health

Department of
Health
FREE STATE PROVINCE

POLICY

CONDUCTING RESEARCH IN PUBLIC HEALTH INSTITUTIONS: GUIDELINES FOR APPROVAL OF HEALTH RESEARCH IN THE FREE-STATE DEPARTMENT OF HEALTH

JUNE 2015

Protocol Review Committee

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Abbreviations

FSDoH: Free State Department of Health

FSPHRC: Free State Provincial Health Research Committee

PRC: Protocol Review Committee

HOD: Head of Department

1. Background

There is a lack of proper coordination and prioritization of research to maximally benefit health sector development and achieve the desired impact on the quality of life for the Free State community and South Africa at large. The Head of Department (HOD) of health is the only authority that can approve research to be conducted in the Free State Health institutions. To enable the HOD's informed decision a Protocol Review Committee was established.

1.1 Goals

The goals of this policy are:

To inform the research community on the processes to be followed if they would like to conduct research in the Free State health institutions.

To review the feasibility of the ethically approval research proposals, considering the impact of such research proposals on the Free State Department of Health (FSDoH) in terms of financial, human resources and service delivery.

To provide approval of such research requests based on compliance with research prescripts.

1.2 Free State Provincial Health Research Committee

The National Health Research Policy in South Africa (2001) recommends that the Provincial Health Research Committee is an important system for the coordination of health research and facilitation of efficient utilization of limited research resources. Accordingly, the FSDoH has established a multi-sectorial Free State Provincial Health Research Committee (FSPHRC).

A sub-committee known as a Protocol Review Committee was established for the purpose of reviewing the protocols and recommend approval of research protocols to the HOD of FSDoH.

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 the Free State community and South Africa at large;

3) To ensure that services are not overburdened by research;

4) To ensure that all research has undergone relevant scientific and ethics review;

5) To ensure that the findings of studies conducted in the province are made available to local and provincial government officials;

6) 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

All research to be conducted at public health institutions in the Free State Province needs to be approved by the FSDoH and includes but is not limited to the following types of research:

- All research at public sector facilities including research to be conducted at tertiary and 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 of public sector facilities;

- Clinical trial research that is conducted at public sector facilities and/or requires the recruitment of patients as stipulated in the previous bullet

- Health systems research
- Records review and Case records, Secondary health data analysis, etc

4. Approval of Research Proposals/Protocols

The authority of approval of research conducted in the public health institutions is vested in the Head of the Department of Health (HOD). The Protocol review committee advises the HOD regarding compliance of submitted protocols with standard requirements for approval. It is the responsibility of the researcher to provide the committee with all the required documents. In addition the documents requested in 4.1 need to be submitted if applicable. Protocols need to be submitted online via the NHRD (http://nhrd.hst.org.za) website.

4.1 Insurance, Indemnity and Commercialization

The following will apply to applications for clinical trials of new drugs:

1. Proof of insurance cover indemnifying the Free State Department of Health against any potential medical legal liability or any loss or damage arising out of clinical trials. Documentary proof indicating terms of the insurance must be submitted together with the protocol.

2. Proof of insurance covering any loss or damage suffered by persons used in the experiment.

3. Proposal on the spread of profit in case of commercialization to be indicated in the agreement. The applicant must indicate how profit will be spread between parties inclusive of the Free State Department of Health. [This part is not applicable to employees on Joint Staff establishment as the matter is covered in the Memorandum of Agreement between the University of the Free State and Free State Department of Health].

4. Medicine control council (MCC) approval and any other approvals for the study and contracts are needed.

5. Review Criteria and Approval Process

On receiving a research proposal/protocol the committee has to ensure the necessary research processes and the correct documentation has been submitted. The protocol submitted with insufficient documents will be referred back to the researcher without being distributed for review.

The secretariat will submit the proposal to two relevant nominated review committee members.

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, funds, etc?

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, South Africa, the international community and provide outputs that could be implemented as such?

4. Financial implications to the FSDOH

5. Any other condition deemed necessary depending on the nature of the research.

Contact details

The secretariat at is the primary contact for researchers at sebeelats@fshealth.gov.za

Tel 051 408 1646/1240.

Only research that has received ethics approval from a South African accredited research Ethics Committee will be considered

Any queries or comments raised by reviewers will be forwarded to the researcher via the NHRD, for a response. Once the reviewers' comments have been satisfactorily addressed then recommendation for approval will be made. The protocol review committee will receive all approved, non-approved and pending proposals monthly. As part of the approval process, researchers may be requested to deliver a succinct presentation of the research proposal to the review team to address the concerns raised.

Researchers may only proceed with research once the approval letter has been received from the approving authority in this case the FSDoH.

This applies to pilot studies as well, which are regarded as part of the formal study. The **researcher** notifies the CEO/ facility managers of the approval and they both operationalize the research at the institution. **No** additional approval will be required.

