GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

STANDARD OPERATING PROCEDURE/S RESEARCH APPLICATION PROCESS IN GAUTENG

Definitions

DRC	District Research Committees
GDoH	
HRC	Hospital Research Committees
NHRC	National Health Research Committee
NHRD	National Health Research Database
NHA	National Health Act
NHREC	National Health Research Ethics Committee
PHRC	Provincial Health Research Committee
GDoH	Gauteng Department of Health
PPRC	Provincial Protocol Review Committee
Research (as per the NHA)	'Health research' may be understood to include but is not limited to research that contributes to knowledge of • biological, clinical, psychological, or social welfare matters including processes as regards humans • the causes and effects of and responses to disease • effects of the environment on humans • methods to improve health care service delivery • new pharmaceuticals, medicines, interventions and devices • new technologies to improve health and health care

Contents

1. BACKGROUND

1.1 Management and coordination of research

Research co-ordination and management is fundamental to ensure limited health research resources are put to the best use for the greatest health gain. It also offers an opportunity for exploration and development by the researchers. Chapter 9 of the National Health Act mandates establishment of the National Health Research Committee (NHRC).
According to the Act: NHRC will coordinate the research activities of Public Health authorities by:

- Determine health research to be carried out
- Ensure that Health Research agendas and Research resources focus on priority health problems.
- Ensure that research is properly regulated.

1.2 Establishment of PHRCs

The Health Research Policy in South Africa (2017) identified Provincial Health Research Committees (PHRCs) as an important mechanism for coordinating health research. Although the Provincial Health Research Committees are not mentioned in the National Health Act (No. 61 of 2003), their function and organisation is provided for in the 2001 Health Research Policy. This Policy requires PHRC's to manage and coordinate research within province.

Gauteng has established a PHRC in line with this national directive. This committee seeks to inform and facilitate health research in the province by liaising with all research stakeholders conducting research within the province. It also ensures 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.

1.3 Composition of the PHRC

The members of the PHRC should be appointed by the MEC.

- The PHRC should consist of a maximum of 15 members.
- As per need individuals or groups can be co-opted to the committee
- The members should be representative in terms of gender and race.
- The members should be drawn from within the GDoH and other external stakeholders.
- The Directorate: Policy, Planning and Research should act as a secretariat, provide capacity and strategic advise

1.4 The core functions of the PHRC are to:

i. Coordinate and lead the process of priority setting, to develop and continuously review health research priorities, and develop a research agenda for the province.
ii. To coordinate research undertaken in the province.
iii. To mobilize resources for research undertaken in the province by:
iv. Lobbying and giving advice to the provincial department on equitable use of internal research funding; and
v. Promoting training and research capacity development.
vi. Promote the use of health research outcomes in policy development and service provision at all levels of the provincial health care system by:
vii. Reviewing preliminary and final research reports and give advice on policy implications of completed research projects.
viii. Organizing and coordinating the dissemination of research findings from research conducted in the province through activities such as seminars, symposia, open research days etc.
ix. In collaboration with research stakeholders, develop and implement capacity development strategy for research capacity in the province.
x. Support the development and appropriate use of the National Health Research Database (NHRD), as a research coordination tool.
xi. To use international best practices in setting the provincial health research agenda, including:

    a. Identifying provincial research needs and gaps to inform the relevant research stakeholders in the province; and
    b. Identifying research priorities for health facility based research

The roles and responsibilities are clearly outlined in the PHRCs Guidelines (2017).

- PHRC has devolved permission of research to DRCs and hospital CEOs, except for clinical trials.

1.5 Operational research committees

There are three research committees that are currently operational in the province. These are

i) Provincial Health Research Committee,
ii) District Research Committees – Johannesburg, Tshwane, Ekurhuleni, Sedibeng and West Rand and
iii) Hospital Research Committees
iv) Provincial Protocol Review Committee (PPRC)

1.5.1 District Research Committees

The District Research Committees are responsible for the following:

- Facilitate permissions of research within districts.
- Promoting research in the districts.
- Building research capacity amongst health workers within districts.
- Identifying district specific research priorities.
- Ensure all ethics committees within the district comply with the requirements of NHREC.
- Communicating with PHRC on any issues through the regional representative.

