NATIONAL HEALTH RESEARCH ETHICS COUNCIL

www.nhrec.org.za

HREC Annual Report Form

Annual report form for Human Research Ethics Committees (HRECs) registered with the National Health Research Ethics Council (NHREC)

Approved by the National Health Research Ethics Council: 2023-11-01

Version 3.00

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

Date submitted by HREC			
Date received by NHREC		**…this date for office use only**	
Reporting period - from	2023-01-01	to	2023-12-31
HREC full name			
HREC acronym / short name		**Note!** Please ensure that you use the CORRECT full name and acronym of you HREC, and in particular the EXACT registration number as it appears on your registration certificate *(i.e., no omissions of any letters, numbers, 0's, or hyphens, or even addition of wrong spaces in the number).*	
HREC registration no.			
Registration status	- select -		
Name of primary organisation/institution			

Illustrative example

Date submitted: 2024-02-28
Date received: *…leave open…* ***(office use only)***
Reporting date: 2023-01-01 to 2023-12-31
HREC full name: South Africa Dummy University Health Research Ethics Committee 1
HREC acronym: SADU-HREC1
HREC reg. no.: REC-123456-078 ***(NB! exact number)***
Reg. status: Registered
Name of primary institution: South Africa Demo University

Important Information

Purpose

In South Africa, **Health Research Ethics Committees (HRECs)** *involving human participants* must report annually to the **National Health Research Ethics Council (NHREC)** on their activities, as required by the Guidelines, South African Guidelines on Ethics in Health Research Principles, Processes and Structures (**NDoH 2024**, 3rd ed. or latest version), . For continued registration with the NHREC, 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 **NDoH 2024** or latest version.

Reports are due by **28 February annually** on this HREC annual reporting form (see NHREC website). To prevent unnecessary delays in the current annual reporting process, please ensure that the information provided is complete and accurate. The HREC may be contacted if additional information is needed, and will be advised of the outcome.

Instructions

Basic instructions

- Please complete the HREC annual report electronically in this original, fillable PDF application form (*for ease of accurate data capturing purposes*). Therefore, please do NOT submit a scanned copy.
- ALL questions MUST be answered in the spaces provided. All information provided in this application must be accurate, to the best of your knowledge. Also note:
  - Useful instruction tips will appear when you move your mouse over the fields to be completed.
  - Ensure that ALL required fields have been completed *(note required field indicated by "red" borders)*, otherwise your form will not submit.
  - Some text boxes allow a specific maximum number of characters (e.g., *indicated as "250 char. max"*) and will truncate beyond the maximum, limiting how much you can type. If you have reached the limit and need to say more, or when supporting documentation is required to fully answer a particular question, summarise your answer in the text box, attach an additional document with your full answer and clearly reference this attached document in the space provided for your answer in this report form (e.g., *"See full answer in the document attached, named [Answers.docx], par 3.2"*).
- Have this original, completed PDF document signed electronically *(preferred)* by all indicated authorised signatories. Only when a printed version of the declaration *(see Section 3)* is signed by a signatory, scan a high quality copy of that page in PDF or JPG format for submission as a separate page, and refer to the name of the scanned document with the signed page in the space provided in this PDF form.
- Give the completed annual report form an appropriate name (e.g., "*HREC Annual Report*" + "*reporting year*" + "*the acronym for your HREC name*", for example [HREC Annual Report 2023 SADU-HREC1.pdf]). Click on the "Submit" button (executes an e-mail action) in this original, fillable PDF report form, write a brief cover e-mail message and also attach all other supporting documentation. Save a copy for your own records.

Contact information

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

Use of information

Information about the registered 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. **Please note!** It is understood that this document is still under revision after the 1st circulation for comment in 2023 *(i.e., not yet published)*.
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.

Reporting Period

The reporting period is typically one calendar year, since your last report, unless specified otherwise.

Dates for this report	*from*	2023-01-01	*until*	2023-12-31

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

1.1 HREC identification

HREC's full name			
HREC's acronym or short name		NHREC registration no.	
Date of registration at NHREC		Status of registration	- select -

1.2 Any changes during the reporting period?

	Yes	No
Have there been any changes since your last annual report to NHREC with regard to the below-mentioned (par. 1.4 – 1.7) HREC contact person, head of administrative functioning, chairperson, responsible organisation and/or contact information?	○	○

If "Yes", identify which information has changed in the space below:

NB! *If 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)*	

1.3 Any changes foreseen during the next year?

	Yes	No
Do you foresee any changes during the upcoming reporting period (year) with regard to the below-mentioned (par 1.4 – 1.7) 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:

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.*

Details of any changes *(if applicable)*	

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

1.4 HREC contact person

Contact person			
	title	*first name*	*last name*
E-mail		REC Web URL1	
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.*

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

Contact person			
	title	*first name*	*last name*
E-mail		REC Web URL2	
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.*

1.6 HREC chairperson

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

1.7 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***.