5.1. Students Protocols

The protocol review committee recognizes that a substantial proportion of research in the public health institutions in the province is conducted by students and for this reason protocols will be reviewed timeously. Students must have their research evaluated by the Ethics committee as their protocols still need to be accompanied by an approval letter from a nationally accredited Ethics committee. Students must describe the technical and academic support they will receive from their supervisors. All protocols submitted to the FSDoH protocol review committee should be in **English**.

5.2. Research approval NOT recommended

A research proposal may not be recommended for approval on one or more of the following grounds:

- The researcher has not demonstrated that there is sufficient funding to conduct the study;
- The research will pose a burden on the human and financial resources at the public institution/s;
- The facilities selected for the proposed research are overburdened by concurrent research;
- The existence of other serious and legitimate concerns that have been identified by reviewers.
- Prospective research is a duplication of similar studies
- Any other reason that may arise depending on the nature of the study

Such researches will be recommended for approval when all the PRC proposed amendments are addressed.

5.3. Appeal process

In the event of a research proposal being returned back to the researcher and not recommended foe approval, the researcher has the right to lodge an appeal to the FSPHRC **(via the FSPHRC secretariat** at sebeelats@fshealth.gov.za or Tel 051 408 1646/1240). The FSPHRC will provide independent review of the research proposal and advise the relevant authorities regarding the relevance, appropriateness and feasibility and compliance of the proposed research. Open and honest discussion among all relevant stakeholders is considered necessary in such instances.

5.4. Requirements of Researchers

Annexure A is the Meeting dates and Annexure B is the Checklist of Minimum Required Documents. Please submit all the other necessary documents depending on the nature of your study e.g

approvals from other bodies you may have. The documents requested in 4.1 needs to be submitted as well if applicable.

5.4.1 The Standard Operating Procedures

1) Submit proposals in line with the requirements for research proposal shown in Annexure C and the proposal summay. All tools (including standardized tools) that will be used in the research must be included in the submission.

2) Researchers must obtain Ethics approval from a nationally accredited Research Ethics Committee prior to the submission of the study to the FSDoH and provide a copy of the approval; a list of Ethics Committees accredited by the National Department will be available on request.

3) Researchers from foreign (non-South African) institutions must also provide letters of approval from their home institutions, ethical approval from their home institution as well as acquire mandatory local Ethics Approval.

4) Foreign researchers are strongly encouraged to establish partnerships with local researchers.

5) 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.

6) Researchers must have the appropriate skills and ability to complete the research and must provide documentation to that effect.

7) The FSDoH should be part of the agreements pertaining to contractual clinical trial research.

8) All clinical trials/research should have insurance that indemnifies the FSDoH as stipulated in 4.1.

9) All protocols submitted to the FSDoH protocol review committee should be in **English**.

5.4.2 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 as this will allow the Committee to facilitate this required support.

2) 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.

3) Should logistical arrangements of the research at the facility change from those specified in the submitted proposal, researchers should inform the facility manager and the Review committee and Ethics Committee. Generally, researchers should inform facility managers/ Review Committee annually and briefly of the progress of his or her study.

4) Researchers are encouraged to present their research findings at the Provincial health research day organized in October- November of each year.

5.4.3 FSPHRC Committee

The FSPHRC committee provides an oversight role to the Protocol Review committee. The distribution of all the protocols reviewed, successes and challenges will be discussed in the FSPHRC committee quarterly meetings.

6. Research Funding

- Researchers may be charged for undertaking research in public facilities in line with the agreed and fair contribution of the public facility.
- Researchers may not personally benefit financially from clinical trials; funds generated must be paid into a research account of the concerned unit/department to support further research in the unit/department of the researcher.
- The FSDOH should be recognized in any research contractual negotiations
- The FSDOH will make some Research Funds available to support research in the province
  The funds are however limited and would need to be applied for. There is no guarantee that such funds will be available to every applicant. Priority will be given to research that meets immediate/priority needs of the FSDOH. Researchers are still encouraged to apply for alternative funding even in such immediate/priority cases.

7. Reporting on research

1) Researchers must as a minimum provide annual progress report and feedback final report at completion to the FSDoH secretariat within a negotiated time frame from completion of the study. The relevant FSDoH authorities reserve the right to deny further projects from any researchers and research institutions that do not comply with this requirement.

2) Researchers may be required to present the outcome of the study to the relevant FSDoH authority and/or the FSPHRC.

3) Published work must include full acknowledgement of all those involved and relevant government stakeholders.

4) Input may also be acknowledged in the form of co-authorship as determined before the start of the research project when substantial contribution has been made in developing the proposal, analysis and/ or report writing.

5) Researchers are requested to send summary proposals for any secondary data analysis projects covering such an analysis to the protocol review committee for approval and updating of the database of research.