1.5.2 Hospital Research Committees

- Central, tertiary and specialized hospitals review their respective protocols.
- Regional hospitals should be represented within DRCs

1.5.3 Provincial Research Committee (PPRC)

Comprised of central, tertiary and specialized hospitals research chairpersons / focal research person as well as district research chairpersons. Responsibilities are:

- Report on status of research permissions within their institutions.
- Review studies pertaining to multiple sites.
- Report on activities within respective research committees.
- Share best practices.

1.6 Research Policy

- Research within Gauteng is guided by the National Health Research Policy and GDoH will develop research guidelines in line with the National Health Research Policy.

2. Objectives of the SOP

- To outline the process to be followed by researchers when applying to conduct the research in a public health care facility in Gauteng.

3. Scope of the SOP

- These Standard Operating procedures are intended for use by all researchers that apply to conduct research in a public health facility in Gauteng.
- This includes all research where
    - Recruitment takes place in the public sector even if the actual research take place in a private institution
    - A private researcher is based in a public sector institution

- Research is undertaken by an employee of the Gauteng Department of Health even when not for qualification purposes
- Undergraduate and post graduate research.
- Quality assurance and quality improvement studies (audits), programme evaluation activities and performance reviews.

NB: In terms of the 2015 Policy on Ethical Research in South Africa, audits usually do not constitute research and thus usually do not undergo formal ethics review. It should be noted, however, that if publication of such studies is desirable, it is prudent to obtain ethics approval before the study begins. RECs may not grant retrospective ethics approval

4. THE PROCESS

4.1 Consultation process:

4.1.1 The following stakeholders were consulted:

4.1.1.1 National Health Research Committee

4.1.1.2 Provincial Health Research Committee.

4.1.1.3 All five (5) District Research Committees

4.1.1.4 Human Research Ethics Committees based in Gauteng

4.1.1.5 All Hospital Research Committees (Central, tertiary and regional hospitals)

4.1.1.6 Provincial Policy Analysis Committee

5. RESEARCH APPLICATION PROCESS IN GAUTENG

APPLICATION PROCESS FOR CENTRAL AND TERTIARY HOSPITALS

- All researchers that wish to conduct research within GDOH central and tertiary hospitals should obtain provisional permission directly from HOD's of units of the hospital facilities.
- Researchers should then obtain ethical approval letter from a South African research ethics committee that is registered with the NHREC.
- Researchers should upload their research protocol, provisional permission from HOD's of hospitals and ethics approval letter from an approved ethics committee on the NHRD.
- Guidelines for NHRD application and support are on this website http://nhrd.health.gov and the NHRD will issue an automated NHRD number.
- Once an application is received on the NHRD, it will be downloaded by the Provincial NHRD administrator, screened for relevant documents, and submitted to relevant review committee.
- Clinical trials will be sent to PHRC for review and to the DDG for approval, within 2 weeks.
- NHRD administrator uploads provincial permission letter on the NHRD for researcher to download.

- It is the responsibility of the researcher to check the availability of the permission letter(s) and/or comments on the NHRD.

