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STANDARD OPERATING PROCEDURE (SOP)

1. INTRODUCTION

The KwaZulu-Natal (KZN) Department of Health (DoH) seeks to promote the provision of access to prospective researchers to conduct research relevant to the Department at its institutions. Institutions within the KwaZulu-Natal Department of Health include the Head Office, Health Programmes, District Offices, Hospitals, CHCs and PHCs.

2. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to set out in systematic detail the process of obtaining permission from institutions for purposes of conducting research. This SOP seeks to ensure that the process for obtaining approval from the Provincial Health Research & Ethics Committee (PHREC) is streamlined and there are no unnecessary bottlenecks in the process. PHREC currently has a turn-around time of approximately three weeks to approve a research proposal once it has been supported by an Institutional manager. However, the process of obtaining approval to conduct research has been hampered by the slow or non-response from Institutional Management as well as a lack of understanding of the approval process. This has cast a poor reflection on the Department. The SOP also sets out procedures and considerations that should be taken into account and adhered to when reviewing proposals for purpose of obtaining permissions from institutions.

3. SCOPE

This SOP covers the operational processes and procedures that Institutional Management is expected to adhere to when reviewing and engaging in decision-making about the permissibility of research to be conducted at the relevant Institution. The SOP also informs Managers on the requirements for obtaining approval to conduct research within the KwaZulu-Natal Department of Health by the Provincial Health Research & Ethics Committee (PHREC) since it is mandatory for researchers to obtain “support” from management to conduct their study.

4. LEGISLATIVE BACKGROUND

The South African National Health Research Policy (2001) promotes the practice and conduct of research since it contributes towards the improvement of the health and welfare of the South African population. Subsequently, the National Health Act (Act No. 61 of 2003) established statutory bodies called Provincial Health Research Committees to coordinate and regulate research. PHREC was established in terms of the KwaZulu-Natal Health Act (2009) and its Regulations. The Secretariat of PHREC, the Health Research & Knowledge Management (HRKM) sub component reviews research protocols to ensure that all research falling within its jurisdiction is carried out to high scientific standards and meets ethical considerations. HRKM will recommend approval for those proposals and protocols that meet these standards.

5. OUTLINE OF THE RESEARCH APPLICATION PROCESS TO PHREC

1. The Researcher/ Principal Investigator (PI) obtains ethics approval (either provisional or full) for the study from an ethics committee that is registered with the National Health Research Ethics Council (NHREC).
2. Researchers approach the manager of the facility or health district or health programme (depending on how many facilities or districts are involved (please see below section 7) that will be part of their study to obtain a letter of support.
3. The researcher then registers their application online via the National Health Research Database (NHRD) webpage: <http://nhrd.hst.org.za> in order to obtain the approval of the PHREC.

Documents to be uploaded on the NHRD as part of the application include:

- Research proposal (including information sheet, informed consent form and questionnaires),
 - Ethical clearance letter (full/provisional) and
 - Letter(s) of support from DoH managers.
4. Clinical Trial studies require the following additional documents:
 - The South African Health Products Regulatory Authority (SAPHRA) (full/provisional) approval,
 - DoH Clinical Trial Application form and checklist,
 - Insurance certificate and
 - Dispensing license.

6. LETTER(S) OF SUPPORT FROM INSTITUTIONAL MANAGERS

Researchers/PI will have to **FIRST** approach institutions and obtain a letter of support from the Institutional Manager BEFORE submitting their research proposal and the necessary documentation to HRKM on the NHRD.

If the research will be conducted at three or fewer facilities, individual facility support is required.

If the study will be conducted at four or more facilities in a particular District, the Researcher will require a letter of support from the relevant District Manager. Individual facility support will not be required. It is the responsibility of District Management to inform the individual facilities of the impending study that will be taking place at their institution.

If the study will be conducted at four or more Districts, approval from the relevant Programme Manager within the KZN Department of Health is required. Individual district support is not required. It is the responsibility of Programme Managers to inform District Management of impending studies that will be taking place at their institution.

Usually the researcher will approach District or Facility Management once the researcher has finalized their proposal and their study has obtained ethical clearance (full/provisional) from a

recognized ethics committee in South Africa. Hence a repeat of the ethical review is not required at the District or Facility level. Some researchers may engage with Institutions during the proposal development phase to ensure that their proposal has buy in and is relevant to the institution.