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	

1.8 Succession planning

	Yes	No
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)?	○	◉

If "No", then please explain any progress or obstacle in executing your succession plan in the past year	

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

Section 2: General Reporting Information

Requirements of an HREC

2.1 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**.

Guideline:	**NDoH 2023**		**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?	○	●
If "Yes", specify which and why *(500 char. max)*:		

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

the Protection of Personal Information Act 4 of 2013 (POPIA)?	**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)*:			

2.2 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.*

Are the HREC's ToR updated and operational?	**Yes** ○	**No** ○
Do the HREC's ToR include the abovementioned critical elements?	**Yes** ○	**No** ○
Can the HREC's ToR be accessed online?	**Yes** ○	**No** ○
If yes, provide the URL:		
If no, attach any newly developed ToR, or ToR with substantive updates (not necessary for minor updates)		
When last were the HREC's ToR updated?		
Any comments *(optional; 500 char. max)*:		

2.3 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.*

Are the HREC's SOPs updated and operational?	**Yes** ○	**No** ○
Do the HREC's SOPs include the abovementioned elements?	**Yes** ○	**No** ○
Can the HREC's SOPs be accessed online?	**Yes** ○	**No** ○
If yes, provide the URL:		
If no, attach any newly developed SOPs, or SOPs with substantive updates (not necessary for minor updates)		
When last were the HREC's SOPs updated?		
Provide the name, date and one-sentence description for any new SOPs or substantive changes/updates to existing SOPs *(if applicable; 750 char. max)*:		

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

2.4 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.*

Are the HREC's forms/templates updated and operational?	**Yes** ○	**No** ○
Do the HREC's forms/templates include the abovementioned examples?	**Yes** ○	**No** ○
Can these forms/templates be accessed online?	**Yes** ○	**No** ○
If yes, provide the URL:		
When last were the HREC's forms/templates updated?		
Provide an action plan and/or explanation if any form is NOT available or insufficient *(750 char. max)*:		

2.5 Research Ethics Policy

Please answer below:

	Yes	No
Has the Research Ethics Policy *(or an overarching governance document that pertains to research conduct and research infrastructure of the institution)* been updated during the reporting period?	○	○

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

2.6 HREC administrative support

Please explain the nature, strengths and/or limitations of the 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.*

Section 3: HREC Composition

3.1 HREC member names and profile

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.

Please note!

- Please complete the table below comprehensively, as the information is extracted and used to verify compliance with **NDoH 2024**. Use additional note 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 human 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 -

Name of member *(title, initials, surname)* *This column duplicates from the previous page*		HREC membership requirements *(see NDoH-2023)*	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	*e.g.,* 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 -
		- select -	- select -		
4.		- select -	- select -		- select -
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5.		- select -	- select -		- select -
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6.		- select -	- select -		- select -
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7.		- select -	- select -		- select -
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11.		- select -	- select -		- select -
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12.		- select -	- select -		- select -
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13.		- select -	- select -		- select -
		- select -	- select -		
14.		- select -	- select -		- select -
		- select -	- select -		
15.		- select -	- select -		- select -
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16.		- select -	- select -		- select -
		- select -	- select -		
17.		- select -	- select -		- select -
		- select -	- select -		
18.		- select -	- select -		- select -
		- select -	- select -		
19.		- select -	- select -		- select -
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20.		- select -	- select -		- select -
		- select -	- select -		
21.		- select -	- select -		- select -
		- select -	- select -		
22.		- select -	- select -		- select -
		- select -	- select -		
23.		- select -	- select -		- select -
		- select -	- select -		
24.		- select -	- select -		- select -
		- select -	- select -		
25.		- select -	- select -		- select -
		- select -	- select -		
26.		- select -	- select -		- select -
		- select -	- select -		
27.		- select -	- select -		- select -
		- select -	- select -		
28.		- select -	- select -		- select -
		- select -	- select -		
29.		- select -	- select -		- select -
		- select -	- select -		
30.		- select -	- select -		- select -
		- select -	- select -		

If you indicated "other (specify below)" in the two tables above for any member under that member's "position in HREC", "requirements" or "discipline and expertise", please indicate in the text box below the name(s) of the member(s) you refer to and then specify the "other".

Please note!

- *Use additional notes ONLY 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.*

3.2 HREC composition and appointment

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**).

NB! *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)*:		

3.3 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.

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.*

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.

NB! *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[2]		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	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 ◯

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

Briefly describe the typical training your HREC provided during the reporting period, and/or that your members participated in (attended or completed online). Also indicate how you will ensure compliance in cases of any insufficiencies.

