health
Department:
Health
REPUBLIC OF SOUTH AFRICA

HREC Annual Report Form

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

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: 14 February 2018

Version 2.00

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.

- Office Use Only –

Date received	
Reporting period - from	to
HREC full name	
HREC acronym / short name	
HREC registration no.	
Registration status	- select -
Name of primary organisation/institution	

Important Information

Purpose

In South Africa, **Human Research Ethics Committees (HRECs)** must report annually to the **National Health Research Ethics Council (NHREC)** on their activities, as required by the guidelines, Ethics in Health Research: Principles, Processes and Structures, Department of Health (DoH 2015; 2nd ed. or latest version), Section 4.6 iii. 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 DoH 2015 or latest version.

Reports are due by **28 February annually** on the 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 2017 SAU-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 Ethics in Health Research: Principles, Processes and Structures, Department of Health (DoH 2015; 2nd ed. or latest version).
- Maintain an updated and publically accessible database of registered HRECs.

Protection of disclosure of information

The Protection of Personal Information Act No 4 of 2013 and the ethical principles supporting confidentiality govern disclosure of information collected by the NHREC about HRECs and organisations/institutions.

Additional information on the NHREC can be retrieved from

http://www.health.gov.za/ and http://www.nhrec.org.za/

Abbreviations, terms & definitions

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

Abbreviation/Term	Definition
Active monitoring	Refers to active validation of compliance to the ethical aspects of the approved study, including an onsite inspection of the execution of a study
HREC	Human Research Ethics Committee
Authorised institutional official	The authorised member of senior administration/management of the institution/organisation bearing ultimate responsibility and accountability for research practices
Authorised signatory	The person taking responsibility for indicated functions related to the HREC, according to institutional policy – see also Section 7 of this form below
NDoH	National Department of Health
DoH 2015	Ethics in Health Research: Principles, Processes and Structures, Department of Health, 2nd ed. 2015
NHA 2003	National Health Act, Act No 61 of 2003
Organisation/institution	The organisation/institution taking responsibility of the HREC
Passive monitoring	Refers to regular (typically annually) written reporting by the principal investigator about research involving human participants, progress and problems with the study
NHREC	National Health Research Ethics Council
Serious adverse event (SAE)	Relates to an unforeseen harmful event related to the study (e.g. injury/death due to an experimental intervention)
Serious incident (SI)	Relates to an unforeseen harmful event unrelated to the study itself (e.g. unexpected patient response)
SOP	Standard Operating Procedure
ToR	Terms of Reference
Unanticipated problem	Relates to any obstacle that negatively affects a study and the possibility to achieve the outcomes, other than due to a SAE or SI defined above

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

Reporting Period

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

Dates for this report	*from*		*until*	

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		Web Address	
Telephone		Fax:	
Physical address		Postal address	

Please note! *All correspondence to the HREC, including to the chairperson, will be sent to the HREC contact information as indicated above. This should be an address that does not change when individuals of the secretariat, the HREC chairperson or other office bearers change.*

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

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

Please note! *Some HRECs may be supported by a central administrative office, and in some instances this office may have a senior manager. If this is the case, this manager's details may be provided here.*

1.6 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

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

Section 2: General Reporting Information

Requirements of an HREC

2.1 Guidelines and standards

As indicated in the Ethics in Health Research: Principles, Processes and Structures, Department of Health (**DoH 2015**; 2nd ed. or latest version), all HRECs must be familiar with and comply with the DoH 2015 guidelines or latest version. Other guidelines may be used in addition, as long as they do not contradict DoH 2015.