Ideally, researchers should provide the Facility and/or District Managers with a synopsis of their proposed research, highlighting the research activities that will take place at the facility or district (please refer to the attached appendix for a sample of the template). When considering the request to conduct research, Institutional managers should take into account the following:

- Required documentation (Section 6.3).
- Aims and Objectives of the Study
- Planned Period of the study (Start and End Date)
- Planned Visit Dates to Institution (Start Date and End Date)
- Study Design - Observational Study, Experimental (eg. Clinical Trial/Intervention)
- Who will be the study participants? either patients/health care workers/managers
- Details of Participants e.g. Ante Natal Care clients presenting for the first time/ Theatre Nurses etc.
- Planned Sample Size - Number of participants that will be recruited from the relevant institution and it's relevant Departments
- Data Collection Tool (s) Eg. Interviews, questionnaires, focus group discussions, drawing of blood samples, laboratory testing etc
- Ethical Clearance - Yes/ No/ Provisional
- Valid time period for ethical clearance (check that it hasn't expired)
- Potential Benefits and Relevance of the Study to the Institution
- Are similar studies being conducted at the institution?
- Are the same patients being targeted for recruitment repeatedly?
- If it is a clinical trial, please refer to Section 6.4. Particular attention should be drawn to Sections B, C & D of the DoH Clinical Trial Application Form.
- Researcher's plan to report back study findings.
- Will there be additional load for nursing/institutional staff? Eg. asking nurses to recruit patients or interpret for researchers?
- Would the study disrupt services?
- Would researchers require the following from the Institution?
 - Facility support services. Eg. Administrative staff such as clerks/receptionist
 - Facility consumables Eg. Swabs, gloves etc
 - Facility equipment be used Eg. BP machine, ECG etc
 - Facility laboratory testing services
 - Facility space Eg. Office space/Counselling cubicles

It is the discretion of management to critically assess whether the above will have any financial impacts on the institution and whether management is willing to bear the costs thereof.

The letter of support from the institution acknowledges that the researcher has approached the institution and has made the institution aware of their study and its requirements. District or Facility Management should ensure that the research is feasible, relevant and beneficial to the District or Facility population and that the research can be accommodated in the institution. Management should also ensure that the proposed study will not hamper the delivery of services. Please note the template of a support letter is attached as an appendix for your information.

The Chairperson of PHREC will NOT provide final approval to the researcher if the letter of support by the institutional manager is not submitted by the researcher. It is greatly appreciated that due regard be given to the above process when Institutions are approached by the researcher to ensure efficient and timeous approval of research at the Department.

Institutions should take cognizance of students requesting to conduct research necessary for their training and ensure that requests are processed quickly and smoothly and avoid any unnecessary delays since students normally have a very short period to complete their research.

7. RECOMMENDATIONS:

It is highly recommended that the management team and administration within management is made aware of these SOPs.

It would be beneficial if administration staff members are assigned the task of receiving research requests and ensure that the researcher has submitted the relevant documents required by the institution. Administration staff should be the communication link between researchers and management as well as between researchers and the prospective Department at which the research will be conducted. If there are any queries regarding the research, administration should request a presentation/meeting with the researcher.

If the manager of the institution is unavailable, provision should be made for the next responsible manager to be delegated the task of providing “support” for the researcher.

Each institution should keep their own repository of the research that is being conducted at their institution (see attached appendix for template). This should include an in house reference number (e.g. KEHdd-mm-year), PI's Name, PI's Organisation, title of the study, classification (Disease specific and operational, e.g. TB, HIV/AIDS, Health Systems etc), date of commencement, date of termination, PHREC reference number (once the study receives full gatekeeper approval), whether it is a clinical trial, which Departments within the institution the study will take place and whether a report was submitted or not. This can be captured in Microsoft Excel.

Institutions should also advertise their procedure and requirements for obtaining support for conducting research at their institution and contact details of administration staff responsible for processing applications on their hospital web pages and through the PRO of the institution.

