Department of Surgery

Guidelines on the Process of How to Complete the

RESEARCH COMPONENT OF THE MMED

Department of Surgery 2022

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DURING THE COVID-19 LOCKDOWN PERIOD, ALL SUBMISSIONS OF PROTOCOLS, FORMS AND REPORTS ARE ELECTRONIC.

MMed PROCESS:

1. General information

This document is a guide from the Department of Surgery for registrars from all surgical disciplines on how to submit, collect, write-up and review your MMed research report data and documents from start to finish. Please note the following:

- The Department of Surgery will be tracking your progress and you are expected to keep us informed of developments.

- You should decide on a topic for your MMed research within the first year of your junior registrar tenure. You should plan to do the bulk of your work for the MMed research project after the first 12-18 months of your junior registrar tenure, immediately following your intermediate exams and before becoming a senior registrar.

- In General Surgery, the department expects you to complete your MMed research project during your research block, or at least have all your study data collected by the end of it.

2. Research methodology and statistics courses

You are required to attend both a research methodology and an introductory statistics course. You should submit copies of your certificates of attendance by the end of your 2nd year as a registrar. The Department of Surgery runs an in-house research methodology course biannually in January/July, and other similar research methodology and statistics courses are on offer in the Faculty of Health Sciences throughout the year. These courses will help to guide you through the various aspects of developing, implementing and writing up a MMed research report. Please contact any of the individuals listed above for more details.

3. Project ideas

There are 2 options to choose a research question for a MMed Research Report:

Projects on offer

Department and Division Heads in Surgery may have projects that they would like to supervise as priority research within their units. These are novel projects that aim to address 'gaps' in the field of interest. These projects are either distributed via email or are not listed. The following applies:

- You should ask the Unit Head of the department of interest if he/she has any projects on offer. The Unit Head has the final decision on who gets to do his/her project.

- You have 3 months to submit your first protocol draft. Failing to do so will result in your project title being 'up for grabs' once again for other registrars.

- The Unit Head who offered the project will become one of the supervisors on your project.

Own project

You may have a research question/idea of your own which you wish to pursue for your MMed Research Report in Surgery. The following applies:

- Your project title/idea has to be novel in the way that it is not duplicating research already being done or done in the recent past within the Faculty of Health Sciences.

- You are responsible for getting permission to do your project from the person who heads up the unit in which you wish to do your project.

4. Supervisor(s)

We advise you to have 2 supervisors on your MMed Research Project, although this is not compulsory. If possible, one should be an expert in the field in which your project will be undertaken, and the other should be qualified and thus knowledgeable on research methodologies and processes. **At least one of your supervisors has to have a MMed/MSc degree or higher**.

You have to approach your supervisor(s) of choice, with help from the Department, and get them to agree to supervise you for the duration of your project. At the same time he/she should give permission to do the study in their Unit/Department. If you have chosen one of the projects on offer, the Consultant / Surgeon / Unit Head who offered the project will automatically become the supervisor on your project.

5. Research Support

The Department of Surgery has further support and training available to you in order to make your research journey as smooth as possible. These include:

- *Regular Research Methodology and Statistics Courses – Faculty & Departmental*
- *One-on-one MMed research support* at the Medical School by appointment with any of the contact persons listed at the start of this document. Alternatively, you may just drop in and we will be happy to help you if we do not have previous commitments at that point in time.

6. Registration

It is imperative to register every year by the end of January at the Postgraduate Office (Phillip V Tobias Building, 2nd Floor, Cnr York & Princess of Wales Terrace, Parktown) for your MMed components. You will then receive all the necessary information in a MMed Research Protocol pack to help you submit the correct documents in the correct format (attached). The MMed specialities each have a unique Research Report registration code. Specifically, you may not submit your MMed protocol to the Protocol Assessment Committee unless you have registered for the MMed Research Report component.

