GUIDELINES FOR APPROVAL OF HEALTH RESEARCH IN THE WESTERN CAPE

2012/13

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IN THE WESTERN CAPE

1. Background

In the past decade, South Africa has seen an increase in research inputs and outputs in areas such as clinical trials and epidemiological and other health-related studies. On the whole, research activities have tended to lack coordination and prioritisation to maximally benefit health sector development and achieve the desired impact on the quality of life of the greater population. As part of a national health reform agenda, the National Department of Health has sought to respond to this poorly regulated developmental approach by formulating and adopting a research policy framework summarised hereunder.

National Health Research Policy Framework

The White Paper on the Transformation of the Health System in South Africa[1]

National health reform and transformation activities took place during the years 1995 to 2001 and culminated in the adoption of 'The White Paper on the Transformation of the Health System in South Africa' and subordinate policy guidelines for various health care management and service delivery areas. The main goal of this policy was to tackle the transformation of the health services with the aim of reducing health care provision inequalities and long standing imbalances in past government policies. The White Paper stressed the importance of knowledge, information and empirical evidence as the backbone of health policy. Research must be linked to and the findings integrated into broader health policy planning and health programmes management and implementation. The linkages between health research and health systems management are captured in the Essential National Health Research (ENHR) Strategy.

Essential National Health Research (ENHR) Strategy[2]

The Essential National Health Research (ENHR) strategy promotes an integrated, multidisciplinary approach to health related research that improves the health status of the population while supporting development, equity and social justice. This strategy proposes key research fields within which health research priorities need to be determined by national and provincial level departments, namely:

- Epidemiology, including the Burden of Disease (BOD);
- Social and behavioural research;
- Clinical and biomedical research;

- Health systems management and policy research.

"Given the history of a poorly coordinated health research environment both nationally and provincially, the Western Cape wishes to adopt measures to set a health research agenda aimed at fostering firm linkages between research, programme management and service delivery. The Western Cape Province is privileged to have significant intellectual capacity in the form of academic institutions, major national research institutions and a vibrant research community. Even though this is a national resource, it is however in our "back yard" and thus the coordination and efficient utilisation of this limited resource" [3] are provincial goals.

Health Research Coordination

South Africa has a heritage which has resulted in dual management within the public health care system by local & provincial authorities. In the Western Cape, all districts excluding the City of Cape Town district have successfully changed over to a unified management system under the authority of the Provincial Department of Health. The City of Cape Town district is currently still administered by two authorities. In respect of health facilities in the City of Cape Town district, the clinics are mostly managed by City Health while most of the Community Health Centres (CHCs), Community Day Centres (CDCs) and all of the hospitals (District, Regional, Psychiatric, Tuberculosis and Central Hospitals as well as Emergency, Rehabilitative and Dental services) are managed by the Provincial Department of Health. Some facilities within the City of Cape Town district are managed by both local and provincial authorities (see Annexure 6).

Provincial Health Research Committee (PHRC)

The Health Research Policy in South Africa (2001) identified Provincial Health Research Committees as an important mechanism for coordinating health research and facilitating the efficient utilization of limited research resources. Although the Provincial Health Research Committees are not mentioned in the National Health Act (Act No. 61 of 2003), which establishes the National Research Coordination Committee, plans are under way to develop regulations which specify these. Accordingly the Western Cape has established a multi - sectoral Provincial Health Research Committee (PHRC).

The purpose of the Western Cape Provincial Research Health Committee (PHRC) is to inform and facilitate health research in the province by liaising with all research stakeholders conducting research within the province to ensure that research activities are directed towards the greatest health needs in the province. This committee serves to advise on and oversee the approval of health research by the relevant authorities. The Terms of Reference for the Western Cape Provincial Health Research Committee are:

1) To inform and facilitate the process of priority setting and to develop and continuously review health research priorities (research agenda) for the province
2) To facilitate the conduct of relevant research in the province
3) To aid the mobilisation of resources for research undertaken in the province;
4) To advise on the translation of health research findings into policy development and service provision at all levels of the health care system;
5) In collaboration with research stakeholders, to develop and implement a capacity building strategy to strengthen research capacity in the province.

The PHRC is not an ethics committee nor does it routinely review proposals submitted for approval.

See **Annexure 9** for a list of the Current PHRC members.

