The cover features a teal background with a faint ECG (heart rate) pattern. A large, semi-transparent circular graphic is centered on the page. Overlaid on this graphic is a stethoscope, which is also semi-transparent. The text is white and positioned within the circular graphic.

# GETTING STARTED IN Clinical Research

*Guidance for junior researchers*

**2014**

Department of Paediatrics and Child Health  
Faculty of Medicine and Health Sciences  
Stellenbosch University



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## *Foreword*

Welcome to the first edition of this guidebook for clinical research mainly towards a Masters degree in the Faculty of Medicine and Health Sciences at Stellenbosch University, but this book might also be of great benefit to all junior researchers. I am always struck by the deep commitment to excellent clinical research by the authors of this book, and their strong desire to share their expertise with you, our postgraduate students and future research leaders. It is important to embark on high-quality clinical, health and medical research, which is a powerful driver for improvement of health services in our region. We also need the innovation that you young clinicians and researchers will bring with your fresh ideas and enthusiasm, and hope that this guidebook will be of great value to you. You will have probably already started thinking about your research topic and your supervisor, who will be the mentor for your research study and of tremendous importance during your research endeavor. This book will, additionally, provide advice regarding the choice of a topic, the research question, the appropriate research methodology, statistics and other aspects important in the research process. I do wish you great success, enjoyment and conclude with the words by the Nobel Prize winner for physiology, Albert Szent-Gyorgyi: *“Research is to see what everybody else has seen, and to think what nobody else has thought”*.

Mariana Kruger  
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October 2014

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# *Introduction 1: Purpose of the guide*

We, the authors, are enthusiastic researchers and have experienced the pleasure research brings. We have also experienced all the frustrations, the lows and the highs of research, attended many courses, some of which were very helpful and some of which did not seem to help at all, and initially we did not have mentors to help us. Much later in our careers we had the privilege of meeting good mentors and realised the importance of having a mentor who could guide us through the ups and downs of research. Many people have helped us but we especially acknowledge Don Enarson and Peter Pare who have set the bar of what an outstanding mentor should be and without whose help and guidance we would not have been able to experience the joys of research. We hope that we can now transfer that guidance and enthusiasm to you, our junior colleagues, and that you too will experience the camaraderie and guidance of working together with your mentors. We thank Mariana Kruger who wrote the ethics step and Carl Lombard who wrote and assisted with the study design and statistics sections. We thank the following reviewers Don Enarson, Wynand van der Merwe, Amy Slogrove, Julie Morrison and Andre Gie who have played an important role in making this a user-friendly guide.

The purpose of this guide is to try and make your research study a little easier, to assist you to complete your study and experience the elation of seeing your research published. This is not a comprehensive guide. There will be many aspects that we have not thought about, areas where we have not provided enough guidance and have made numerous assumptions concerning a junior researcher's abilities. For these we apologise.

The guide is arranged with 17 easy-to-read steps that are essential to carry out your research and to get the results published. We have included appendices, templates, regulatory sections and websites/references as additional reading material to provide more detailed information you may require for your study. Downloads of the templates and some of the appendices are available at websites provided or at [www.sun.ac.za/paediatrics](http://www.sun.ac.za/paediatrics). The whole manual can be downloaded from [www.sun.ac.za/paediatrics](http://www.sun.ac.za/paediatrics).

This is a first attempt to prepare such a guide and it will need to be updated regularly to ensure that all the material reflect the changing world of research and the ever-changing requirements. We started off writing the guide for registrars and junior researchers in the Department of Paediatric and Child Health, Stellenbosch University with the examples appropriate for paediatrics. However, the steps in the guide are fairly general and the appendices, templates and electronic version can be adapted to be more appropriate for other disciplines. Please feel free to do so. If there are areas, and there will be many, you can suggest to improve please e-mail ([rpg1@sun.ac.za](mailto:rpg1@sun.ac.za) and [nb@sun.ac.za](mailto:nb@sun.ac.za)) or discuss it with us. We will be too pleased to make the appropriate changes.

