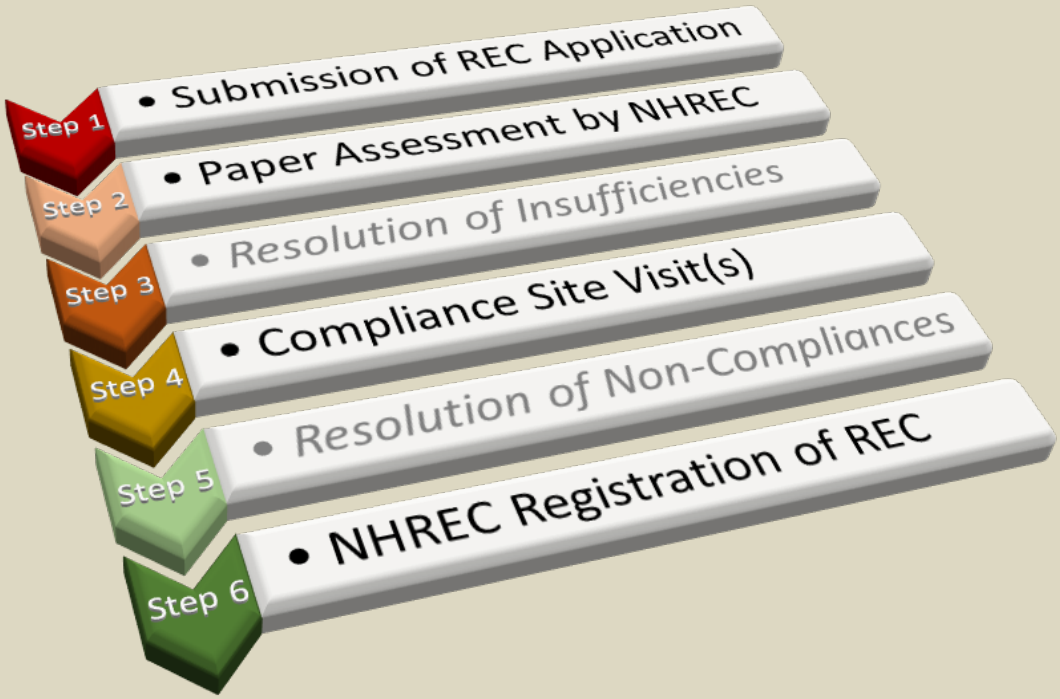
Illustrative example

Date submitted:	2025-02-28
Date received:	*…leave open…* ***(office use only)***
Reporting date:	2024-01-01 to 2024-12-31 ***(01 Jan – 31 Dec of the reporting year)***
HREC full name:	South Africa Dummy University Health Research Ethics Committee 1 *(i.e., Institution's full name + REC's full name)*
HREC acronym:	SADU-HREC1 *(i.e., institution's acronym hyphen REC acronym)*
Name of primary institution:	South Africa Demo University

Please note! The NHREC will assign a registration name and acronym in the format *[Institution Name] + [Research Ethics Committee Name]*, as shown in the example above. This assigned name may differ from the name your institution commonly uses if the latter does not comply with the NHREC naming format.