2. Objectives of the Research Approval Process

1) To provide strategic oversight of research in the province thereby increasing the likelihood that research projects ultimately benefit patients and the population at large, and are aligned with provincial priorities;
2) To ensure that services are not overburdened by research;
3) To ensure that all research has undergone relevant prior scientific and ethics review ;
4) To ensure that the findings of studies conducted in the province are made available to local and provincial government officials;
5) To develop a database of research that is accessible to researchers for coherent planning of research and preventing unnecessary overlap in content and/or geography.

3. Scope of the Approval Process

As part of the management responsibility of the health authorities, it is necessary for all health research proposals to be conducted in the Western Cape public health sector, to be submitted to and **approved by the relevant authorities** as a prerequisite for the conduct of health research. This is considered to be "access approval" and should be distinguished from ethics approval which must be obtained independently.

This requirement applies to the following types of research:

- All research at public sector facilities including research to be conducted at central hospitals;
- Community-based or laboratory-based research that affects referral to and workloads at public sector facilities;
- Recruitment of patients from public health facilities to be involved in studies that themselves are conducted outside public sector facilities.

Research proposals that do not fall into the above categories do not need approval. However, researchers are encouraged to submit for entry into the database proposals whose findings could have implications for the organisation of health care or public health practice in the province. This applies particularly to health systems research.

4. Procedures for Approval of Research Proposals

The Western Cape public sector has five independent administrative authorities that are responsible for research approval (see Annexure 5). It is the responsibility of researchers to submit the required documents (see Annexure 4) to the research-coordinator of *each* of the authorities relevant to their research. In order to facilitate application for approval the PHRC has standardised the application procedure and required documentation for the five authorities.

The PHRC will work collaboratively with Research Ethics Committees in the province to promote rigorous review of the ethics and scientific quality of research proposals, and to ensure that these review processes are optimally coordinated with the provincial approval process.

4.1. Review Criteria and Approval Process

On receiving a research proposal that has been approved by an accredited Research Ethics Committee (REC), the research coordinator (see annexure 5) will submit the

proposal to relevant managers for review. They will consider whether or not approval can be recommended based on the following criteria:

1. Is the research feasible in facilities within the limitation of space, staff, patients, timing and funds?
2. Does the research duplicate or clash with other research in the relevant facilities?
3. Does the research have the potential to answer questions of interest to the province, and provide outputs that could be implemented by the province?

The research co-ordinators listed in Annexure 5 are the primary contact persons for researchers. However, researchers are encouraged to engage with the relevant service managers at the research proposal development stage. This is best done initially via the provincial research co-ordinator who will assist with access to the relevant service people. This applies particularly to research that seeks access to many facilities or patients and/or contact with a facility over a prolonged period of time, and that will have a significant impact on the facility or staff. *Agreement or approval by service managers at this preliminary stage does not constitute approval in terms of the procedures in this document.* Such approval must still be sought following the procedures outlined.

Only research that has received ethics approval from an accredited research ethics committee, or an ethics committee which has applied to be nationally accredited, will be considered. See Annexure 3.

Any queries or comments raised by reviewers will be forwarded to the researcher for a response. Once the reviewers' comments have been satisfactorily addressed and the proposed facilities have confirmed their capacity to accommodate the researcher, **an approval letter will be drafted by the relevant research coordinator for approval by the relevant director.** As part of the approval process, researchers may be requested to deliver a succinct presentation of the research proposal to the managers of the relevant authority and to address the concerns raised. **Researchers may only proceed with research once the approval letter has been received from the relevant authority.** This applies to pilot studies as well, which are regarded as part of the formal study. This letter will contain the contact details of staff that can assist researchers to access the requested facilities and/ or staff.

Researchers wishing to access dual authority (City and Provincial) facilities need to make separate applications to both authorities. Central hospitals, although falling within the jurisdiction of the Provincial Department of Health, each have their own

administrative authority to approve the requests to conduct research within these facilities. **Thus five independent administrative authorities exist for approval of research proposals. Researchers requesting access to conduct health research within the City of Cape Town district are required to make separate applications to the relevant authority (ies).** See Annexure 5 for list of research coordinators at City Health, Provincial Department of Health (excluding Regional Hospitals) and Central Hospitals.

4.1.1. Approval guidelines for access to patient data by other government departments

The approval guidelines are designed to manage access to identified patient information and non-identified patient information by other government departments. For identified data, government departments must have ethics approval. For non-identified data, data will be released to departments for planning purposes. However, if the data are needed by a third party outside of government, ethics approval is required.

The PHRC reviews the list of all approved, non-approved and pending proposals monthly and is committed to assisting service managers and researchers to minimise delays.

