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# Application for registration of a Research Ethics Committee (REC)

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- Office Use Only -

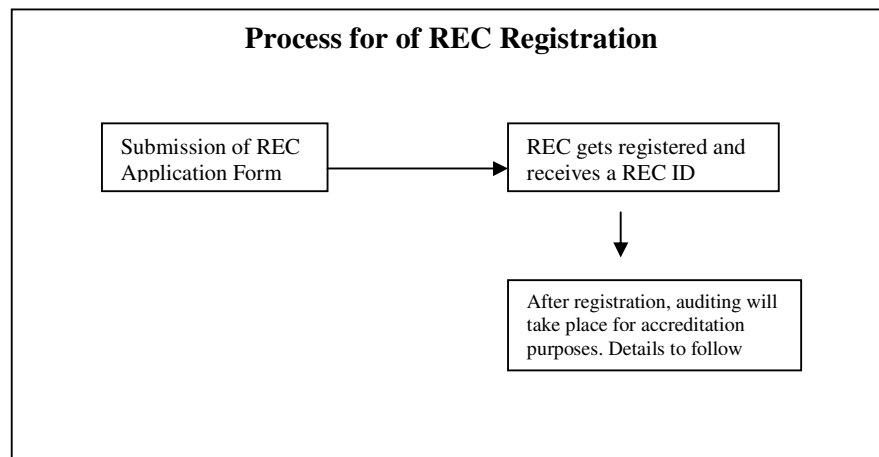
Date received:

REC name

REC ID

Name of primary organisation

Organisation ID



## Important Information

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Levels of Accreditation

Level 1: RECs that have the capacity to assess straightforward research designs that involve minimal risk to human participants. These include research proposals that do not involve drug research, biomedical research involving human tissues, high-budget research (more than R250000.00 per annum). In brief, Level 1 committees are meant to review 'minimal risk' research only

Level 2: RECs that may review all types of health research proposals, including collaborative international health research, multi-centre studies and long-term studies exceeding one year in duration

### **Applying for registration**

An organisation or independent REC may apply for registration of a Health Research Ethics Committee (REC) with the National Health Research Ethics Council. To be eligible for registration the organisation and REC must demonstrate compliance with Section 73 of the National Health Act, Act No 61 of 2003.

This application must be signed by the head of the organisation or independent REC (e.g. CEO or Vice-Chancellor, Chairperson of REC). If the REC serves more than one organisation, the head of each of these organisations must also sign the form.

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

### **Instructions**

- Please type or print clearly.
- All questions MUST be answered
- If an answer space provided is not sufficient, please attach additional pages.
- Please retain a photocopy of your completed application.

Information provided in this application must be, to the best of your knowledge, true and accurate.

**Please forward the signed, original completed form to:**

**National Health Research Ethics Council  
C/O Directorate: Health Research  
Secretariat for NHREC  
Private Bag X 828  
PRETORIA  
0001**

**Tel: 012 395-8119/8113**

**E-mail: [nhrec@health.gov.za](mailto:nhrec@health.gov.za)**

### **Use of Information**

Information relating to the REC and the organisation will be used to determine whether the REC meets the requirements for registration and to promote best practice with regard to ethical conduct of research.

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

- Send information relevant to research and ethics to the organisation and REC;
- Monitor and review REC compliance with the National Health Act, Act No 61 of 2003
- Generate lists of REC/organisation contact details (excluding personal information)
- Maintain a record of correspondence, enquiries and complaints;
- Assists in the development of initiatives to support RECs and research organisations;
- Consult with RECs/organisations on policy with regard to health ethics, research ethics and RECs.

**Privacy disclosure of information**

Information collected by the NHREC about the RECs and organisations is subjects to the government policy on confidentiality of information.