8. Policy Review

The Free State Research Policy will be reviewed every second Year in an effort to make any amendments depending on the changes in the research community

Approved by:

Dr D Motau

HOD: Health

Free State Health

Date: 15/07/2015

ANNEXURE A

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FROM: Protocol Review Committee Members Department of Health

P.O.Box 227

BLOEMFONTEIN

9300

To: THE RESEARCHERS

SCHEDULED MEETINGS: PROTOCOL REVIEW COMMITTEE FREE STATE DEPARTEMNT OF HEALTH DURING 2015

Kindly note protocols can be uploaded at any time and will be processed as soon as possible. Only protocols that require committee discussion will stand over to a meeting date of the Free State of Health Department. Meetings will normally be held on Fridays.

MEETING DATES
27 March 2015
24 April 2015
29 May 2015
26 Jun 2015
31 Jul 2015
28 Aug 2015
25 Sep 2015
30 Oct 2015
27 November 2015
18 December 2015

ANNEXURE B

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TICK SHEET FOR RESEARCH TO BE APPROVED BY FSHOD (MINIMUM REQUIREMENTS FROM RESEARCHER)

Numbers of documents submitted	Requirements	Available Yes	Not available No
1.	Typed letter to request approval from HOD		
2.	Summary of the research		
3.	Letter of approval from ethics committee (University) or any accredited ethics committee		
4.	Full Protocol of the study		
5.	Questionnaire or data collection tool		
6.	Consent form for voluntary participation		
7.	Information sheet containing the information to be provided to the clients (If applicable)		
8.	Any other relevant documents including the organisation funding the project if any		
9	MCC Approval where applicable		
10	Any other documents depending on the nature of the study		
Please include the following information in your protocol			
1. The effect of your study on service delivery			
2. The approximate time spend with health care worker/patient who is participating in your study			
3. The source of funding for your study. If the CEO of an institution has agreed to fund your study a confirmation letter from the CEO will be required			
4. All the information indicated in **5.4.2 section** of the policy			

The Documents should be loaded at: http://nhrd.hst.org.za . Communicate to Mr Tumelo Sebeela for assistance at sebeelats@fshealth.gov.za. Tel 051 408 1646/1240. 3rd Floor A-B East, Bophelo House, if you need any assistance

ANNEXURE C

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Guidelines for research proposals

Research protocols must comply with the following framework:

- Title and authors: the title must be clear. All researchers involved in the research together with their qualifications and institutional affiliations must be indicated. The corresponding researcher's details must be provided.
- Summary or abstract of proposal: A concise summary of the research proposal
- Literature review or background: This section must clearly describe the current literature relevant to the research.
- Aims and objectives of the proposal: The specific aims and objectives of the research must be clearly defined.
- Motivation for proposing the research: The motivation for wanting to conduct the research must be clearly stated and must explain the benefit of doing the research.
- Methods:
- The study design: The type of study must be described. Is it qualitative or quantitative? Is it descriptive or analytical?
- The study setting: The proposed site for the research as to be described in detail. The name of the facility and its location must be clearly stated.
- The study population: The gender, age and demographics must be specified. If this is a vulnerable population this must be stated and it must be explained how they will be protected.
- The inclusion and exclusion criteria: The specific inclusion and exclusion criteria and the rationale for deciding on it needs to be clarified.
- The sampling framework: The technique for sampling must be described and the sampling size stated. In the case of qualitative research the rationale for selecting participants must be explained. If no sampling is done this must be stated and the reasons stated.
- The data collection and management: The process of data collection must be described. The data collection tools must be included. The management of the data describing confidentiality and safe keeping of the data has to be explained.
- The data analysis: A concise explanation of how the data will be analysed must be provided.
- The pilot study: If a pilot study will be done it must be described.
- Ethical Considerations: The researcher has to explain ethical considerations and how these will be address. If informed consent or assent from minors are required then the consent form has to be included. The ethics clearance certificate must be included or it should be demonstrated that the proposal has been submitted to an appropriate ethics committee and the outcome is pending. All proposed research must comply with standard ethical considerations.
- The budget for the research: The researcher has to give a substantive budget indicating the cost for the project. The researcher must indicate funding that has been secured for the project. If funding still in the process of being secured then this must be indicated. The purpose of this section is to demonstrate to the committee that the research is feasible and can be completed. The Free State Department of Health has no funding available for research.
- The timeframe for the research: Realistic timeframes must be included. The timeframe should also include the dissemination of findings.
- The framework for dissemination of data: A clear strategy of how findings will be disseminated and to who the information will be distributed must be described. The funding for the dissemination of the findings must be indicated.
- References and appendices: The references must be clearly and properly indicated. Relevant and up to date information must be used. All appendices such as informed consent, ethics clearance certificates and other supporting documents has to attached.