4.2 Students

Postgraduate students are expected to follow the same procedure outlined in this document for their research proposal to be approved.

It is expected that research undertaken by *undergraduates* will take place within the context of agreements between their supervisors and the facilities for which formal approval has previously been obtained. Undergraduate students will therefore not be required to follow the formal approval procedure outlined in this document for each individual project. However, they or their supervisors will still need to liaise with the relevant facility managers at the facility where research is to be undertaken.

4.2.1 Ethics approval for international researchers and foreign students

The PHRC expect international researchers and foreign students planning to conduct research in the Province's health facilities to be affiliated to a South African university or other research institution. Such researchers must also have a local research collaborator or supervisor as well as local ethics approval. Similarly, students will have to acquire local ethics approval and supervisor for their research projects.

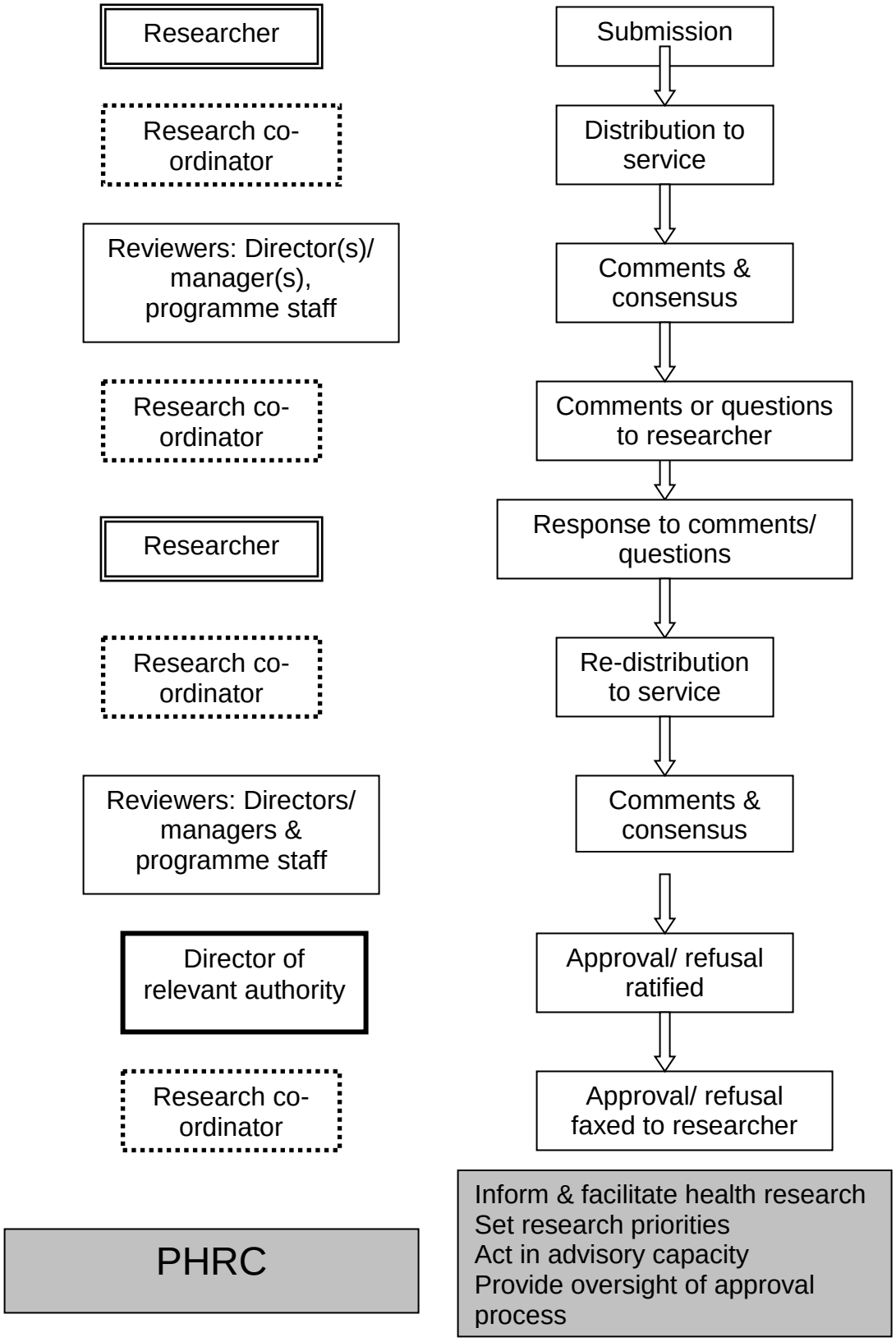
4.3. Appeals Process

A research proposal may be denied approval on one or more of the following grounds:

- Proposed facilities are unable to accommodate the researcher;
- The proposed research will negatively affect or unduly burden health facilities and/or services, without foreseeable benefits to the facility or community at large;
- The existence of other serious and legitimate concerns that have been identified by reviewers, and ratified by the PHRC.