**Additional information on the NHREC can be retrieved from <http://www.nhrec.org.za>**

# Section 1

## Organisation and Research Ethics Committee (REC) Details

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### REC details

#### 1. Name of the Organisation

#### 2. Name of REC

#### 3. REC Mailing Address (both physical and postal)

All REC related correspondence would be sent to this address
Please provide address exactly as it should appear on mailing label
E-mail to be used for REC contact/correspondence
Specific Website for REC information (if applicable)

#### 4. REC Contact Officer

Name	_____
Title	Name                    Surname
Position	_____
Phone (    )	
Fax (    )	
E-mail	_____

#### 5. REC Chairperson

Name	_____	Title	_____	Name	_____	Surname	_____
Phone	(	)	_____				
Fax	(	)	_____				
E-mail	_____						

All correspondence to the chairperson will be sent to the “REC Mailing Address” above.

**Organisation with primary responsibility for the REC (‘Applicant’)**

Every organisations/institutions, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council (Section 73 of the National Health Act, Act No 61 of 2003).

A health research ethics committee must:

- (a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and
- (b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standard as described in the Regulations and guidelines governing the conduct of health research.

**Organisations with primary responsibility for the REC (‘Applicant’)**

**6. Name of organisation**

**7. Name of head of organisation**

**8. Position of head of organisation**

**9. Contact details for head of organisation**

Phone (      )	_____	Fax (      )	_____
E-mail	_____		

**10. Mailing address for head of organisation (Physical & Postal)**

All correspondence to the head of the organisation will be sent to this address. Please provide address exactly as it should appear on a mailing label

<b>Physical Address:</b>
<b>Postal Address:</b>

**11. Please indicate which category best describes the organisation (Tick one only)**

<input type="checkbox"/>	Hospital/health service –public
<input type="checkbox"/>	Hospital/health service – private
<input type="checkbox"/>	University/educational institution – public
<input type="checkbox"/>	University/educational institution – private
<input type="checkbox"/>	Government Department
<input type="checkbox"/>	Government statutory agency (e.g. HSRC, MRC, NRF, CSIR)
<input type="checkbox"/>	Private Research Ethics Committee (not for profit)
<input type="checkbox"/>	Private Research Ethics Committee (for profit)
<input type="checkbox"/>	Other organisation/institution –not for profit
<input type="checkbox"/>	Other organisation/institution – for profit

**12. How many organisations (stakeholders) does this REC serve?**

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**Anticipated activity level of the REC**

**13. How many research proposals/protocols did the REC review in the last 12 months?**

**14. How many meetings (for the purpose of review research proposals/protocols) did and does the REC hold respectively?**

In the past 12 months?	
In the next 12 months?	

# Section 2

## Registration Information

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Questions in this section relate to the requirements of REC

### Establishment of REC

(In accordance with Guidelines of DoH (2004) Ethics in Health Research: Principles Structures & Processes)

The organisation (s) or institution(s) must, when establishing a REC, set out terms of reference including the scope of its responsibilities, relationship to non-affiliated researchers, accountability, mechanisms of reporting, and remuneration, if any, for members.

1. Has the REC been established with specific terms of reference?

Yes (go to question 2)

No

1a. if NO, please provide an explanation:

2. What percentage of work best describes the role of your research ethics committee?

%

**Research** i.e. Review and monitoring of research proposals and associated activities

%

**Non-research** e.g. policy development, monitoring of clinical practice

### REC Composition

(In accordance with the Guidelines of DoH (2004) Ethics in Health Research: Principles Structures & Processes)

The research ethics committee should consist of members who, collectively, have the qualifications and experience to review and evaluate the science, health aspects and ethics of the proposed research. Research ethics committees should be independent, multi-disciplinary, multi-sectoral and pluralistic.

3. Is the REC membership constituted in accordance with the guidelines: DoH (2004) Ethics in Health Research: Principles, Structures and Processes?

Yes (go to question 4)

No

3a. In NO, please provide an explanation



**4. Please indicate how the membership of your REC is constituted**

Please ensure that each individual member is assigned to one category of membership only.