APPLICATION PROCESS FOR RESEARCH TO BE CONDUCTED AT DISTRICTS AND REGIONAL

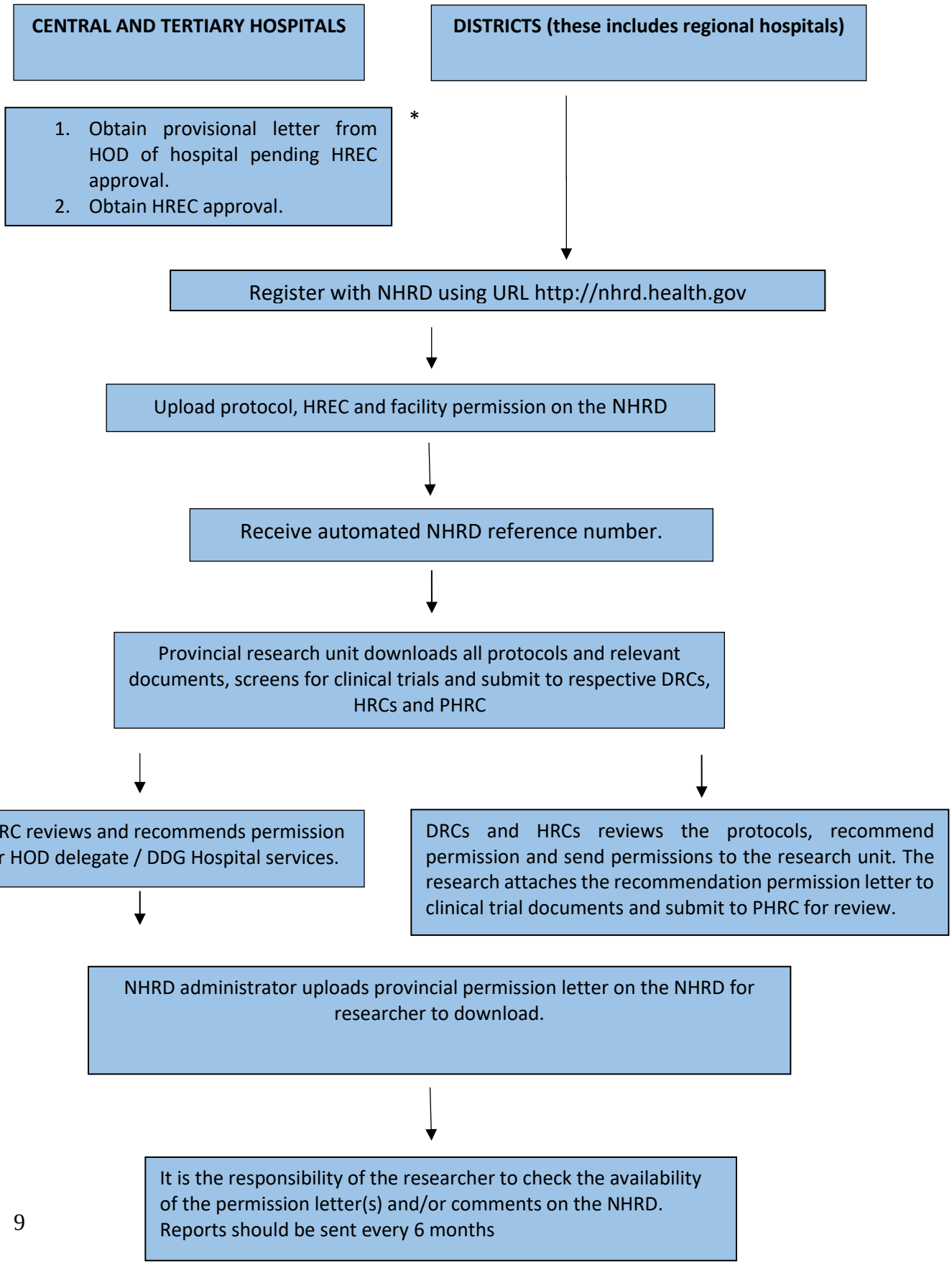
- All researchers that wish to conduct research within GDOH districts, researchers should obtain ethical approval letter from a South African research ethics committee that is registered with the NHREC.
- Researchers should then upload Protocol and ethics clearance on the NHRD.
- Guidelines for NHRD application and support are on this website http://nhrd.health.gov and the NHRD will issue an automated NHRD number.
- Once an application is received on the NHRD, it will be downloaded by the Provincial NHRD administrator, screened for relevant documents, and distributed to the DRCs for review and final approval.
- Protocols pertaining to multiple hospitals and multiple districts will be reviewed by the a multi hospital and multi district committee, separately.
- The district and PPRC approval processes shall be six (6) weeks.
- Research Committees will communicate directly with researchers, if there are any queries.
- On completion, the Research Committees should upload the research permission letters / comments related to the outcome of the review process.
- Once the application process and review process are complete, it is the responsibility of the researcher to check the availability of the research permission letter and /comments.
- The Research Sub-Directorate will upload the permission letter of clinical trials and multiple studies, as well as hospitals without NHRD pins, once it is received from the research committee.
- Researchers are required to provide feedback within 6 months and plan an interactive session with facility staff to share research findings.