In the event of a research proposal being denied approval, the researcher has the right to lodge an appeal to the PHRC (via the PHRC secretariat). The PHRC will provide independent review of the research proposal and advise the relevant authorities regarding the relevance, appropriateness and feasibility of the proposed research. Open discussion among all parties will be sought to try to find a mutually satisfactory solution.

Flow chart of approval process:



Hears appeals by researchers in case of refusal

4.4 Requirements of Researchers

See **Annexure 4:** Checklist of Required Submission Documents

A. The Proposal

1) Submit proposals in line with the minimum requirements for research proposal shown in annexure 1 and the proposal summary in annexure 2. All questionnaire and data capture tools that will be used in the research must be included in the submission.
2) Researchers must have their research evaluated for appropriateness of the science of their research by their relevant departmental or faculty Research Committee or similar body and provide a letter to this effect.
3) Researchers must obtain ethics approval from a nationally accredited Research Ethics Committee prior to the commencement of the study and provide a copy of the approval; a list of Ethics Committees accredited by the National Department of Health is attached in Annexure 3.
4) Foreign researchers must establish partnerships with local researchers and/or be affiliated to local research institution(s).
5) Researchers from foreign (non-South African) institutions must also provide letters on point 2) and 3) above from their home institutions as well as acquire local ethics approval.

6) Clinical trials must in addition have Medicines Control Council approval and be registered on the National Clinical Trials Register. Researchers must provide proof of both.
7) Researchers must have the appropriate skills and ability to complete the research and must provide a list of qualifications and publications. Students must describe the technical and academic support they will receive from their supervisors.
8) Proposals submitted in other South African official languages (e.g. Afrikaans) must be accompanied by a one page abstract in English.

B. Expected impact on services

1) Researchers must provide a detailed outline of their requirements for space, equipment and staff from the facilities and as well as the support required from the facilities and staff and provide a plan of how these will be managed so that

service delivery is not negatively affected. This information must be presented in Annexure 2.

2) Researchers may be charged for undertaking research in public facilities in line with Financial instruction G50/2002 (copy available from department on request).
3) Researchers must provide a plan of how they will facilitate site preparation of the health services and how and when they will provide feedback to **end users** and disseminate their results to stakeholders.
4) Should logistical arrangements of the research at the facility change from the submitted proposal, researchers are obliged to inform the facility manager and can use the "Monitoring implementation of research" template (Annexure 7).

C. Reporting on research

1) Researchers must submit at least the feedback as stated in the "Minimum requirements for reporting" to the relevant research co-ordinator within a negotiated time period from completion of the study and may be required to present the study to the relevant authority and/or the PHRC. **The relevant authorities reserve the right to deny access to further projects from any researchers and research institutions that do not comply with this requirement**.
2) Published work must include full acknowledgement of all those involved in the project including the relevant government stakeholders. Input may also be acknowledged in the form of co-authorship when substantial contribution has been made in developing the proposal, conducting the research, analysis and/ or report writing).
3) Further or later analyses of the same data, i.e. secondary data analysis, do not require approval as above. However, researchers are requested to send summary proposals covering such analyses to the provincial coordinators for updating of the database of research.

D. Submission logistics

1) The minimum time for the approval of research proposals is 6 to 8 weeks. For larger, multi-site and/or more complex proposals, this may take longer.
2) Acknowledgement of receipt will be provided within five working days.
3) As far as it is possible, research proposals and supporting documents should be submitted electronically.
4) The PHRC will publish information on an annual basis with contact details on

where proposals must be sent. See Annexure 5.

5) Approval should be renewed on an annual basis by submission of Annexure 7 by researchers, which requires the signature of the relevant line managers (in the case of a health facility, these will be the facility and sub-district managers). Subject to the receipt of Annexure 7, the relevant authorities will provide researchers with a letter of ongoing approval.