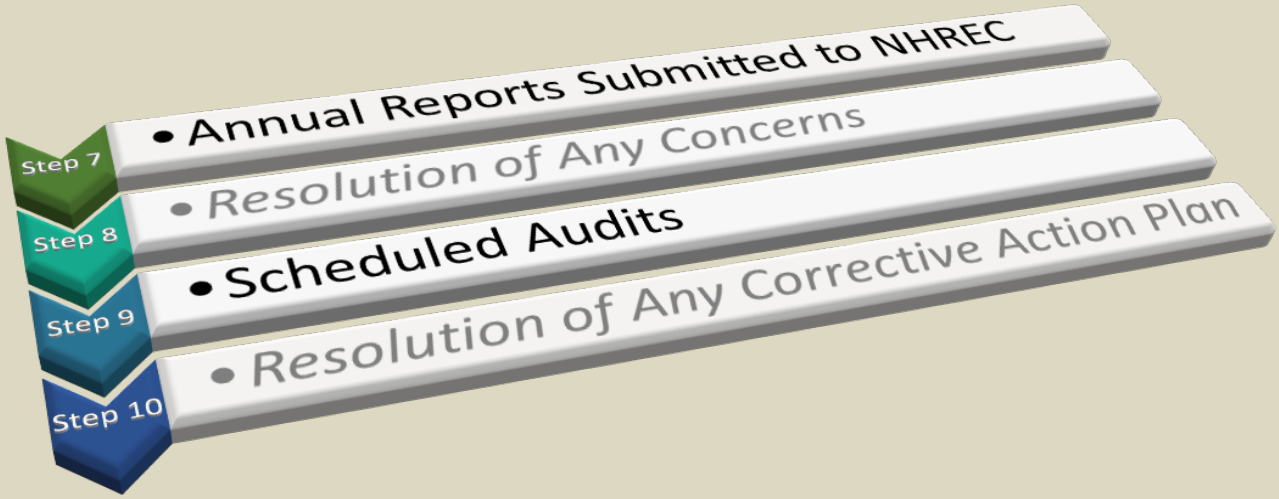
Important Information

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 South African Ethics in Health Research Guidelines: Principles, Processes and Structures (NDoH 2024; 3rd 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" 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 HREC registration form electronically in this original, fillable PDF application form (*for ease of accurate data capturing purposes*). Therefore, please do NOT submit a scanned copy.
- ALL questions MUST be answered in the spaces provided. All information provided in this application must be accurate, to the best of your knowledge. Also note:
  - Useful instruction tips will appear when you move your mouse over the fields to be completed.
  - Ensure that ALL required fields have been completed *(note required field indicated by "red" borders)*, otherwise your form will not submit.
  - Some text boxes allow a specific maximum number of characters (e.g., *indicated as "250 char. max"*) and will truncate beyond the maximum, limiting how much you can type. If you have reached the limit and need to say more, or when supporting documentation is required to fully answer a particular question, summarise your answer in the text box, attach an additional document with your full answer and clearly reference this attached document in the space provided for your answer in this report form (e.g., *"See full answer in the document attached, named [Answers.docx], par 3.2"*).
- Have this original, completed PDF document signed electronically *(preferred)* by all indicated authorised signatories. Only when a printed version of the declaration *(see Section 3)* is signed by a signatory, scan a high quality copy of that page in PDF or JPG format for submission as a separate page, and refer to the name of the scanned document with the signed page in the space provided in this PDF form.
- When saving on your computer, give the completed annual report form an appropriate name (e.g., "*HREC Registration*" + "*application year*" + "*the acronym for your HREC name*", for example [HREC Register 2024 SADU-HREC1.pdf]).
- Write a brief cover e-mail message and also attach all other supporting documentation. E-mail the completed form to the NHREC secretariat as in the contact information below, with the e-mail subject "Application to register a new HREC".

Contact information

E-mail:	nhrec@health.gov.za
Tel:	012 395 8119/8125
Fax:	012 395 9249

Use of information

Information about the registered HREC and its organisation/institution is used to confirm compliance with the requirements for continued registration. The requirements include scrutiny of compliance with best practice regarding ethical conduct of research with human participants including education.

Information collected during annual reporting will be used for the following purposes:

- Promote constructive communication between the HREC and NHREC.
- Update contact and other details to the NHREC's database of HRECs.
- Maintain a record of HREC activities, enquiries and complaints.
- Support and advise RECs and 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 South African Guidelines on Ethics in Health Research Principles, Processes and Structures (**NDoH 2024**; 3rd ed. or latest version).
- Maintain an updated and publicly 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

https://www.health.gov.za/nhrec-home/

Abbreviations, terms & definitions

The following common abbreviations and terminology are used in this application:

Abbreviation/Term	Definition
Active monitoring	Refers to active validation of compliance to the ethical aspects of the approved study, including an onsite inspection of the execution of a study
Authorised institutional official (AIO)	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 1.7 & 8 of this form below
DTA	Data Transfer Agreement
NDoH 2024	South African Guidelines on Ethics in Health Research Principles, Processes and Structures, 3rd ed., 2024.
HPCSA	Health Professions Council of South Africa
HREC	Human Research Ethics Committee. There should be a clear distinction between "health" and "human".
IHHRP	Institutional human health research programme
MTA	Material Transfer Agreement *(i.e., regarding human biological material)*
NDoH	National Department of Health
NHA 2003	National Health Act, Act No 61 of 2003
NHREC	National Health Research Ethics Council
Organisation/institution	The organisation/institution taking responsibility of the 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
Policy	High-level governance or operational principles formally adopted by an institution
SA GCP 2020	South African Good Clinical Practice: Clinical Trial Guidelines, 3rd ed. 2020. SAHPRA.
SANCTR	The South African National Clinical Trials Register
SAHPRA	South African Health Products Regulatory Authority
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.