APPLICATION PROCESS FOR RESEARCH TO BE CONDUCTED AT CENTRAL OFFICE

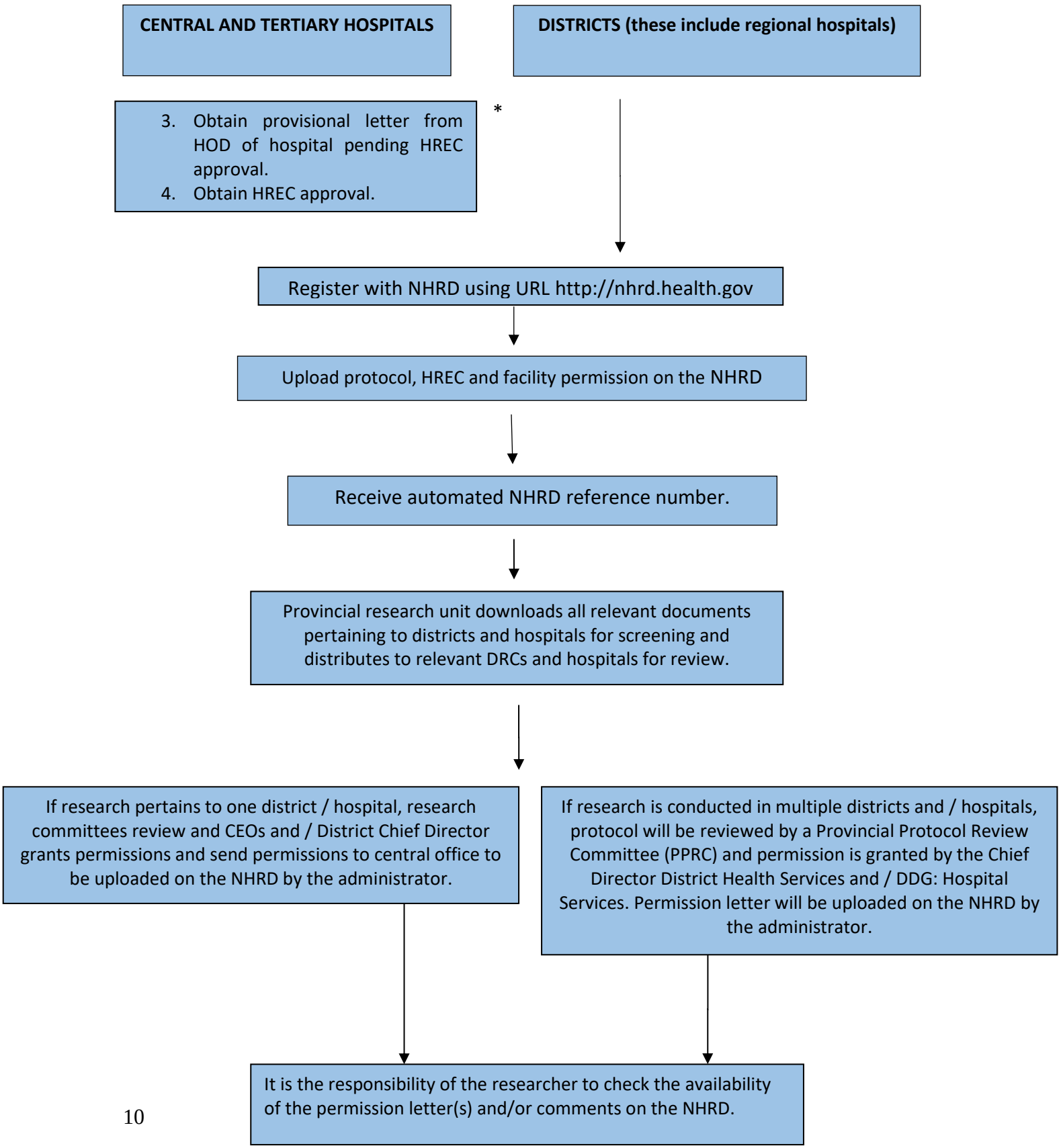
- All researchers that wish to be conduct within the central office; researchers should obtain ethical approval letter from a South African research ethics committee that is registered with the NHREC.
- Researchers should then upload their Protocol and ethics clearance letter on the NHRD.
- Guidelines for NHRD application and support are on this website http://nhrd.health.gov and the NHRD will issue an automated NHRD number.
- Once an application is received on the NHRD, it will be downloaded by the Provincial NHRD administrator, screened for relevant documents, and reviewed by the research directorate and relevant head of branch for recommendation and submitted to HOD for final approval (depending on the nature of the study).