5. Annexures

ANNEXURE 1

RESEARCH PROPOSAL STRUCTURE

Research Proposal Structure (Minimum Requirements)

The structure of the research proposal will be as follows:

- ☐ Title and authors
- ☐ Introduction/Literature Review
- ☐ Motivation
- ☐ Objectives/ hypotheses
- ☐ Methods (appropriate to methodology, e.g.)
  - ☐ Study Design and Study Population
  - ☐ Sampling and Measurement Tools (including quality assurance)
  - ☐ Exclusion/inclusion criteria
  - ☐ ±Pilot Study
  - ☐ Data Collection and Data Analysis
- ☐ Ethical Consideration and Dissemination of the Findings
- ☐ Budget
- ☐ Time table
- ☐ References
- ☐ Appendices
  - ☐ Consent forms
  - ☐ Data collection tools

ANNEXURE 2

PROPOSAL SUMMARY

Name of Institution/organisation conducting research	
Name of Investigators	
Postal Address	
Telephone Number	
Fax number	
Mobile Number	
Email Address	
Institution which gave ethics approval	
Date of ethics approval	
Date research expected to commence	
Proposed data collection dates at requested facilities	
Date research expected to end	
Western Cape Districts where research will be done: (Please mark with an X)	Metro □ West Coast □ Cape Winelands □ Overberg □ Central Karoo □

	Eden □

Western Cape Department Of Health (WC DOH) Facilities where research will be done: (Please list the name of the facility under appropriate category)	Central Hospitals: Regional Hospitals: District Hospitals: Community Health Centres/Community Day Centres: Clinics:
Other facilities in the WC DOH where research will be done (Please specify)	Psychiatric Hospitals: TB Hospitals: Databases: Other:
Research title	
Research aim	
Research objectives	

Key Words		
Brief description of methodology (Please specify estimated sample size and duration of contact with each participant e.g. interview length, clinical exams)		
Type of Study Design: e.g. Case Control, RCT, Survey		
Budget for research		
Source of funding for the research		
The research will have implications for the requested facilities regarding:	YES or NO	If Yes, what are these implications and how does your project plan to mitigate the impact
1. Additional load on nursing		
2. Support services		
3. Consumables		
4. Laboratory tests		
5. Equipment		
6. Space (office space/counselling cubicle)		

7. Communications		
8. Additional OPD visits		
9. Admission of patients		
How will the sites be prepared to participate in your research?		
Results dissemination plan 1. Other than publications, and reports to peers and funders, who do you think will benefit from getting a summary or presentation of your findings?" Tick	1. Senior Provincial managers ☐ District Directors ☐ Facility manager & staff ☐ Patients ☐ Community ☐ Other (please specify):_____	
2. What is the earliest date or time period from the end of research date collection that the feedback (at least the minimum requirements*) can be expected? * See Annexure 8	2. Within one month ☐ Within one to three months ☐ Within three to six months ☐	

ANNEXURE 3

NATIONALLY ACCREDITED RESEARCH ETHICS COMMITTEES (REC)
*These RECs will consider applications from researchers outside the institution.

REC name	Province	Nearest town	Institution type	Contact name & details	Address
Ekurhuleni Metropolitan Municipality	Gauteng	Alberton	Metropolitan Municipality	Mr. Matthysen Email: brentm@ekurhuleni.com Phone: (011) 861-8856/ 0839827105 Fax: (011) 861- 8835	The Executive Director Ekurhleni Metropolitan Municipality Department of Health(Corporate Office) PO Box 4 Alberton 1450
McCord Research Ethic Committee	KwaZulu-Natal	Durban	Hospital/Research	Chair: Prof E Preston-White Contact person: Dr. Kerry E-mail: kerry@futurenet.co.za Phone: (033) 344 - 3301 Fax: (033) 344-3301	McCord Research Ethic Committee McCord Hospital PO Box 37587 Overport 4067
Medunsa Research Ethics Committee(MREC)	Limpopo	Pretoria	University	Mrs. Mans E-mail: research@medunsa.ac.za Phone: (012) 521- 5671 Fax: (012) 521- 4749	Research Directorate: University of Limpopo(Medunsa Campus) PO Box 163, Medunsa 0204
Human Research	Gauteng	Johannesburg	University	Mr. Burns	University of the