Explanation of your RECs health or health-related research to be reviewed and monitored

As outlined in the NHREC's mandate above, the Council registers **Health** Research Ethics Committees (RECs), which include both **Human Research Ethics Committees (HRECs)** and **Animal Research Ethics Committees (ARECs)**.

The **National Health Act (NHA)**, read together with the **NDoH 2014 Section 1.1** definition of *health research*, defines it as research that contributes to knowledge of:

a) biological, clinical, psychological, or social processes in human beings
b) improved methods for the provision of health services
c) human pathology
d) the causes of disease
e) the effects of the environment on the human body
f) the development or new application of pharmaceuticals, medicines, and related substances
g) the development of new applications of health technology

This definition includes studies involving **human participants** or the use of **animals** for the purpose of investigating any of the aspects of human health listed above.

Purpose of this section:

This form is for **application to register an HREC**. Please describe the **types of health or health-related research** your HREC will review and monitor, ensuring it is clear how these activities fall within the NHREC mandate (i.e., health research). Your explanation should be a maximum of **600 words**.

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

1.01 HREC identification

HREC's full name			
HREC's acronym or short name		Date submitted by the HREC	

Please note! There is no 1.02, and 1.03 follows 1.07 – this is intended and not a mistake.

1.04 HREC contact person

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.*

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

1.05 HREC head of administrative functioning *(if applicable)*

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.*

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

1.06 HREC chairperson

Please note! *Appointment date when the chairperson took office for the first time (compare NDoH 2024 Section 5.3.2).*

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

1.07 Responsible organisation/institution and person

The institutional governance of the entire ***institutional human health research programme (IHHRP)***, including institutional policies, the HREC(s) and institutional research site(s), is overseen by the **Authorised Institutional Official (AIO)** (see **NDoH 2024**). This individual represents senior administration/ management, and bears the mandate, authority and ultimate responsibility (and accountability) to align, allocate, enact and ensure all support and resources needed by all institutional stakeholders (including the HREC(s) to effectively fulfil their respective responsibilities within the ***IHHRP***. The **AIO** must also work in close collaboration with applicable institutional line managers, HREC(s) and any relevant research facility managers, professional supervisor(s) and other supervisors and managers within the ***IHHRP***.

Please note! *Each institution appoints the AIO in line with its own policies. Without being prescriptive, this individual is typically a chief executive officer (CEO), or Deputy Vice Chancellor Research & Innovation.*

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

Please note! As mentioned above, 1.03 below follows 1.07 – this is intended and not a mistake.

1.03 Any changes foreseen during the next year?

	Yes	No
The reporting period is typically one calendar year. Do you foresee any changes within the first reporting period (year) with regard to the below-mentioned (par 1.4 – 1.7) HREC contact person, head of administrative functioning, chairperson, responsible organisation and/or contact information?	○	○

If "Yes", identify which information will change and when in the space below:

Please note!

- *Any changes need to be communicated with the NHREC as they are implemented. It is of particular importance that details of the contact person and chairperson are kept up-to-date with NHREC.*
- *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.*

Details of any changes *(if applicable)*	

Please note! As mentioned above, 1.03 is now followed by 1.08 – this is intended and not a mistake.

1.08 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.

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

Do you have proper succession planning and/or capacity building in place, particularly for the future chairperson and senior positions in the secretariat (i.e., to ensure preparedness & competence for future appointments and to facilitate smooth processes during transition or unplanned absence)?	**Yes** ◯	**No** ◯
Please explain briefly your succession plan and the current status of implementation. If applicable, explain any remedial action plan, progress, and/or any related obstacles experienced in the past year		

1.09 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

1.10 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*)

1.11 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: General Reporting Information

Requirements of an HREC

2.01 Legislation, guidelines and standards

As indicated in the South African Guidelines on Ethics in Health Research Principles, Processes and Structures (**NDoH 2024**; 3rd ed. or latest version), all HRECs must be familiar with and comply with the **NDoH 2024** guidelines or latest version. When an HREC reviews, approves and oversees any clinical trials, compliance with the South African Good Clinical Practice: Clinical Trial Guidelines (**SA GCP 2020**) of SAHPRA is also required. Other guidelines may be used in addition, as long as they do not contradict the **NDoH 2024** or **SA GCP 2020**.