- Protocol review process at central office shall be two (2) weeks.
- Final permission letters are then uploaded on the NHRD for the researchers to download.
- Researchers are required to provide feedback within 6 months and plan an interactive session with facility staff to share research findings.

PROCESS FOR PPLICATION OF CLINICAL TRIALS RESEARCH PERMISSIONS



PROCESS FOR PPLICATION OF non-CLINICAL TRIALS RESEARCH PERMISSIONS



5.1 APPEAL PROCESS

- If researchers are not satisfied with the outcome of their application process, they have to opportunity to appeal the decision, in writing to the appeal committee.
- The appeal committee will consist of
    - A representative from the PHRC
    - A representative from one DRC and one HRC
    - The facility manager of the institution where the research was intended to be carried out (or district if more than one facility)
    - A senior manager from the Department of Health
    - The outcome of the appeal will be communicated to the researcher in writing

5.2 CRITERIA FOR CONSIDERATION OF PROTOCOLS

Introduction/background: The PHRC is mandated to *facilitate research* in health facilities across the province, aligned with the Departments' key priorities. The goal of this facilitation is to ultimately foster a culture of research that enables the following activities: critical inquiry; the creation of new knowledge; the ability to implement evidence-based patient care; and, the continuous quest for quality in health service provision.

Researchers who wish to access patients, patient files and/or patient data from Gauteng public health facilities are expected to liaise with facility managers in advance of conducting their research in order to reflect upon and assess the impact of their proposed research*Is the research feasible in facilities within the limitation of space, staff, patients, timing and funds?*

1. *Does the research duplicate or clash with other research in the relevant facilities?*
2. *Does the research have the potential to answer questions of interest to the province, and provide outputs that could be implemented by the province?*

This is in contrast to the process of seeking approval to conduct research—a statutory function that has been vested with accredited Human Research Ethics Committees (HRECs)—which evaluate both *the science* and *the ethics* of research protocols. The Gauteng PHRC undertakes to work with the HRECs operating in the province to ensure the rigorous assessment of research protocols that involve the residents of our province.

The granting of permission to conduct research in a specific health facility lies with the manager of that facility, and/or his/her designate. In central and tertiary hospitals, research committees currently review protocols and make recommendations to the CEO; likewise, at district level, the five District Research Committees (DRCs) advise district and facility managers regarding the

feasibility of particular requests in both municipal and provincial health facilities.

Ideally, the managers of facilities are best placed to grant permission for research to be conducted at their sites; however, given that this is a transitional process to build capacity and devolve authority to managers, it is expected that hospital and district research committees will play a more 'hands on' role in the interim, working with facility managers to assist them in assessing the research on the basis of established criteria. These research committees will work with both researchers and facility managers to reach common ground—with the aim of enabling quality research to occur across our health facilities. In the event of a rejection, an appeals process is described below.

The common criteria against which research proposals will be evaluated have been developed in order to standardise and harmonise the process for granting permission for research to be conducted in public health facilities. At the moment, these criteria apply to all types of research, except clinical trials

5.2.1. SPECIFIC CRITERIA TO BE ASSESSED:

5.2.1.1. Financial implications – Research must be independently funded and should not be a financial burden on the facility. This includes ensuring that funding is available for all consumables to be used.

In exceptional cases the researcher may be provided with permission to access/use facility resources as part of the research project but this will require prior agreement. This type of research would usually be done as part of the healthcare system's own interest in the results, for instance as part of quality improvement. A written agreement to this effect would have to be kept at the institution and a copy provided to the researcher.

5.2.1.2. **Service implications** - the research project should not interrupt normal service provision. If there are requirements for additional space to conduct the research this should not in any way impede the normal functions of the facility.

5.2.1.3. **Staff implications** - facility staff who are not part of the research team must not be expected to be utilized in the project unless prior arrangements are agreed upon with the healthcare facility manager (see #1).