Ethics Committee(Medical)				E-mail: lain.burns@wits.ac.za Phone: (011) 717- 1231 Fax: (011) 717- 1149	Witwatersrand, Johannesburg Private Bag 3 P O Wits 2050
HPCA Research Ethics Committee	Western Cape	Cape Town	Research	Ms. Nicky Bartlett E-mail: nicky@hpca.co.za Phone: (021) 531-0277 ext 217 Fax: (021) 531- 1706	PO Box 38785 Pinelands 7430
REC name	**Province**	**Nearest town**	**Institution type**	**Contact name & details**	**Address**
Polokwane Mankweng Hospital Complex	Limpopo	Polokwane	Hospital/Research	Prof Mashego E-mail: teresam@ul.ac.za Phone: (015) 287- 5000 ext 5330/082 200 5362 Fax: (015) 297- 7554	Private Bag X9537 Polokwane 0700
Research Ethics Committee, UCT	Western Cape	Cape Town	University/Research	Ms. Emjedi E-mail: Lamees.Emjedi@uct.ac.za Phone: (021) 406- 6338 Fax: (021) 406- 6411	E 52 Room 23 Old Main Building Groote Schuur Hospital Observatory 7925
Pharma-Ethics Research Ethics Committee(Pty)Ltd	Gauteng	Pretoria	Research	Mrs. Haskins E-mail: marzelle@pharma-ethics.co.za Phone: (012) 664 - 8690 Fax: (012) 664 - 7860	Pharma-Ethics (Pty) Ltd. P.O. Box 786 Irene 0062
Biomedical	KwaZulu-	Durban	University	Mrs. Anusaha Marimuthu	The Chair

Research Ethics Committee	Natal			E-mail: marimuthu@ukzn.ac.za Phone: (031) 260 – 4769 Fax: (031) 260- 4609	Biomedical Research Ethics Committee UKZN Private Bag X54001 Durban 4000
Committee for Human Research - Health Research Ethics Committee 2	Western Cape	Bellville	University	Chair- Dr Malcolm De Roubaix Dr. Horn E-mail: lhorn@sun.ac.za Phone: (021) 938- 9075 Fax: (021) 931- 3352	Research Development and Support Division P O Box 19063 Tygerberg 7505
REC name	**Province**	**Nearest town**	**Institution type**	**Contact name & details**	**Address**
Ethics Committee of the Faculty of Health Sciences, UFS	Free State	Bloemfontein	University	Ms. Strauss E-mail: gndkhs.md@mail.uovs.ac.za Phone: (051) 405- 2812 Fax: (051) 444-4359	The Chairperson Ethics Committee of the Faculty of Health Sciences Deans's Division, Block D, Room 115, Francois Retief BLD, Nelson Mandela Road, P O Box 339, International Post Box G40, Bloemfontein 9300
Health Research Ethics Committee 1	Western Cape	Bellville	University	Chair - Prof Soraya Seedat Dr. Horn E-mail: lhorn@sun.ac.za Phone: (021) 938- 9075	Research Development and Support Division P.O. Box 19063 Tygerberg

				Fax: (021) 931- 3352	7505
SA National Blood Service Medical and Research Ethics Committee	Gauteng	Johannesburg	Research	Dr. Gwangwa E-mail: Nancy.Gwangwa@sanbs.org.za Phone: (013) 243- 6772 Fax: 086 6467171	Private Bag X14 Weltevreden Park 1715/1 Constantia Kloof 1715
Health and Wellness Sciences Research Ethics Committee, CPUT	Western Cape	Bellville	University	Chair: Prof Penelope Engel-hills E-mail: engelhillsp@cput.ac.za Phone: (021) 442 6162 / (021) 959- 6352 Fax: (021) 959- 6096	Cape Peninsula University of Technology P O Box 1906 Bellville 7535
HSRC Research Ethics Committee	Gauteng	Pretoria	Research	Chair: Prof Wassenaar Contact Person: Mrs. Botha E-mail: jebotha@hsrc.ac.za Phone: (012) 302- 2006 Fax: (012) 302-2005	HSRC Research Ethics Committee Private Bag X41 Pretoria 0001
REC name	**Province**	**Nearest town**	**Institution type**	**Contact name & details**	**Address**
South African Medical Association Research Ethics Committee(SAMAREC)	Gauteng	Pretoria	Research	Ms. Behrtel E-mail: ulindib@samedical.org Phone: (012) 481- 2044 Fax: (012) 481- 2098	P O Box 74789 Lynnwood Ridge 0040
Durban University of Technology	KwaZulu-Natal	Durban	University	Chair: Prof J K Adam Contact Person: Mr. Singh	P O Box 1334 Durban