Guideline:	**NDoH 2024**		**SA GCP 2020**		
	Yes	**No**	**Yes**	**No**	**n/a**
Are electronic/printed copies of the indicated guidelines available to the HREC management?	◯	◯	◯	◯	◯
Are electronic/printed copies of the indicated guidelines readily available to each HREC member?	◯	◯	◯	◯	◯
Are electronic/printed copies of the indicated guidelines readily available to researchers involving human participants in research?	◯	◯	◯	◯	◯
Does the HREC comply with the indicated guidelines, being knowledgeable about its requirements?	◯	◯	◯	◯	◯

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.*

	Yes	No
Does the HREC comply with any other national or international guidelines or standards related to the participation of humans in research? *(**Note!** excluding South African legislation/Acts).*	◯	◯
If "Yes", specify which and why *(500 char. max)*:		

Does the HREC have appropriate institutional policies, SOPs and/or other guidance/processes in place and operational to ensure compliance with:

the Protection of Personal Information Act 4 of 2013 (POPIA)?	**Yes** ○	**No** ○	
responsible management of information and research data (i.e. any relevant policy, plan, procedures & best practices)	**Yes** ○	**No** ○	
requirements for national and international material transfer agreements (MTAs) and data transfer agreements (DTA)?	**Yes** ○	**No** ○	**n/a** ○
delegated ministerial consent for non-therapeutic health research with minors?	**Yes** ○	**No** ○	**n/a** ○
Any comments of notes on the above that the HREC wishes to bring to the attention of the NHREC? *(1000 char. max)*:			

2.02 Terms of reference (ToR)

The organisation(s)/institution(s) must, when establishing an HREC, set out Terms of Reference (ToR) as specified in the **NDoH 2024**. The HREC'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 HREC members);
  - promote proper reviewing, approval and monitoring of approved studies and human participants wellbeing;
  - manage potential conflicts of interest and to maintain confidentiality;
  - establish clear reporting lines and accountability channels for the HREC, 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 HRECs.
- Financial compensation (remuneration), if any, for non-affiliated 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.*

Have the HREC's ToR been developed?	**Yes** ○	**No** ○
Do the HREC's ToR include the abovementioned critical elements?	**Yes** ○	**No** ○
Have the HREC's ToR been formally approved by your institution?	**Yes** ○	**No** ○
Any comments *(optional; 500 char. max)*:		

2.03 Standard operating procedures (SOPs)

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. – see **NDoH 2024**)). The organisation/institution and the HREC must have instructions in one or more SOPs explaining the following elements:

- Development and management (review, monitor, approve) of SOPs
- Frequency of meetings
- Preparation of agendas and minutes
- Distribution of documentation prior to meetings
- Review and approval of proposals/protocols (including expedited)
- How final decisions are reached
- Prompt notification of decisions
- How to address conflicts of interest and conflict of commitment for HREC members
- How to address conflicts of interest and conflicts of commitment for researchers and teachers
- Informed consent
- Privacy and confidentiality regarding participants and their health care information
- Reporting of unanticipated problems/incidents/adverse events
- Protocol amendment procedures
- Protocol deviations and protocol violations
- Maintenance of records in accordance with the **NDoH 2024** guidelines
- Reporting of allegations of misconduct/non-compliance
- Mechanisms for "whistle-blower" protection
- Complaints procedures
- Post-approval passive monitoring[1] of proposals/protocols
- Post-approval active monitoring[1] of proposals/protocols
- Continuing review and recertification procedures
- Suspension and termination
- Research involving minors
- Research involving vulnerable persons
- Biological materials collection and storage
- Data bases, registries and repositories
- Developing memoranda of understanding/agreement (MoUs/MoAs) and (MTAs) for national and international multi-institutional research collaboration
- …and others as appropriate and added from time to time

- ***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.*

Whereas all of the above elements must be included in one more of the SOPs, indicate whether the following specific elements have been properly addressed:

	Yes	No
1. Do the HREC have instructions in one or more SOPs describing the **frequency of meetings**[2]?	◯	◯
Comment if "No"		

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

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

	Yes	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**?	◯	◯
Comment if "No"		

[1] Refer to the table on p. 4 for a definition of passive and active monitoring, respectively.