7. Writing and submitting a MMed protocol

You have to write your protocol according to the Faculty guidelines (attached). It is the responsibility of your supervisor(s), to revise and edit your protocol and suggest any changes required for submission. Only once these changes have been incorporated may you submit the **6 copies** of your protocol to the Post Graduate Office on the 2nd floor of the Philip V Tobias Building. This submission includes the white **protocol cover sheet** form that needs to be stamped by the Postgraduate Office (attached). The Faculty Officers will verify the candidate's enrolment, stamp and sign the coversheet, retain one copy and give back the other **five copies of your stamped protocol to submit to Dr Emmanuel Nweke or Dr Pascaline Fru in the Department of Surgery** on the 9th floor in the Medical School by 4pm on the deadline. **Please also supply us with an electronic copy of your protocol**

– this is required to run a plagiarism check. If your protocol passes the plagiarism check, it will be assessed at the next Protocol Assessors Meeting and your <mark>supervisor needs to attend this meeting</mark>. The recommendation of appointment of supervisors form must accompany your protocol submission (form shown below, Word Doc electronic version available from Research Office website and Research Coordinators). <u>ALL FORMS MUST BY TYPED</u>. Deadline dates for submission of protocols cannot be extended – this means no late submissions will be accepted. These dates can also be viewed on the Faculty Almanac.

<mark>DURING THE COVID-19 LOCKDOWN PERIOD, ALL SUBMISSIONS OF PROTOCOLS ARE ELECTRONIC. PG OFFICERS WILL CONFIRM YOUR REGISTRATION ELECTRONICALLY, RATHER THAN STAMP THE COVERSHEET.</mark>

8.   Applying for Ethics

As with all research, and particularly as your MMed research is for degree purposes, you have to submit it to the University of the Witwatersrand Human Research Ethics Committee (HREC) (Medical) for approval. Please contact the Department of Surgery for guidance and ensure you use the correct HREC (Medical) form (https://www.wits.ac.za/ethics/human-research-ethics-committee-medical/). Your supervisor should check and sign your original application, whereas this final signature has to be either that of <u>Prof Martin Smith, Prof Deirdré Kruger, Dr Emmanuel Nweke</u> or <u>Dr Pascaline Fru</u> before submitting to the HREC (Medical) online. **The Department of Surgery's deadline for** <u>assisting</u> **with ethics applications is the** <u>last day of every month</u>. Should you miss this deadline we will only consider your application for the next month's deadline.

9.   Data Collection and Analysis

You should contact the Department of Surgery once you start your data collection. We will guide you as to how to collect this data in a format that will simplify data analysis thereafter. Statistical consultations are available through the Faculty Office this information is relayed via emails and courses.

10.   Writing up and Submitting your final MMed Research Report

You have to write your MMed research report according to the Faculty guidelines (attached). Once your report draft is complete, you have to send it to your supervisor to **review** it for you and suggest any changes required for submission. **Only once these changes have been incorporated and your** <u>Nomination of Examiners</u> **has been approved** may you submit the **3 copies** (2 hardcopies and 1 electronic copy) of your report for examination to the Postgraduate Office of the Faculty, **including all the necessary documents required by the PG office**. Please ensure to include the MMed report submission forms upon submission of your final report, as well as your HREC clearance certificate and supervisor report.

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11. **Research Block in General Surgery**

Registrars in General Surgery get a 2-month research block during their senior rotation. **You are not permitted to take leave during this time**. The research block is intended for data collection or data analysis and writing up of your final MMed research report. It is not intended for research administrative purposes. In addition, registrars are expected to facilitate on the BESST course during their research block.

12. **Forms – Faculty of Health Sciences Research Office**

All forms that you will required during the process of your MMed degree can be accessed here.

These forms and information documents include:

- Protocol Coversheet
- Appointment of Supervisors
- Statement of principles for postgraduate supervision
- Human and Animal Research Ethics Declaration
- Plagiarism Declaration
- Application for change of approved title
- Application for change of approved Supervisor(s)
- Certificate of submission for Examination - signed by Student
- Certificate of submission for Examination - signed by all Supervisor(s)
- Supervisor(s) Report

Ideal MMed Timeline 2022

Example 1

Process	2022					2023				
	Jan	Feb	Mar	Apr	Jun	Jan	Feb	Mar	Apr	May
Project idea	X									
Literature review	X	X								
Preparing protocol		X	X							
Protocol deadline		23/02/22								
Protocol assessment			23/03/22							
Ethics application			30/03/22							
Collecting data					X	X				
Data analysis							X	X		
Writing up – report								*Research Block**		
Report submission										X
Finalise//Submit - publication										X

*Each MMed's research block is different. We strongly recommend that you use your 2-month research block for either Data Analysis OR Writing-up your MMed Report.

