



Standard Operating Procedures for Master of Medicine Protocol Committee (MMPC)

Document type: Standard Operating Procedure

Document number:

Policy Category: Guidance on the Management of Post-Graduate Training

Table of Contents

1. Definitions and Abbreviations	1
2. Purpose of this document	2
3. Mandate	2
4. Aim	2
5. Alignment of the MMPC in the research process	2
6. Degree courses submitting to the MMPC	2
7. Submission process of Protocols	2
8. Protocol assessment criteria	3
9. Reviewing Process	3
10. Composition of the MMPC	4
11. Record keeping	4
12. Conclusion	4

1. Definitions and Abbreviations

MMed	Master of Medicine
MPhil	Master of Philosophy
MSc	Masters of Sciences
MMPC	Masters of Medicine Protocol Committee
Committees	A group of people appointed for a specific function by a larger group and typically consisting of members of that group.
TNM	Applied Research Methodology course
Research Protocol	Written to detail a clinical study's plan to meet specified ethical norms for participating subjects.
UP	University of Pretoria

2. Purpose of this document

This document is compiled to describe the aim, mandate and operating procedures of the MMPC of the School of Medicine, Faculty of Health Sciences, University of Pretoria.

3. Mandate

To review and assess research protocols for degree purposes to adequately deliver research publications and dissertations of sufficient quality and scope for the awarding of a masters degree in the School of Medicine in the Faculty of Health Sciences of the University of Pretoria.

4. Aim

The aim of the MMPC is firstly to ensure high quality research at an adequate level for the awarding of a MMed, MPhil or MSc degree. Secondly, to protect students from attempting research projects that may not be feasible due to technical or time constraints. Thirdly, support students in the refining of protocols and ensuring sound scientific research methodology.

5. Alignment of the MMPC in the research process

The MMPC will review protocols (research proposals) of students enrolled for a masters degree in the School of Medicine only after the student has completed an Applied Research Methodology course (TNM) and has been assigned a supervisor by the head of the department in which the researcher works. The MMPC will then assess the protocol and once approved the student will be allowed to submit the proposal to the Faculty of Health Sciences Research Ethics Committee (FHSREC), Hospital Research Committee and to register the protocol in the National Health Research Database.

6. Degree courses submitting to the MMPC

The following Masters degree courses submit proposals to the MMPC:

- All students enrolled for a MMed degree of all departments who train medical specialists
- All students enrolled for a MPhil degree of all departments where subspecialists are trained
- Students enrolled for MSc courses in selected disciplines where the MSc research is part of course work of a clinical nature e.g. Aviation medicine and Sports medicine.

7. Submission process of Protocols

All protocols and accompanying documents should be submitted before the closing date for each monthly meeting of the committee. Dates are determined and fixed in the beginning of each year and is published on the MMPC web page on the website of the School of Medicine.

The documents to be included are:

MMPC application form (form 1)

The research protocol

Letter of statistical support (form 3)

MMed Post Graduate Supervisor Form (form 2)

Self-evaluation form (form 4)

The closing date for submission of protocols is 2 weeks before the date of the next committee meeting. Apart from public holidays, the committee will meet on the second Monday of each month (except December). Feedback or approval will be given to students in writing within 2 weeks of the date of the committee meeting. This will allow timely submissions to the FHSREC.

The committee meetings are currently taking place on an online platform (Google meet) but was an in person meeting prior to the COVID pandemic and may be in person again in future.

All protocols are submitted to the administrative officer of the committee by at the following e-mail address: protocols.medicine@up.ac.za.

8. Protocol assessment criteria

All protocols are assessed on the protocol assessment form (attached). The criteria for assessment are stipulated on the form but the committee will specifically focus on the following:

1. Feasibility of the protocol and adequacy of the scope
2. Congruency between different sections of the proposal. This is to ensure that the title, aims and objectives are congruent and that the methodologies are appropriate for the aim of the study.
3. The scientific methods planned for the study are sound and adequately described.
4. Referencing is correct and in the Vancouver format

Although not primarily the aim of the review process, the committee will not approve a protocol written using poor non-scientific language, with significant typographical errors or poor layout.

9. Reviewing Process

All protocols are divided between 3 teams of reviewers by the administrative officer of the committee. Each team consist of 3 to 5 reviewers elected from the School of Medicine every 3 years. Reviewers have 1 to 2 weeks to evaluate protocols and to submit the review form with comments on the reviewers sections of the Google Teams folder.

At the meeting each protocol is presented by one of the reviewers and then discussed, after which feedback or approval are decided on that are communicated to the researcher (student).

Feedback are usually one of the following:

1. Approved as it is.
2. Approved with minor changes advised – in this case the student needs to make minor changes and submit the changes before submitting the protocol to ethics.
3. Not approved with revisions required – in this case the student needs to make suggested changes and submit changes to the administrative officer who will then send the amended protocol to the team who reviewed it to

assess acceptability. If it is acceptable, it can be approved without serving at a meeting again.

4. Not approved with major revisions required – in this case the protocol has to be re-submitted for review at a committee meeting again after corrections are made.

All recommended changes are sent to the student in a feedback document. If there are serious methodological problems the student and the supervisor are invited to make an appointment with one of the committee members where the methodological problems can be discussed and advice communicated before amendments are made and the protocol resubmitted.

10. Composition of the MMPC

The MMPC is elected for a three-year term by the School of Medicine. The same procedure for the election is taken for all of the school committees. Because of the nature of the committee and the expertise required the committee can also co-opt members to ensure that at least 50% of the members are from the previous three-year period which allows continuity and a minimum level of expertise in each review team. This system also allows for junior members to grow in knowledge and ability. The chairman of the committee is selected by the committee. The committee should have a minimum of 6 academic members, but preferably 12. One registrar is elected by the registrars to represent them on the committee. There is also a paid administrative person appointed by the School of Medicine to assist with the administrative duties of the committee.

11. Record keeping

All protocols and accompanying documents with the reviewer's feedback and the feedback document to the student as well as all communication and revised protocols are kept in electronic format on the committee's Google Teams folder as long as the review process is active. Once the review process is completed the student's folder is removed from the active Google Teams drive and moved to an Archive Google Teams folder which cannot be changed by committee members and can only be accessed by the chairman of the committee and the administrative officer. Please see the document on the "Team Drive strategy for MMPC".

12. Conclusion

The MMPC would aspire to be an interactive and supportive committee in order to promote and support quality research in the School of Medicine without adding to student frustrations and time delays. However, the committee cannot assume the role of supervisor for any student.