[2] **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.

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

	Yes	No
6. Do the organisation/institution and the HREC have instructions in one or more SOPs outlining guiding timelines for REC operational efficiency of application review and approval processes, and do these include that records will be kept of actual time spent on various administrative, review, feedback and response processes, thereby to effectively manage efficiency?	○	○
Comment if "No"		

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

	Yes	No
8. Do the HREC have instructions in one or more SOPs describing how to **report allegations of non-compliance or violation of good research practice, or complaints**?	○	○
Comment if "No"		

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

	Yes	No
10. Do the HREC have instructions in one or more SOPs describing the process for **post-approval *passive* monitoring[3] of proposals/protocols**?	○	○
Comment if "No"		

	Yes	No
11. Do the HREC have instructions in one or more SOPs describing the process for **post-approval *active* monitoring[1] of proposals/protocols**?	○	○
Comment if "No"		

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

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

13. 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"		

14. Do the HREC have instructions in one or more SOPs describing how to maintain **records in accordance with the NDoH 2024 guidelines**?	**Yes** ◯	**No** ◯
Comment if "No"		

15. 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"		

Are the developed SOPs in an appropriate and official SOP format? (including document number/code, SOP title & description, version & date, purpose, scope, responsibilities, instruction(s), authorised signatures, etc.).	**Yes** ◯	**No** ◯	**n/a** ◯
Which of the SOPs still need to be developed so that the collection contains all of the critical elements?			

2.04 HREC forms/templates

HRECs develop forms to support their function, in line with its SOPs, including to facilitate application, notification, reporting, monitoring, inspection and queries. These forms are used by applicants and researchers when applying for approval or when reporting on any matter related to approved projects. Typical examples of forms may include the following:

- Ethics application form for approval of a study
- Reviewer report forms for study applications
- Ethics application for approval of sub-studies under a larger/umbrella/parent study
- Application form to amend an approved study
- Form for annual passive monitoring of an approved study
- Form for active monitoring of an approved study in progress
- Report form for serious adverse events or incidents
- Form for raising a query or complaint

- ***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 some of the HREC's forms/templates been developed?	**Yes** ○	**No** ○
Which of the forms/templates still need to be developed so that the collection contains all of the critical elements?		

2.05 Research Ethics Policy

Please answer below:

	Yes	No
Has the Research Ethics Policy *(or an overarching governance document that pertains to research conduct research infrastructure and research ethics of the institution)* been developed and approved?	○	○

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

2.06 Processes for the 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)*	

2.07 Documentation for the appointment, indemnification of HREC members and code of conduct

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** ◯
Members should sign a code of conduct when appointed. Does the HREC have a code of conduct for its members?	**Yes** ◯	**No** ◯
Any comments		

2.08 HREC management/administrative support

Please explain the nature, strengths and/or limitations of the management/administrative support available to the HREC during the reporting period (see **NDoH 2024**, e.g., secretariat/human resources, office space, computers, printers, financial support).

NB! *If any comments in the question below require more space than maximum provided (max 1,500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

2.09 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.*

	Yes	No
1. Is the template of the HREC membership appointment letter (that includes term of office and indemnification of members) attached?	○	○
Comment if "No"		

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

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

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

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

	Yes	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?	○	○
Comment if "No"		

	Yes	No
7. Is the confidentiality agreement form for HREC members and reviewers attached?	○	○
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[1] form (e.g. annual report by researchers or teachers) attached?	Yes ◯	No ◯
Comment if "No"		

11. Is the post-approval active monitoring[1] forms (e.g. onsite inspection of active studies) attached?	Yes ◯	No ◯
Comment if "No"		

12. The code of conduct form for HREC members	Yes ◯	No ◯
Comment if "No"		

13. 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.*

Section 3: HREC Composition

3.1 HREC member names and profiles

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

Please note!