Faculty of Health Sciences Research Committee				E-mail: Vikeshs@dut.ac.za Phone: (031) 373 -2701 Fax: (031) 373- 2407	4000
University of Pretoria Faculty of Health Sciences Research Ethics Committee	Gauteng	Pretoria	University	Deputy Chair : Dr. Sommers E-mail: rsommers@med.up.ac.za/ manda@med.up.ac.za Phone: (012) 354 - 1330 Fax: (012) 354 - 1367	Private Bag X169 Pretoria South Africa 0001
1 Military Hospital Research Ethics Committee	Gauteng	Centurion/ Pretoria	Hospital	Prof. Baker E-mail: malcolmkb@worldonline.co.za Phone: (012) 314- 0487 Fax: (012) 314- 0489	C/O Department of Neurology Private Bag X 1026 Thaba Tshwane 0143
Walter Sisulu University Health Research Ethics& Biosafety Committee	Eastern Cape	Mthatha	University	Prof. George E-mail: ggeorge.grace@gmail.com/ ggeorge@wsu.ac.za Phone: (047) 502- 2425 Fax: (047) 502- 2425	NMD Campus Walter Sisulu University PMB X1 UNITRA Mthatha, 5117
Tshwane University of Technology(TUT) TUT Research Ethics Committee	Gauteng	Pretoria	University	Dr. K Dyason E-mail: DyasonK@tut.ac.za Phone: (012) 382-4223 Fax: (012) 382-4223	Directorate: Research, Innovation and Partnership, Private Bag X680, Pretoria, 0001
Medical Research Council (MRC) Ethics Committee	Western Cape	Cape Town	Research Institution	Ms. Adri Labuschagne e-mail: adri.labuschange@mrc.ac.za Phone: (021) 938-0341	Medical Research Council P.O.Box 19070 Tygerberg 7505

				Fax: (021) 938-0201	
Rand Afrikaans Universiteit (RAU) OR Univerity of Johannesburg (UJ)	Gauteng	Johannesburg	University	Dr Readmilla Razlog e-mail :readmillar@uj.ac.za or andres@uj.ac.za Phone : (011) 559 6233 Fax : (011) 559 6227	P.O. Box 524, Auckland Park Johannesburg, Postal Code 2006 South Africa
University of South Africa (UNISA)	Gauteng	Pretoria	University	Prof. L. Roets e-mail : roetsl@unisa.ac.za Phone : (012) 429 2226 Fax : (012) 429 6688 Dr Moleki (queries) Ph : (012) 429 6369	P O Box 392 UNISA 0003

**If your Ethics institution is not on this list and you show proof of that it has applied for National Accreditation – it will be accepted

ANNEXURE 4

CHECK LIST OF REQUIRED SUBMISSION DOCUMENTS

	YES	NO	Not Applicable
Research Proposal			
CV Principal Investigator			
Annexure 2			
REC approval[1]			
Proof of scientific quality review			
Proof of collaboration with local research institutions[2]			
MCC approval*			
Proof of Registration with National Clinical Trials Register*			

[1] Issued by a local accredited Research Ethics Committee (see Annexure 3)
[2] Strongly recommended for foreign researchers
* Only required for drug trials

ANNEXURE 5

CONTACT DETAILS

Research Co-ordinators

5 Independent administrative authorities for research approval; submit required documents to the contact person of every authority which pertains to your research:

City Health:	**Groote Schuur Hospital:**	**Red Cross Children's Hospital:**	**Tygerberg & Tygerberg Children's Hospitals:**	**Other PGWC**
Contact Dr Helene Visser Helene.visser@capetown.gov.za Tel: +27 21 400 3981	Contact Dr Bhavna Patel Bhavna.Patel@pgwc.gov.za Tel: +27 21 404 4469	Contact Dr Thomas Blake Thomas.Blake@pgwc.gov.za Tel: +27 21 685 5788	Contact Ms Lynne Bindeman Lynne.Bindeman@ pgwc.gov.za Tel: +27 21 938 5752	(All other health facilities/services where the service site authority is the PGWC, except Central Hospitals): Contact Administrator: Health.Research@westerncape.gov.za Tel: +27 21 483-

ANNEXURE 6

FACILITY LIST

List of City Health Facilities: available from: URL: http://www.capetown.gov.za/health

List of Provincial Health Facilities: available from:
URL: http://www.capegateway.gov.za/eng/directories#facilities

List of dual authority facilities in the City of Cape Town district:

Eastern & Khayelitsha	**Klipfontein & Mitchell's Plain**	**Northern & Tygerberg**	**Southern & Western**
Macassar	Crossroads	Durbanville	Albow Gardens
	Heideveld	Scottsdene	
	Nyanga	Kasselsvlei	
		Bishop Lavis	
		Ravensmead	
		Scottsdene	
		Parow	
		Dirkie Uys	

Note: in the other districts, excluding the City of Cape Town district, all public health facilities are managed by the Provincial Department of Health.