## *Introduction 2: Why is research important to you?*

Of course the quick and obvious answer is that you need to complete a research study if you want to register with the HPCSA. But that is focusing only on the end product of research. Research can be defined as the systematic investigation of a topic in order to increase knowledge. Using this definition, there are two aspects of research namely (1) the process of systematic investigation and (2) the final product of creating knowledge. Therefore while you need the final product for registration, the process of doing research and developing a disciplined systematic way of critical thinking, is really the final long lasting advantage of doing clinical research and this process of developing critical thinking is part of your education as a registrar or junior researcher.

*“Education is not filling a bucket, but lighting a fire”.* (W.B Yeats)

If this guide can kindle that fire of critical thinking in you – Hurray!

Critical thinking should not be viewed as a requirement solely for research, but it should become part of your clinical practice and patient management – you should always be asking questions about your patients and their clinical course. During your training you learn and have to remember many facts. There is a danger in overfilling one’s brain with information and not spending enough (or any) time on thinking about the information and facts. Critical thinking is not the collection of a bunch of facts, but involves the systematic thinking about a topic using the knowledge you already have from the available facts and then developing the ability to reason and figure out why some facts do not fit. Critical thinking is asking the “why” question and research is investigating the “why” question in a systematic way before making a decision or drawing a conclusion.

Critical thinking in research means that you have to know your field of interest (literature review) and then ask a question (research question) and collect the necessary information and compare your findings to the already existing knowledge (research results and analysis). Critical thinking in patient care follows the same discipline – know your field (know the clinical course of your patient), and then constantly and systematically ask the “why” question and compare to your experience (Why is this patient different from all the others that I have seen? Why does this patient not respond to the treatment?). If you use this research opportunity to develop critical thinking, then you will complete your research study, but more importantly, you will incorporate critical thinking into your day-to-day practice and management of patients, and if you keep on asking the “why” question, your research will benefit you for the rest of your career.

*“Research has been called good business, a necessity, a gamble, a game. It is none of these – it’s a state of mind.”* (Martin H Fisher)

## ***Introduction 3: How much time do you need?***

You cannot start soon enough with finding your field of interest, research idea and finding a mentor willing to help you. The following timeline is suggested for a registrar following a four-year training program. Your final year will be spent preparing for your final clinical examinations so the research project must be completed within the first three years. There are a number of obstacles that you might not be aware of before you start your research project. Examples of time consuming obstacles include: discussing your research idea with colleagues, arranging meetings with other Departments, writing your research proposal, presenting your proposal to the Departmental research committee, submission of your protocol to the Human Research Ethics Committee and getting permission from the hospital authorities. All these have to be successfully concluded before you can even start collecting data.

To be able to complete your research project within three years we would suggest the following time-line:



### **First year of training: The year of planning**

1. Decide what area of clinical care you are interested in.
2. Discuss with colleagues/consultants various research ideas.
3. Approach a mentor to help you with your research.
4. Review the literature.
5. Develop a research question.
6. Consult the necessary expert(s) like the biostatistician.
7. Write your research proposal, including case report forms (CRF) and consent forms.
8. Present your research proposal to the Departmental research committee.
9. Submit your protocol to the Human Research Ethics Committee (HREC).
10. Simultaneously request permission from the hospital management to do the study.
11. Develop your database.
12. And that is just the beginning.

**TIP:** Although it takes time to settle into Department as a registrar you will have to start the process within 3-6 months otherwise you will not complete the necessary formalities.

## Second year of training: The year of collecting data

1. Do a pilot study to test the case report forms (CRF) etc.
2. Collect the necessary data.
3. Transcribe the data onto a database.
4. Clean the database of all mistakes, missing data or duplicate data.
5. Sharpen your analysis plan.
6. Analyse the data with your mentor and biostatistician's help.
7. Plan to present the results of your research at a local, national or international scientific meeting.