- Please complete the table below meticulously, as the information is extracted and used to verify compliance with **NDoH 2024** Sections 5.3.1 & 5.2.3. Additional notes for when "*other (specify below)*" is selected in the table, is on the next page below the table. Use this only when the table does not accommodate the information you wish to share.

	Name of member *(title, initials, surname) This column duplicates on the next page*	Position in HREC	Years serving on HREC	Assessed re-. search ethics training in past 3 years	Relation to organisation / institution	Demo-graphics	Age group	Sex
						…see NDoH 2024		
0	*e.g.*, Prof XX Example	*e.g.*, Vice-Chairperson	*e.g.*, 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 -
21.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
22.		- select -	- select -	- select -	- select -	- select -	- select -	- 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 -
31.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
32.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
33.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
34.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
35.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
36.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
37.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
38.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
39.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
40.		- select -	- select -	- select -	- select -	- select -	- select -	- select -

3.2 Required expertise of full members

Indicate the represented expertise discipline & profession of full HREC members *(i.e., excluding non-voting members)* by completing the fields in the table below.

Please note!

- At least one full member (or more) must represent the expertise listed below and must be qualified and experienced to serve in that capacity.
- One person may represent more than one category of expertise, and more than one person represent a particular category of expertise.

Required expertise		
Expertise	**#**	**Name(s)**
Expertise and experience in quantitative research methodologies		
Expertise and experience in qualitative research methodologies		
Knowledge of, and current experience in, the professional care, counselling, or health- related treatment of people		
Layperson *(see NDoH section 5.3.1, footnote 84)*		
Entirely independent of the institution		
Expertise in biostatistics		
Expertise in research ethics		
Legally qualified		
Other (specify below)		
Specify "Other"		

For notes on any member and descriptions above or below that may require further explanation, please indicate in the text box below the name(s) of the member(s) you refer to and then specify.

Please note!

- *These additional notes are optional. Please use this ONLY when necessary, when the table does not accommodate the information you wish to share.*
- *If any comment in the question below requires more space than maximum provided, provide a brief summary here and refer to the name of your attached document (ONLY when necessary) containing the full details.*

3.3 Membership categories

Indicate the categories of HREC members by completing the fields in the table below.

Please note!

- The total number of full (voting) members must be at least 9, as per NDoH 2024. The alternate and non-voting members do not count towards the minimum of 9 full members required for a REC.
- The EXCO and Adverse Event/Incident committees must include the chairperson plus one representative of cat A, B, C & D. The EXCO may also serve as Adverse Event/Incident committee.

Total number of full members - including the chairperson and vice chairperson(s)		Is it expected that full members attend meetings regularly?	Yes ◯	No ◯
Category	**#**	**Category**		**#**
Chairperson - full member, one person		Vice-chairperson(s) - from full members below		
Full members, excluding above - excluding the chairperson and vice chairperson(s)		Alternate member - stands in when another expert is not available		
Ad hoc member (expertise) – nonvoting		Advisory member – nonvoting		
Secretariat (e.g., meeting support) – nonvoting		Capacity building member – nonvoting		
EXCO members		Adverse event/incident committee		
Names of EXCO members		Names of adverse event/incident committee members		

For notes on any member and descriptions above or below that may require further explanation, please indicate in the text box below the name(s) of the member(s) you refer to and then specify.

Please note!

- *These additional notes are optional. Please use this ONLY when necessary, when the table does not accommodate the information you wish to share.*
- *If any comment in the question below requires more space than maximum provided (max 1000 char.), provide a brief summary here and refer to the name of your attached document (ONLY when necessary) containing the full details.*

3.4 Diversity and representation of full members

Indicate the diversity and representation of full HREC members *(i.e., excluding non-voting members)* by completing the fields in the table below. **Note!** **%** / **%** **= auto calculated, do not type in these columns.**

Demographics *(...for equity and representation purposes)*								
	#	**%**		**#**	**%**		**#**	**%**
Black		NaN **%**	Coloured		NaN **%**	Indian		NaN **%**
B + C + I	0	NaN **%**	White		NaN **%**	Other *(specify)*		NaN **%**
Specify if "Other"								

Sex *(...for equity and representation purposes)*								
	#	**%**		**#**	**%**		**#**	**%**
Male		NaN **%**	Female		NaN **%**	Other		NaN **%**