Example 2

Process	2022					2023				
	Jun	Jul	Aug	Sept	Nov	Jun	Jul	Aug	Sep	Oct
Project idea	X									
Literature review	X	X								
Preparing protocol		X	X							
Protocol deadline			03/08/22							
Protocol assessment			31/08/22							
Ethics application			31/08/22							
Collecting data					X	X				
Data analysis							X	X		
Writing up – report								*Research Block**		
Report submission										X
Finalise//Submit - publication										X

*Each MMed's research block is different. We strongly recommend that you use your 2-month research block for either Data Analysis OR Writing-up your MMed Report.

FINALLY, we are here to help you from start to final submission of your MMed research report. If you are having difficulties with it, you have not been to see us!

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

CANDIDATE'S SURNAME: [Please print]		FIRST NAME/S:		STUDENT NUMBER:
CURRENT QUALIFICATIONS:				
TEL:	CELL:	E-MAIL:		FAX:
DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED:				
PART-TIME OR FULL-TIME:				
FIRST REGISTERED FOR THIS DEGREE:	TERM :		YEAR:	
DEPARTMENT:				
TITLE OF PROPOSED R...				
CANDIDATE'S SIGNATU...				
SUPERVISOR 1 (NAME &...			...sion	
SUPERVISOR'S QUALIF...				
SUPERVISOR'S DEPART...				
SUPERVISOR'S ADDRE...				

> This is a screen shot of the protocol coversheet.
> Download the form via the link below.
>
> ALL FORMS MUST BE TYPED.
>
> http://www.wits.ac.za/health/research/postgraduate-research-support/protocols--research/

SUPERVISOR 2 (NAME & SURNAME):	% Supervision
SUPERVISOR'S QUALIFICATIONS	
SUPERVISOR'S ADDRESS / TEL / E-MAIL:	
SUPERVISOR 3 (NAME & SURNAME):	% Supervision
SUPERVISOR'S QUALIFICATIONS	
SUPERVISOR'S ADDRESS / TEL / E-MAIL:	

SYNOPSIS OF RESEARCH:(Brief summary of proposed research project; between 200-300 words only; with sub-headings: an introduction and justification for study, aim/s, proposed methodology and expected outcome/s)
[Use reverse side of this page if
more space is required]

WITS ETHICS NOT REQUIRED: Yes No WITS ETHICS PENDING: Yes No WITS ETHICS APPROVED: Yes No (circle appropriate symbol)* ***Please note the final human ethics clearance certificate or animal ethics certificate must be available prior to starting research**	IF Y SUPPLY ETHICS CLEARANCE CERTIFICATE AS ATTACHMENT AND INCLUDE ETHICS NUMBER HERE:
As supervisor/s, I/we confirm that I have read the protocol which has been submitted for assessment.	

SIGNATURE OF SUPERVISOR/S:	…………………………………..	…………………………………..
SIGNATURE PG OFFICE STAFF …………………………………..	REGISTERED YES….. NO…..	STAMP

SYNOPSIS OF RESEARCH CONTINUED

11 March 2019/MP

CONTENTS OF THE RESEARCH PROPOSAL

A proposal is a plan for a research project. It is one of the most important phases of the study. If it is inadequate, misguided, or incomplete, it is unlikely that the research will be successful. Formulating the proposal may, for some research projects, take longer than the collecting of data.

A proposal must not be very long. It is a plan of action, not a full research report, dissertation or thesis itself. The proposal document in entirety should not exceed **10 typed pages** for a MMed and **15 pages** for a PhD. It should be typed in 12 point either Arial or Times New Roman script with double spacing (including the references). The page limit does not include questionnaires that should be placed in an appendix. Proposals may be rejected if they are too long (more than 5 pages over stated length).

Protocols must be accompanied by a **protocol cover sheet**, completed, signed by the student and supervisor(s) and stamped by the postgraduate office. This sheet can be found on the page preceding this page and is also available from the postgraduate office.

Department of Surgery dates for submission of protocols in 2021: **3rd March, 5th May, 4th August, 13th October.**

A proposal should include the following:

1.   **A TITLE**

A title should be brief, and precise, and should avoid redundancies and unnecessary phrases such as "An investigation into...". Below the title, state your name, student number and the degree for which you are registered. Also give the name(s), qualifications and position(s) currently held, of your supervisor(s).

2.   **INTRODUCTION / Background**

The introduction should explain, for the non-expert but intelligent reader of your document, what the background is to your proposed study. You should formulate the question being asked, or the hypothesis of the study, in the context of the prevailing scientific knowledge on the subject. Therefore in this section you should also include a brief review of the relevant literature that has led to the idea or conceptualization of your project. Usually about **five pages** and between ten to twenty references will suffice.