NB! *If any 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.*

Section 5: Functions and Operations of the HREC

5.01 HREC meetings

Number of HREC meetings[3] held during the reporting period?	…total scheduled		…total held	
	…total not quorate[3]		…total cancelled	
What are the main reasons for non-quorate[3]**?** *(max 1000 char.)*				
Steps taken when non-quorate[3]**?** *(max 1000 char.)*				
Number of other meetings held during the reporting period?		…by the Executive Committee		

[3] Here "meetings" imply an interactive (i.e., physical / face-to-face / teleconferencing / videoconferencing) discussion of applications (including project overview, reviewer feedback, deliberation, consensus decision, etc.) by a quorum of members present in term of number and representation. "Quorum/quorate" is defined by the guidelines, including that >50% of members be present when ≤15 members, or 33% when >15 members (**NDoH 2023**).

Second opinions: List and provide details of any second opinions by experts (compare **NDoH 2024**) sought / provided during the reporting period.

NB! *If any comments in the question above 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.*

Agendas, Minutes and other meeting documents:		
Were agendas, minutes and other meeting documents made available before HREC meetings during the reporting period?	**Yes** ◯	**No** ◯
How many days prior to meetings are agendas, minutes and other meeting documents made available to HREC members?		
Were minutes approved at the next meeting during the reporting period?	**Yes** ◯	**No** ◯
How are conflicts of interests recorded and managed?		

Approval of applications		
Is it a requirement of the HREC that applications can only be approved following deliberation at interactive (face-to-face or technology-based) HREC meetings?	**Yes** ◯	**No** ◯
Can you confirm that the abovementioned requirement of interactive meetings for ethics approval is indeed implemented by the HREC?	**Yes** ◯	**No** ◯

Review of Applications

5.02 General statistics

Provide the information below as accurately as possible.

Number of applications during the reporting period?	…considered		…in process	
	…approved		…not approved	
Total number of applications approved involving…	…clinical trials		…children	
	…of total children, how many under delegated ministerial consent[4]			
	…innovations in therapy		…human materials (e.g., blood, tissue, genetic materials)	
	…reciprocal reviews		…environmental impact	
	…qualitative data			
Total number of applications approved characterised as…	…medium risk		…high risk	

5.03 Operational efficiency & record keeping

Operational efficiency of application review and approval processes is essential for RECs, in particular to manage timelines optimally to avoid undue delays, while also allowing sufficient time for administrative processes and proper ethical review.

Notes: *Ethical approval processes have often been criticised for delaying the commencement of research for postgraduate students (i.e., long turn-around times). Whereas such processes may play a role, delays may also relate to insufficient planning by investigators, time spent on rebuttals (e.g., slow response/procrastination) and delays to obtain external approvals and permits. Having the information below at hand would greatly assist the HREC to assess its administrative and review time efficiency, and to address any issues accurately and/or determine (even defend) to which extent the HREC and its processes are truly responsible for the delays.*

It is hence important that your SOP guides on, and you keep record of how many days…

- before a scheduled meeting the agenda closes for the submission of new applications, as per deadline communicated to all stakeholders?
- are afforded to reviewers to review an ordinary *(i.e., not expedited/rapid)* applications (i.e., from the date of receipt until submission of the review report to secretariat)?
- are typically spent on an ordinary HREC application from the date of closure of the agenda to first communication to the researcher (i.e., feedback on the HRECs decision at the meeting)?
- are afforded to investigators (i.e., applicants) to address comments (e.g., 60 days) in a rebuttal to HREC comments, after receipt of the first decision letter (i.e., not within the control of the HREC or secretariat)?
- are afforded to reviewers to review an expedited/rapid HREC application (i.e., from the date of receipt until submission of the review report to secretariat)?
- are typically spent on an expedited/rapid HREC application from the date of closure of the agenda to first communication to the researcher (i.e., feedback on the HRECs decision at the meeting)?

Does your SOP outline guiding timelines for REC operational efficiency of application review and approval processes, as indicated above?	Yes ◯	No ◯
Does your REC keep record of actual time spent on various administrative, review, feedback and response processes, thereby to effectively manage efficiency?	Yes ◯	No ◯

[4] See NDoH 2015 par. 3.2.2.1(d)

Briefly comment on any challenges you experience with the above (SOP and record keeping), or mention any accolades of any newly implemented, successful strategies that others may learn from.

Please note! *There is no 5.04 to 5.07 in this report 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.

Note: *Compare 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** ◯

Monitoring

Please note! *There is no 5.09 in this report form. This is intended and not an error.*

5.10 Post-approval passive monitoring of proposals/protocols

Post-approval passive monitoring (during the reporting period)	Is reporting (at least annual) required by the HREC?	**Yes** ◯	**No** ◯	…total number of studies overseen (reports required)	
	…number of monitoring reports received			… number of monitoring reports NOT received	
	…number of studies that could continue			…number of studies suspended/terminated	

Please note! *Refer to the table on p. 4 for a definition of passive monitoring.*

Describe the general status of post-approval passive monitoring (e.g., annual written reports) by researchers/teachers on their approved involvement of human participants in research during the reporting period. Also describe any deviations or non-compliance.