<b>Name of a member</b>	<b>Lay person</b>	<b>Institutional</b>	<b>Non-institutional</b>	<b>Qualifications</b>	<b>Research Ethics Training</b>

**5. Please describe the role/expertise of “other/additional” members:**

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**6. What is the gender composition of the REC?**

<b>Number of Males</b>	<b>Number of Females</b>

**7. Indemnification of REC Members**

Members must receive a formal notification of appointment and assurance that the organisation/institution will provide legal protection in respect of liabilities that may arise in the course of *bona fide* conduct of their duties as committee members.

**7a. How are REC members informed about their appointment? (please tick)**

	Letter (posted/faxed)
	E-mail
	Personal communication (telephone)
	Other, please state:

**7b. How are REC members selected?**

**7c. How are they notified?**

**8. Has the organisation provided assurance of legal protection for REC members?**

Yes (go to question 9)

No

**8a. If NO, please provide an explanation of current arrangements:**

## REC Procedures

Institutions and organisations and their RECs must have working procedures

**9. Has the organisation and the REC established working procedures for the following**

*(If Yes, please indicate if these are documented or not documented. If procedures are not documented, please provide a general explanation)*

	Yes	Documented	Not Documented	No
Frequency of meetings If NO, Please explain: ..... ..... .....				
Preparations of agendas and minutes If NO, Please explain: ..... ..... .....				
Distribution of papers prior to meetings If NO, Please explain: ..... ..... .....				
Consideration and Review of research protocols If NO, Please explain: ..... ..... .....				
Methods of decision –making If NO, Please explain: ..... ..... .....				
Prompt notification of decisions If NO, Please explain: ..... ..... .....				
Reporting of adverse events If NO, Please explain: ..... ..... .....				
Safety Monitoring If NO, Please explain: ..... ..... .....				

**10(a) Has the organisation and the REC developed procedures and processes to address conflicts of interest for REC members? (Please tick the documented box if these are documented, if not, provide a general explanation in a space provided below)**

Yes       No       documented

**10(b) Has the organisation and the REC developed procedures and processes to address conflicts of interest for researchers? (Please tick the documented box if these are documented, if not, provide a general explanation in a space provided below)**

Yes       No       documented

**11(a) If No in 10(a), please provide an explanation of current arrangements:**

**11(b) If No in 10(b), please provide an explanation of current arrangements:**

An REC shall maintain a record of all research protocols received and reviewed as discussed in the DoH (2004): Ethics in Health Research: Principles Structures and Processes guidelines, Section 3.

**12. Has the organisation developed procedures and processes to maintain records in accordance with the DoH (2004): Ethics in Health Research: Principles Structures and Processes guidelines? (Please tick the documented box if these are documented, if not, provide a general explanation in a space provided below)**

Yes

No

documented

**13. Are you applying for level 1 or level 2 accreditation\*? (DoH (2004): Ethics in Health Research: Principles Structures and Processes guidelines, Section 3.3.2)**

Level 1

Level 2

**14. Please attach the following REC supporting documentation:**

- Standard Operating Procedures of the REC
- Application forms for ethical review
- Confidentiality agreement form
- Conflict of Interest Declaration
- Checklist for submissions

**13. If there is other information relevant to this application that may assist, please provide it below.**

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\* Please note ratification of levels will be done by the NHREC during accreditation.  
REC Application Form for registration with NHREC

# Section 3

## Declaration

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This declaration **MUST** be completed and signed by the Head of Organisation/CEO as referred in Section 1

NOTE: If more than one organisation/institution is responsible for this REC, you **MUST** ensure that the authorised person of each organisation/institution signs a separate Declaration. If this is the case, you will need to photocopy this page and attach all declarations to this application.

### **I declare and undertake for the organisation**

- That I am duly authorised to sign this declaration;**
- That information supplied on this form and any attachment is true and correct;**

**Name of REC:**

**Name of organisation:**

**Signature:** \_\_\_\_\_ **Date** \_\_\_\_\_