Calling this section a "literature review" is probably giving the wrong idea. This section should rather be called a "background literature analysis and critique" rather than just a review. You need to review the literature first (read through it) and then analyze and critique the arguments presented in that literature when you write this section.

Only information relevant to the study should be included as the primary purpose to this part of the protocol is to justify the study in the light of previous information. At this stage the "story" of the research should be quite clear to the assessors. The paragraphs should therefore be carefully structured and lead the reader carefully and deliberately towards the final paragraph which should contain the research question/aim. This may be expressed

as: "Therefore the aim of my study is to …". You can then add a sentence indicating your hypothesis which is a statement predicting the outcome of the study.

If you have information such as data from an unpublished Honours project which provides some background to the current study then include the information in this section as well.

3. **STUDY OBJECTIVES**

This section requires you to be specific about the research questions or problems to be studied, which were raised in the introduction. It is probably the single most important section of a proposal. State exactly what it is you intend to do, and what outcomes you will measure to find answers to the questions you have in mind. You may list the study objectives, or specify them in paragraph form, but the reader must be left in no doubt as to what your objectives are.

Objectives are usually written starting with **"to"** and then using words such as **describe, explain, compare, measure etc**. For example, To describe the characteristics of ….

4. **METHODS**

This section should include all the information relating to your plan of action. The methods section has to be particularly clear and be linked to the objectives and thus using headings to clarify these relationships would be preferable. The headings are:

a. **Design**: for example, cross sectional, descriptive, open, or single/ double blind, cross-over or parallel in nature etc; a clinical trial.
b. **Site of study**: give the reader concise information relevant to the study
c. **Study population:** define clearly the group about which information is to be gathered.
d. **Sampling:** which will include –
    i.   Sample size including statistical rationale
    ii. Selection or recruitment of subjects
    iii. Inclusion and exclusion criteria

    For each of the above, give reasons for your choice.

e. **Measuring tool or instrument**: Describe the measuring tool or instrument be it a scale, questionnaire or clinical measurement. If you are going to use a scale, discuss the validation and construction of the scale. If you are going to use a questionnaire describe the content of the questionnaire and justify why questions have been included. Explain how the questions were derived e.g. from another study, from discussion with colleagues etc The level of detail of this section should be such that it is clear to the reader how these measurements are designed to arrive at an answer to your research questions.
f. **Data collection**: describe EXACTLY – step by step - how the data will be collected or measurements done.
g. **Pilot study**: will a pilot study be necessary, and if so, what aspects of the protocol may change depending on the outcome of the pilot study?
h. **Sources of bias**: it's not sufficient merely to mention these; you also need to explain how you will attempt to remedy them.

Ensure the following are addressed:
i)   State who/what participants are to be studied. If they will be animals, give details such as their species, body weight, sex and number. If human beings are to be studied, specify the population and state which of its characteristics are relevant to your study. In both cases specify the inclusion and exclusion criteria you will use in selecting your participants where appropriate.

ii) Explain what experimental groups the animals, participants, or members of the population will form, which participants will act as controls and whether when the study will be open, or single/double blind, cross-over or parallel in nature, or a clinical trial.

For each of (i) and (ii), justify your selection of experimental subjects and sample size. Possible headings to use include: site of study, control participants (if used) – how selected, and study design. It is essential that every detail regarding your methods is explained in your protocol.

iii) State the <u>endpoints</u> you have in mind for your study, which will allow you to know when it has reached its completion.

iv) Consider such issues as sources of bias, and confounding variables.

v) If a pilot study will be necessary, explain what aspects of the proposal may change as a result of its outcome.

vi) If the project is risky, meaning that there may be no results, state if:

- The project is built on previous work
- What the alternative plan is if the first part of the project fails (particularly important if the subsequent sections depend on the success of the first section)
- The work has already started, particularly if there are preliminary results.

vii) Please make sure that you mention, particularly if you are using any retrospective analysis, what data you will be collecting yourself. This includes raw data collection as well as data analysis, in the form of analysis techniques e.g. PCR or estimation of blood glucose you will be doing yourself. This is particularly important for a PhD protocol.