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.*

Were protocol deviations and GCP breaches managed successfully in accordance with your SOP during the reporting period?	**Yes** ◯	**No** ◯
If "No", explain:		

Indicate the ***number of studies*** for which you did site visits during the reporting period	
Indicate the ***total number of site visits*** during the reporting period	
Comments & explanations:	

5.11 Post-approval active monitoring of proposals/protocols by HREC members

There must be a plan for active monitoring of approved studies in place. Clinical trial research requires special ethical oversight from the HREC, and special training, competence, management and reporting from research teams.

Post-approval active monitoring (during the reporting period)	…conducted by the HREC?	**Yes** ◯	**No** ◯	…total number of studies monitored	

Please note! *Refer to the table on p. 4 for a definition of active monitoring.*

Describe the strategies implemented, general status and significant outcomes/findings of post-approval active monitoring (e.g., site visits) of researchers regarding their approved research with human participants during the reporting period. Also describe any deviations or non-compliance.

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.*

5.12 Unanticipated problems, serious incident or serious adverse event reports

Are there mechanisms for the reporting of **unanticipated problems**, **serious incidents (SIs)** and **serious adverse events (SAEs)** to the HREC?	Yes ◯	No ◯
Is immediate reporting of **SIs** and **SAEs** required by the HREC?	Yes ◯	No ◯
Is there a mechanism in place to resolve **SIs** and **SAEs**?	Yes ◯	No ◯

Total number of **SIs** reported during the reporting period		Total number of **SAEs** reported during the reporting period	

Please note! *Refer to the table on p. 4 for a definition of unanticipated problem, serious incident and serious adverse event, respectively.*

Describe how you handle unanticipated problems, serious incidents or adverse events?

NB! *If any 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.*

5.13 Amendments (changes to proposals/protocols)

Is approval of amendments[5] required by the HREC?	Yes ◯	No ◯
Is there an SOP for major and minor amendments in place?	Yes ◯	No ◯
Was there proper record keeping of amendments[5] by the HREC during the reporting period?	Yes ◯	No ◯

[5] Here *"amendment"* refers to any change in the research team, study design and/or participant numbers that requires permission by the HREC.

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

5.14 Number of cases received/handled

Please indicate the number of whistle blowing cases or complaints ("0" for none) submitted to the HREC during the reporting period…

…about misconduct in an approved study	
…from scientists about the outcome of ethics approval	
…about the HREC in general	
Any comments *(optional)*:	

5.15 Types of whistle blowing, complaints or alleged non-compliance or violation of good research practice

Please tick the types of concerns in cases dealt with. Briefly explain what the cases were and how it was dealt with.

Authorship		Conduct of a researcher		Conflict of interest	
Human participant wellbeing / monitoring		Discrimination		Data security	
General HREC processes		Inappropriate communication, etc.		Informed consent process	
Other (specify)					
Any comments *(optional)*:					

5.16 Status or outcome of cases

Please indicate the number of cases that were resolved, referred or escalated in the categories indicated below. If some cases were channelled elsewhere than to the HREC, please explain.

Status/outcomes of cases (during the reporting period)	…resolved by the HREC		…still under consideration	
	…resolved by the responsible organisation/institution		…referred to the NHREC	
	…resulting in disciplinary action against a scientist		…resulting in legal action (in court)	
Any comments *(optional)*:				

Section 6: HREC response to previous reports

Have you addressed all matters related to your HREC's latest NHREC audit report?	Yes ◯	No ◯
Any ongoing matters you wish the NHREC to take note of *(optional)*		

Have you addressed all matters related to the feedback from the NHREC regarding your HRECs previous annual report(s)?	Yes ◯	No ◯
Any ongoing matters you wish the NHREC to take note of *(optional)*		

Section 7: Other matters

Are there any other matters that received attention of the HREC that you wish to report to the NHREC?	Yes ◯	No ◯
Are there any issues for which further advice is needed?	Yes ◯	No ◯
If "YES" to either, please provide details here.		

Section 8: HREC Report Approved and Supported

HREC's full name			
HREC's acronym or short name		NHREC registration no.	
Name of responsible organisation/ institution			

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

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

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

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

First signatory: *HREC Chairperson*

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	

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?	*Digital* ○	*Hard copy* ○	Signature	
If a hard copy was signed, what is the name of the scanned copy of the signed document (attached)?			Date	

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

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

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

Submission

After completion and signing, submit this original, fillable PDF form *(i.e., not a scanned copy)* plus any supporting documentation as attachment(s) to the **NHREC Secretariat** at:

nhrec@health.gov.za