Are electronic/printed copies of the DoH 2015 guidelines available to the HREC management?	**Yes** ○	**No** ○
Are electronic/printed copies of the DoH 2015 guidelines readily available to each HREC member?	**Yes** ○	**No** ○
Are electronic/printed copies of the DoH 2015 guidelines readily available to researchers involving human participants in research?	**Yes** ○	**No** ○
Does the HREC comply with the DoH 2015 guidelines, being knowledgeable about its requirements?	**Yes** ○	**No** ○

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.*

Does the HREC comply with any other guidelines or standards?	**Yes** ○	**No** ○
If "Yes", specify which and why *(500 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 DoH 2015 par 4.3.2. 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)** (DoH 2015 par. 4.5.1), defined here as formally approved and implemented instruction documents in the appropriate format (including document number/code, SOP title & description, version & date, purpose, scope, responsibilities, instruction(s), authorised signatures, etc.). The organisation/institution and the HREC must have instructions in one or more SOPs explaining the following elements:

- Frequency of meetings
- Preparation of agendas and minute
- 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 DoH 2015 & SANS 10386 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
- Development and management (review, monitor, approve) of SOPs

- ***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
- 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 provide brief information (1 page max) of any updated policies over the last reporting period.

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.*

2.6 HREC administrative support

Please explain the nature, strengths and/or limitations of the administrative support available to the HREC during the reporting period (see DoH 2015 par. 4.4.2i, 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.

	Name of member *(title, initials, surname) This column duplicates on the next page*	Position in HREC	Years on HREC	Assessed human ethics training during past 3 years	Relation to organisation/ institution	Demo-graphics	Age group	Sex
0	Prof XX Example	*e.g.* Vice-Chairperson	*e.g.* 4-6	*e.g.* Yes	*e.g.* Affiliated	*e.g.* Black	*e.g.* 50-59	*e.g.* Female
1.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
2.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
3.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
4.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
5.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
6.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
7.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
8.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
9.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
10.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
11.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
12.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
13.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
14.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
15.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
16.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
17.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
18.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
19.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
20.		- select -	- select -	- select -	- select -	- select -	- select -	- select -
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	HREC-relevant discipline and expertise	HREC-relevant experience	HREC-relevant qualifications
		Note! *Select one or two requirements, and one or two disciplines/expertise per member from the drop-down lists below.*			
0	Prof XX Example	*e.g.* Biostatistician; Exp. in qualitative	*e.g.* Nurse; Psychologist	*e.g.* Clinical trial research	*e.g.* BPharm, PhD
1.		- select -	- select -		
		- select -	- select -		
2.		- select -	- select -		
		- select -	- select -		
3.		- select -	- select -		
		- select -	- select -		
4.		- select -	- select -		
		- select -	- select -		
5.		- select -	- select -		
		- select -	- select -		
6.		- select -	- select -		
		- select -	- select -		
7.		- select -	- select -		
		- select -	- select -		
8.		- select -	- select -		
		- select -	- select -		
9.		- select -	- select -		
		- select -	- select -		
10.		- select -	- select -		
		- select -	- select -		
11.		- select -	- select -		
		- select -	- select -		
12.		- select -	- select -		
		- select -	- select -		
13.		- select -	- select -		
		- select -	- select -		
14.		- select -	- select -		
		- select -	- select -		
15.		- select -	- select -		
		- select -	- select -		
16.		- select -	- select -		
		- select -	- select -		
17.		- select -	- select -		
		- select -	- select -		
18.		- select -	- select -		
		- select -	- select -		
19.		- select -	- select -		
		- select -	- select -		
20.		- select -	- select -		
		- select -	- select -		
21.		- select -	- select -		
		- select -	- select -		
22.		- select -	- select -		
		- select -	- select -		
23.		- select -	- select -		
		- select -	- select -		
24.		- select -	- select -		
		- select -	- select -		
25.		- select -	- select -		
		- select -	- select -		
26.		- select -	- select -		
		- select -	- select -		
27.		- select -	- select -		
		- select -	- select -		
28.		- select -	- select -		
		- select -	- select -		
29.		- select -	- select -		
		- select -	- select -		
30.		- 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".