5. DATA ANALYSIS

Specify the methods to be used in the analysis of the data of each section of the work, the statistical tests that will be used and whether expert statistical help will be necessary. If it will, state whose help will be needed. The data analysis required to fulfil each objective should be specified. It is not enough to give every possible test and mention that you will be using one of them "as applicable". The importance here is to let the assessors know that you have thought about the data which will be produced and how you will deal with that data to answer each objective.

6. ETHICS

If the study raises ethical issues, such as research on vulnerable participants or research on children, explain how you will deal with these issues. State whether clearance has already been obtained from the relevant ethics committee, or when you envisage making a submission to the committee. Where there would be problems in obtaining informed consent, e.g., in the emergency situation or trauma research state how this would be approached.

An ethics application form is required for all studies unless there are no human participants involved and then there is an ethics waiver such as would be obtained for cell lines. Different ethics forms need to be completed for animal and human studies.

7. TIMING

State when the study will commence, and its expected duration. It is better in this section to fill in a Gant chart (see below) indicating the time expected to be taken on the various component parts of the project. It is preferable that the time indicated should be appropriate in order to complete the degree in the recommended time.

	Jul	Aug	Sep	Oct	Nov - Jan	Feb - Mar	Apr	May	Jun
Literature review	■	■							
Preparing protocol	■	■							
Protocol assessment			■						
Ethics application				■					
Collecting data					■				
Data analysis						■	■		
Writing up - thesis							■	■	■
Writing up - paper									■

8. FUNDING

Start with providing a predicted budget for your project. Include all expenses including assay kits, photocopying and transport. This is best done as a table.

Explain how the project will be funded. There may be a need to specify the sources of funding for specific aspects of the project, or to pre-empt a question as to where funding would come from, possibly for particularly expensive equipment, agents or tests. If a drug company is donating agents to be used, please disclose this information. It is essential at the protocol submission stage that funding be available or there should be evidence of proposed funding especially if the project (s) are expensive. If funding is available a letter to that effect should be attached from the person holding the funds to confirm that funding is available for this particular project.

9. PROBLEMS

If there are any issues, which you consider may compromise your progress with the project, such as availability of study material or patients, or problems of a technical nature, please raise these issues, so that the Faculty Committee can attempt to help you.

10. REFERENCES

You should list the references in an accepted referencing format – either **Harvard** (author-date) or **Vancouver** (numbering), as long as the referencing style is maintained throughout the document. It is much easier to use the Harvard style in a thesis as the authors and date make sense. All references must be cited in the text and vice versa.

If you obtain journal articles through the web you only have to give the URL if there are no page numbers allocated to the article. If there are page numbers it implies that the article is in printed form somewhere and only the journal reference is required.

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RECOMMENDATION FOR APPOINTMENT OF SUPERVISOR(S) OF RESEARCH REPORT, DISSERTATION OR THESIS

Motivation / Reason for Appointment:

_____
_____
_____
_____

Recommendatio_____

This is a screen shot of the APPOINTMENT OF SUPERVISOR FORM. Download the form via the link below.

ALL FORMS MUST BE TYPED.

http://www.wits.ac.za/health/research/postgraduate-research-support/protocols--research/

Student Surna	
Student numb	
Degree	
Div / Dept / Sc	
Title	

(Supervisor 1): _____
(Name &Surname)

Supervision %: _____

Supervisor Qualifications: _____

Supervisor Department: _____

Supervisor Telephone: _____   E-mail: _____

Supervisor 2: _____
(Name &Surname)

Supervision %: _____

Supervisor Qualifications: _____

Supervisor Department: _____

Supervisor Telephone: _____   E-mail: _____

Student Signature: _____

Supervisor 3: _____
(Name &Surname)

Supervision %: _____

Supervisor Qualifications: _____

1

Supervisor Department: _____

Supervisor Telephone: _____ E-mail: _____

Student Signature: _____

Supervisor 1 Signature: _____

Supervisor 2 Signature: _____

Supervisor 3 Signature: _____

RECOMMENDATION BY HEAD OF DIVISION / DEPARTMENT / SCHOOL:

_____   _____   _____
(Full name(s) and Surname)   (Sign)   (Date)

APPROVAL BY CHAIR OF ASSESSOR GROUP:
(On behalf of the FGSC)

_____   _____   _____
(Full name(s) and Surname)   (Sign)   (Date)

PLEASE NOTE: RECOMMENDATION FOR APPOINTMENT OF SUPERVISOR(S) FOR CIRCULATION TO THE FGSC FOR APPROVAL