Years serving on the REC								
Yrs	**#**	**%**	**Yrs**	**#**	**%**	**Yrs**	**#**	**%**
<1		NaN **%**	1-3		NaN **%**	4-6		NaN **%**
7-9		NaN **%**	>9		NaN **%**			

Age group distribution *(...for equity and representation purposes)*								
Yrs	**#**	**%**	**Yrs**	**#**	**%**	**Yrs**	**#**	**%**
20-29		NaN **%**	30-39		NaN **%**	40-49		NaN **%**
50-59		NaN **%**	≥60		NaN **%**			

Professional body registration							
	#		**#**		**#**		**#**
AHPCSA		HPCSA		SACE		SACSSP	
SADTC		SALPC		SANC		SAPC	
Other		Specify if "Other"					

Note! AHPCSA = Allied Health Professions Council ; HPCSA = Health Professions Council of South Africa ; SACE = South African Council for Educators ; SACSSP = South African Council for Social Service Professions ; SADTC = South African Dental Technicians Council ; SALPC = South African Legal Practice Council ; SANC = South African Nursing Council ; SAPC = South African Pharmacy Council

For notes on any member and descriptions above or below that may require further explanation, please indicate in the text box below the name(s) of the member(s) you refer to and then specify.

Please note!

- *These additional notes are optional. Please use this ONLY when necessary, when the table does not accommodate the information you wish to share.*
- *If any comment in the question below requires more space than maximum provided (max 1000 char.), provide a brief summary here and refer to the name of your attached document (ONLY when necessary) containing the full details.*

3.5 Disciplines & professions of full members

Indicate the represented disciplines and professions of full HREC members *(i.e., excluding non-voting members)* by completing the fields in the table below.

Discipline and profession					
Discipline/profession	**#**	**Discipline/profession**	**#**	**Discipline/profession**	**#**
Advanced training & experience in clinical trials		Advanced training & experience in regulatory medicine		Biokineticist	
Clinical pharmacologist		Dietitian or nutritionist		Environmental health officer	
Legal Professional		Medical practitioner		Nurse	
Occupational therapist		Physiotherapist		Paramedic	
Pharmacist		Psychologist		Psychometrist	
Registered Counsellor		School teacher		Social worker	
Statistician		Other (specify below)			
Specify "Other"					

For notes on any member and descriptions above or below that may require further explanation, please indicate in the text box below the name(s) of the member(s) you refer to and then specify.

Please note!

- *These additional notes are optional. Please use this ONLY when necessary, when the table does not accommodate the information you wish to share.*
- *If any comment in the question below requires more space than maximum provided (max 1000 char.), provide a brief summary here and refer to the name of your attached document (ONLY when necessary) containing the full details.*

3.6 HREC appointment requirements

The composition of members must comply with the requirements set out in **NDoH 2024**. In principle, collectively, they must have the necessary qualifications, knowledge and experience to review and evaluate the science, protection of human participants and ethics. 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 **NDoH 2024**).

Please note! *If any comments in the question below require more space than maximum provided (max 1,000 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

Is the HREC membership at present constituted in accordance with the requirements specified in the **NDoH 2024** guideline?	**Yes** ◯	**No** ◯
Have all HREC members received a formal written notification about their appointment?	**Yes** ◯	**No** ◯
Does the notice specify the term of appointment?	**Yes** ◯	**No** ◯
Does the notice specify provision of legal protection in respect of liability that may arise in the course of *bona fide* conduct of their duties as committee members?	**Yes** ◯	**No** ◯
Members should sign a code of conduct when appointed. Does the HREC have a code of conduct for its members and has this been signed by all members?	**Yes** ◯	**No** ◯
Any comments *(optional)*:		

3.7 Challenges with membership

List any challenges encountered in meeting the membership requirements as stipulated in national guidelines, in the HREC's own ToR/SOP and in additional organisational/institutional policies. Also clearly indicate you action plan to address any sub-optimal matters or inadequacies identified.

Please note! *If any comments in the question below require more space than maximum provided (max 1,500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

Section 4: Research Ethics Training, Resources & Capacity

HREC members are required to have appropriate and up-to-date training in health research ethics involving human participants (compare **NDoH 2024**), on relevant theory, South African legislation, national standards and guidelines, roles as HREC members in the ethics review, approval and ethical oversight processes, etc. These guidelines require specified topics for training (see **NDoH 2024**), refresher training every 3 years, that training be assessed (i.e., not mere attendance), and that a certificate of proof of training be available.