NB! *If any comments in the question below require more space than maximum provided (max 600 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

3.2 HREC composition

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

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

Is the HREC membership at present constituted in accordance with the requirements specified in the DoH 2015 and SANS 10386:2008 guidelines?	**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** ◯
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 the ethics of the involvement of human participants in research, on the relevant South African legislation, national standards and guidelines, and on their respective roles as HREC members in the ethics review, approval and ethical oversight processes.

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

Have all HREC members undertaken **appropriate human research ethics training in the last 3 years**, with some form of assessment (i.e. not mere attendance) and a certificate of proof (mandatory)?	**Yes** ◯	**No** ◯
If "No" above, explain and indicate how compliance will be insured:		
Do you have **induction training for new HREC members** in place?	**Yes** ◯	**No** ◯
Do you facilitate **continuing training for existing HREC members** in place?	**Yes** ◯	**No** ◯

Briefly describe the typical training your HREC provided during the reporting period, and/or that your members participated in (attended or completed online).

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 5: Functions and Operations of the HREC

5.01 HREC meetings

Number of HREC meetings[2] held during the reporting period?	…total scheduled		…total held	
	…total not quorate[2]		…total cancelled	
What are the main reasons for non-quorate[2]**?** *(max 250 char.)*				
Steps taken when non-quorate[2]**?** *(max 250 char.)*				
Number of other meetings held during the reporting period?	…by the Executive Committee			

Second opinions: List and provide details of any second opinions by experts (compare DoH 2015, par. 4.5.1.3) 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** ○

[2] 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 (DoH 2015, par. 4.4.1.3).

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…	…children		of total children, how many under ministerial consent[3]	
	…innovations in therapy		…clinical trials	
	…human materials (e.g. blood, tissue, genetic materials)			
Total number of applications approved characterised as…	…medium risk		…high risk	
Average number of days spent on HREC admin, review, decision making, communication and correction, from start of application to final decision and communicated to researcher?				

5.07 Other sensitive issues in studies approved

Please indicate the other sensitive issues encountered during the review of proposals/protocols during the reporting period:

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	Item	Describe briefly
○	○	Studies with environmental impact	
○	○	Studies that could harm the name of the organisation / institution	

Monitoring

5.09 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.*

[3] See DoH par. 3.2.2.1(d)

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.*

	Yes	No
Were protocol deviations and GCP breaches managed successfully in accordance with your SOP during the reporting period?	○	○
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:	

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

Post-approval active monitoring (during the reporting period)	…required by the HREC?	**Yes** ○	**No** ○	…total number of studies monitored	
	…number of studies found compliant			…number of studies found non-compliant	

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

Describe the general status 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.*

5.11 Unanticipated problems, serious incident or 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 1,500 char.), provide a brief summary here and refer to the name of your attached document containing the full details.*

5.12 Amendments (changes to proposals/protocols)

Is approval of **amendments**[3] required by the HREC?	Yes ◯	No ◯
Was there proper record keeping of **amendments**[3] by the HREC during the reporting period?	Yes ◯	No ◯

Briefly describe the requirements and process for application of amendments at the HREC.

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.*

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

Whistle blowing, complaints or alleged non-compliance, violation and misconduct

5.13 Number of cases received/handled

Please indicate the number of cases submitted to the HREC during the reporting period.

Number of whistle blowing cases		**Complaints**		**Alleged non-compliance, violation and misconduct**	
…about conduct in an approved study		…about conduct in an approved study		…about conduct in an approved study	
…from scientists about the outcome of ethics approval		…from scientists about the outcome of ethics approval		…from scientists about the outcome of ethics approval	
…about the HREC in general		…about the HREC in general		…about the HREC in general	
Any comments *(optional)*:					

5.14 Types of whistle blowing, complaints or alleged non-compliance, violation and misconduct

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)*:					

5.15 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: Other Issues

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.*

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 7: 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

Submit Form via E-mail