In exceptional cases the researcher may be provided with permission to access/use human resources as part of the research project but this will require prior agreement. Examples of this in a protocol would be where staff members are requested to pull patient files or are used to recruit patients into the research project and/or interpret during administration of a research questionnaire. This type of research would usually be done as part of the facility's own interest in the results, for instance as part of quality improvement and/or to assist other staff working at the

facility, e.g. registrars. A written agreement to this effect would have to be kept at the institution and a copy provided to the researcher.

5.2.1.4. **Reputational considerations** - the research proposed should not in any way bring the health care facility into disrepute. A healthcare facility manager who is concerned about the possibility that a particular research project would bring the healthcare facility or the Gauteng Department of Health into disrepute may refuse permission on the basis that these fears/concerns are substantiated.

This clause should not be interpreted as the ability to mask bad practice. In some instances, there may be the need to uncover less than ideal health care provision. For example, we know that there are probably too many caesarean sections being performed for non-medical reasons or that staff attitudes can compromise optimal clinical care. According to a recent review, multiple facilities do not comply with the country's minimum core standards. The concept of reputational damage must be taken very seriously and rigorously justified—never being used as an excuse to refuse legitimate research.

5.2.1.5. **THE FEASIBILITY TO CONDUCT SUCH A STUDY WITHIN THE FACILITY**-
i.e. does the facility have the appropriate study population (subjects/data) that the researcher wants to investigate? This question could best be answered by the staff working in that particular area within the facility.

5.2.1.6. ETHICS APPROVAL
This must be obtained prior to the submission of the research application. No study procedures can be undertaken before an accredited Human Research Ethics Committee (HREC), ideally in Gauteng has provided ethical clearance which will accompany the request for permission to conduct research.
NB: the start and end dates for the research should be noted.

*In some cases, permission from the facility manager to conduct research in a particular health facility is required prior to obtaining ethics clearance from an HREC and forms part of the ethics application Such 'permission' may be given **on the condition** that the above criteria are fulfilled—and that the study will only happen if the HREC approves both the science and ethics of the study. A sample letter for such **conditional approval** is attached.*

5.2.1.7. GROUNDS FOR DENIAL OF ACCESS
Permission to conduct research may be denied based on one or more of the following reasons:

- The health facility is unable to accommodate the researcher, because of space or time constraints;
- The proposed research will negatively affect, or unduly burden, health services without any benefits to the facility.
- The existence of other serious and legitimate concerns that have been identified by the authorised manager or health facility team.

A)Process for appeal. If denied permission, the researcher has the right to appeal the decision to the DRC or PHRC (or designated sub-committee). The aim of such a transparent review will be to achieve a mutually satisfactory solution.

6. **TRAINING PLAN FOR THE SOP AFTER APPROVAL**

Training on the SOP will be provided to the following stakeholders

- All researchers
- All HREC's
- All hospital research committees
- All district research committees
- All facility managers

7. MONITORING AND EVALUATION

- The implementation of his SOP will be monitored by the Research Sub-Directorate in the form of the following:
  - Monthly reports or statistics on the number of protocols uploaded on to the NHRD
  - Monthly reports on the turnaround time of the number of protocols whereby a decision is made within 4 weeks
  - Monthly reports from the PHRC to the DRC's / HRC and vice versa.
- The following steps will be undertaken to ensure compliance
  - Bi monthly meetings with DRC's and HRC's to discuss research undertaken in each facilities
  - Six monthly meetings with HREC's

8. **THE REVIEW PROCESS**

- This SOP will be reviewed by all parties on an annual basis

9. CONTACT DETAILS OF THE RESEARCH COMMITTEES AND DATES OF RESEARCH MEETINGS AS WELL ANY ADDITIONAL REQUIREMENTS THAT THE RESEARCH COMMITTEES MAY HAVE PRIOR TO PROTOCOL REVIEW

Research Committee	Protocols that can be reviewed at this level
Provincial	All clinical trials All research protocols pertaining to central office. All appeals
District	protocols for research to be conducted in the community, a primary health care facility or a district hospital
Central and tertiary Hospital	All protocols for research to be conducted in a hospital

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SOP APPROVAL PROCESS

APPROVAL OF SOP'S	
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Acknowledgements

- Provincial Health Research Committee (2018 – 2021 term)
- District Research Committees
- Hospital Research Committees

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