Please note! *Human research ethics training, as required, is different from Good Clinical Practice (GCP) training for clinical trials, and over and above any professional/clinical ethics training, such as for continuing professional development (CPD).*

Target group	Required Topics[4]		Last 3 years?		Assessed?		Certificate of proof?	
Induction training for all HREC members	Yes ○	No ○						
Health research ethics training for **all HREC members**	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○
Health research ethics education/training for **support staff** *(i.e., admin/secretariat)* of HRECs	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○	Yes ○	No ○

Only when the HREC reviews, approves and oversees clinical trials *(leave open if not applicable)*:

Target group	NA	…or	Last 3 years?		Certificate of proof?	
Good Clinical Practice training for **all HREC members**	○		Yes ○	No ○	Yes ○	No ○

When an HREC reviews a particular application, the following must be required and verified.

Target group	Verified?	
Health research ethics training for all **investigators and collaborators** (i.e., researchers & postgraduate students)	Yes ○	No ○
Health research ethics training specifically for all **international collaborators**	Yes ○	No ○

Briefly describe you action plan to ensure compliance in cases of any insufficiencies.

Please note! *If any comments in the question below require more space than maximum provided (max 2,000 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

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

Section 5: Functions and Operations of the HREC

Please note! *There is no 5.01 to 5.07 in this application form. This is intended and not an error.*

5.08 Other matters related to applications

Please note! *There is no 5.08.01 to 5.08-09 in this report form. This is intended and not an error.*

5.08.10 Prior scientific review

Any study must undergo scientific review prior to ethical review. However, this does not preclude the HREC from commenting on and being satisfied with the scientific integrity of the study. Ethical integrity is inseparable from scientific integrity, and the REC has a responsibility to ensure the latter as well. Even a negligible risk of harm is unlikely to be justifiable if the research lacks scientific merit.

Please note! *Compare with the* ***NDoH 2024*** *.*

Is there a formal process of scientific review and approval of studies prior to ethical review, with evidence of such approval?	**Yes** ◯	**No** ◯
Does the HREC require such evidence to be submitted with the ethics application?	**Yes** ◯	**No** ◯

Please note! *There is no section 6 in this application form. This is intended and not an error.*

Section 7: Other matters

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 8: Declaration

HREC's full name							
HREC's acronym or short name		NHREC provisional no.	**REC-**		**-**		
Name of responsible organisation/ institution							

This declaration must be completed and signed electronically in this original, fillable MSWord document (i.e., not a scanned copy) by the chair. Signatures by others indicated are optional.

Please note! Only when electronic signing by a particular signatory is not possible and a printed version is signed by that person, scan a high-quality copy of that page in PDF or JPG format for submission as a separate page, refer to the signed page in this original MSWord form, and attach the scanned page in addition to this completed original MSWord form.

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

- I am duly authorised to sign this approval,
- information supplied on this form and any attachment is correct to the best of my knowledge.

First signatory: *HREC Chairperson*

Name of signatory	*title*	*first name*		*last name*
Position	HREC Chairperson		E-mail	
How does this signatory sign?	*Digitally* ◉	*Hard copy* ○	Signature	
If a hard copy was signed, what is the name of the scanned copy of the signed document (attached)?			Date	

Do you confirm that the Authorised Institutional Official indeed received a copy of this annual report?	**Yes** ○	**No** ○

Please note! *It is required that the Authorised Institutional Official receives a copy and remains updated on all important matters related to research.*

Second signatory: *Head of Ethics Office or Authorised Institutional Official of the organisation/institution (optional)*

Do you want to add a second signatory?	**Yes** ○	**No** ○

Name of signatory	*title*	*first name*		*last name*
Position			E-mail	
How does this signatory sign?	*Digitally* ○	*Hard copy* ○	Signature	
If a hard copy was signed, what is the name of the scanned copy of the signed document (attached)?			Date	

Third signatory: *Head of Ethics Office or Authorised Institutional Official of the organisation/institution (optional)*

Do you want to add a third signatory?	Yes ○	No ○

Name of signatory	*title*	*first name*		*last name*
Position			E-mail	
How does this signatory sign?	*Digitally* ◉	*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