DOCUMENT TITLE: ANNUAL PROGRESS REPORT

Proposal Reference number	
Proposal Title	
If there have been any changes to the contact details of principal investigator, please update: Name&Surname: - Postal address - Telephone number - Fax number - Mobile number - Email address	
Please answer the following questions based on your assessment of the progress you are making with your project	
1) Is the project going to be completed on the **date** originally set on proposal? **Yes** or **No** (tick appropriate)	
2) If it is delayed, what is the new completion date?	dd/mm/yyyy:
3) Is additional approval necessary? **Yes** or **No** (tick appropriate)	
4) Are there problems which the Health Services should be aware of with regard to completion of the project? **Yes** or **No** (tick appropriate) If yes, explain: ……	
5) Has there been any Ethics approval or renewal since submitting this proposal? Yes or No (tick appropriate) If yes, state date of Ethics renewal? dd/mm/yyyy:	
Ethical considerations (summary of key issues as reported to Research Ethics Committee.)	
Preliminary findings (if applicable)	

Additional approval necessary (For office use only): Yes or No (tick)

ANNEXURE 8

DOCUMENT TITLE: FINAL REPORT

This report should be submitted no later than 6 months after the project end date. It should be sent to…….

Proposal Title			
Proposal Ref. No			
Name of principal investigator			
Institution			
Researcher contact details (Postal address, e-mail, telephone, fax, cell numbers)			
Project start date		Project end date	
Date of report			

Please use a structured narrative, i.e. full sentence format under the headings below. Limit the report to 1000 words. If a report or article is already available, please attach this as well in electronic format.

Project process

Achievements and difficulties of the project , including those of particular relevance to the health services platform where the research was conducted.

Main findings

Main findings of the research, including null and indeterminate findings.

Implications of the findings for:

(a) Understanding the burden and determinants of disease and injury;
(b) Health service delivery or management and/or clinical practice;
(c) Health policy (including law);
(d) Future research.

Dissemination plan

Proposed means of publishing and disseminating the findings and recommendations.

Who within the services should receive this report (if applicable)?

1)
2)
3)
Etc.

ANNEXURE 9

CURRENT WESTERN CAPE PHRC MEMBERS May 2012/13:

Prof. Rodney Ehrlich (Chairperson)	**University of Cape Town (UCT)**: School of Public Health and Family Medicine
Dr Stephanus Fourie (Acting deputy-chairperson)	**Provincial Department of Health:** Director: Specialised Support Services.
Prof Nulda Beyers	**University of Stellenbosch (SUN**): Director, Desmond Tutu TB Centre
Prof Debbie Bradshaw	**South Africa Medical Research Council** (**MRC**): Director, Burden of Disease Unit
Prof Johan Esterhuyse	**Cape Peninsula University of Technology (CPUT)**: Head, Biomedical Sciences
Ms Demaris Fritz	**South African National NGO Coalition (SANGOCO)**: Western Cape Programme Manager
Associate Prof. Debra Jackson	**University of Western Cape (UWC)**: School of Public Health
Dr Tracey Naledi	Provincial Department of Health: Director, Health Impact Assessment (**HIA**)
Ms Surina Neethling	**Provincial Department of Health**, **Cape Winelands District**, Deputy Director:Professional Support Services
Prof. Thomas Rehle	**Human Sciences Research Council (HSRC)**: Director and Senior Advisor, Social Aspects of HIV/AIDS (**SAHA**)
Prof Mark Tomlinson	**University of Stellenbosch (SUN):** Department of Psychology
Ms Yolande Valentyn	**MFESANE Non Profit Organization (NPO),** Rural Community representative
Dr Hélène Visser	**City of Cape Town Health**: Manager: Specialised Health

SECRETARIAT:

Dr SG. Petros	Health Impact Assessment (**HIA**) Deputy Director Research	Health Impact Assessment DoH
Ms C. Roderick	Health Impact Assessment (**HIA**) Assistant Director Research	Health Impact Assessment DoH
Prof L. London	School of Public Health (**UCT**) Public Health Specialist	University of Cape Town (UCT)
Dr B. Willems	Medical Registrar (SU)	Stellenbosch University

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