If there are any queries regarding the process of applying for permission to conduct research within health institutions within the KwaZulu-Natal Department of Health, the following may be

contacted:

- Chairperson of PHREC: Dr Elizabeth Lutge 033 395 2046
Elizabeth.lutge@kznhealth.gov.za
- HRKM: Gugu/Xolani/Rizwana 033 395 3189/2805/3189
hrkm@kznhealth.gov.za

8. ACKNOWLEDGEMENT

The Health Research & Knowledge Management (HRKM) Sub-Component wishes to express its sincerest gratitude to the Department's Data Management and GIS Services that provided guidance for developing these SOPs. Reference is also made to the Research Circulars previously drafted (2009, 2011 and 2018).

Data Management and GIS Services. 2013. Standard Operating Procedure: Collection and Verification of data at Hospital level. KwaZulu-Natal Department of Health, Pietermaritzburg.

9. APPENDIX A: RESEARCH PROTOCOL SYNOPSIS TEMPLATE

Study Institution/District	<i>Institution Researcher wishes to conduct the study at: eg Northdale Hospital</i>		
Name of Researcher			
Researcher's Organisation			
Researcher's Contact Number	Office		Cell
Researcher's E-mail			
Study Title			
Purpose of Study	<i>Clinical Trial/Academic Study/Operational Study</i>		
Aim of Study			
Objectives of Study			
Planned Study Period	Start Date		Completion Date
Planned Visit Dates to Institution	Start Date		Completion Date
Study Design			
Study Participants	Patients	<input type="radio"/> Yes <input type="radio"/> No Number: _____	Health Care Workers
			<input type="radio"/> Yes <input type="radio"/> No Number: _____
Details of Participants	<i>e.g. Ante Natal Care clients presenting for the first time/ Theatre Nurses etc.</i>		
Planned Sample Size	<i>No of participants that will recruited from the relevant institution</i>		
Data Collection Tool (s)	<i>Eg. Researcher administered questionnaires</i>		
Ethical Clearance	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Provisional		
Ethics Valid Till			
		Yes/No	SPECIFY
Will there be additional load for nursing? Eg. asking nurses to recruit patients			
Would you be using facility support services? Eg. Administrative staff such as clerks/receptionist etc			

<p>Would you be using facility consumables? Eg. Swabs, gloves etc</p>		
<p>Would you be using facility equipment? Eg. BP machine, ECG etc</p>		
<p>Would you be using facility laboratory testing services?</p>		
<p>Would you be using facility space? Eg. Office space/Counselling cubicles</p>		
<p>Potential Benefits and Relevance of the Study to the Institution</p>		
<p>Proposed Dissemination Plan of Study Findings To Institution</p>	<p> <input type="radio"/> Presentation to management & staff <input type="radio"/> Electronic copy of report <input type="radio"/> Hard copy of report <input type="radio"/> Copy of publication <input type="radio"/> Other: _____ </p>	
<p>Comments</p>		

10. APPENDIX B: TEMPLATE FOR REPOSITORY

REFERENCE NO	DATE SUBMITTED	STUDY TITLE	PRINCIPAL INVESTIGATOR (PI)	PI CONTACT NUMBER	PI EMAIL	PI ORGANIZATION	PURPOSE OF STUDY	ETHICS REFERENCE NUMBER	DEPARTMENTS ACCESSED FOR STUDY	STUDY PARTICIPANTS	STUDY COMMENCEMENT	STUDY COMPLETION DATE	STUDY SUPPORTED
KEH-01-01-2018	23-01-2018						<i>Academic Operational Clinical Trial</i>		MOPD Emergency Cardiac ward	ANC patients Theatre Nurses EMRS staff			Yes/ No/ Pending

II.APPENDIX C: DISTRICT/FACILITY LETTER OF SUPPORT TEMPLATE

Date:

Principal Investigator

Address 1

RE: PERMISSION TO CONDUCT RESEARCH AT DISTRICT/FACILITY

I have pleasure in informing you that permission has been granted to you by the Name of District Office/Facility to conduct research on "Title of the research study".

Please note the following:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received approval of your study from the Provincial Health Research and Ethics Committee (PHREC) in the KZN Department of Health.
3. Application to PHREC is done online via the National Health Research Database (NHRD): <http://nhrd.hst.org.za>
4. Please ensure this office is informed before you commence your research.
5. The District Office/Facility will not provide any resources for this research.
6. You will be expected to provide feedback on your findings to the District Office/Facility.
7. You are required to contact this office regarding dates for providing feedback when the research has been completed.

Thanking you.

Sincerely

District/Facility/Programme Manager's Name

District/Facility Name

Date: _____