## Third year: The year of writing and communicating

1. Write your provisional report/thesis/article: draft 1.
2. Re-read and re-write your draft a number of times.
3. Submit your draft to your mentor.
4. Carefully address your mentor's suggestions and re-write your draft.
5. Revise your draft (once again).
6. Submit your thesis for marking.
7. Reply to the examiners' comments.
8. Present to department, at conference, to hospital authorities etc.
9. Final submission for degree.
10. Submit article for publication.
11. Go out and celebrate.

**TIP:** The writing seems to be the easiest part of this process but unless you are gifted this is very hard and frustrating work as most of us are not naturally scientific writers.

**TIP:** If there are courses on planning, implementing research, writing proposals, research ethics, writing an article etc. - attend them. We all need all the help we can get.

The Postgraduate and International Office at Stellenbosch University have a number of useful tools to help postgraduate students. The one useful tool is an electronic timeline for staff and postgraduate students called "Ontrack"  
<http://www0.sun.ac.za/ontrack/login.php>

- ▶ See appendix 1 on how to log on to "Ontrack"
- ▶ See Appendix 1 for examples of how to develop a timeline.

# Introduction 4: What is the likely roadmap your research will take?

To do good research you need to develop critical thinking and this must become part of your day-to-day life. This is not an easy adjustment and you need to be careful not to take your critical mind into your personal life!

You will experience many ups and also many downs during your research. Often senior researchers forget to talk to junior researchers about the miserable research days. However, during every research study there are days where one just wants to give up and feels that one is not going forward at all. It is quite normal to feel like this – but do not give up.

When you do get despondent, take a minute and look at this fun cartoon published with permission of Prof Ernest Harburg from Ann Arbor, Michigan University – see where in the Island of Research you are lost, then laugh a bit and get on with the work.

Remember even when you get lost on the lonely island of research, never block the Path of Inquiry.



# STEP 1

## *How do you find a good research idea?*

Finding a good research idea is not easy. Many established researchers also struggle with this problem. Every clinical research idea and question starts with a clinician being faced by a clinical problem at the bedside. Having a critical mind, identifying an unusual clinical presentation, challenging the clinical management or identifying an unusual clinical course or outcome, often leads to very interesting clinical research.

### **How do you start to find a research idea?**

Clinicians are often faced with interesting problems due to their work. In Southern Africa we have many research opportunities due to the burden of infectious diseases (HIV/tuberculosis) and the cycle of poverty (prematurity, small for gestational age babies, malnutrition). Critical evaluation of the literature reveals that there is very little evidence for the management strategies we apply to these children or knowledge on their outcome. This gap in knowledge is evident on nearly every ward round, clinical discussion or academic meeting. Exploring this lack of evidence, outcome or clinical description leads to excellent clinical research ideas. These gaps are relatively easy to investigate and publish as we have the facilities to investigate these problems – many other low and middle-income countries where these clinical problems occur, unluckily do not have the facilities to do the necessary (often high tech) investigations.

### **What opportunities are there to help find a research idea?**

#### **1. At the bedside, clinical discussion or academic meeting:**

1. Pick an area of interest especially those areas in which you would like to become a senior registrar or in which to develop a career. Being interested in and enthusiastic about the subject is very important!
2. Be curious and ask questions on ward rounds and at meetings. Write down areas of uncertainty that could be researched.
3. In each academic meeting, make at least one note of something that you find interesting or did not know– after a few meetings you will have a long list from which to develop ideas.
4. Review the literature to see what knowledge about your idea is already addressed.
5. Discuss the research idea with your colleagues and mentors/consultants.
6. Find a good mentor to help you develop your research idea.

## 2. Join an established researcher or a research group:

1. Many researchers or research groups have research ideas that junior researchers can develop into a research question and on which they can do the research.
2. Make an appointment with the researchers in the area in which you are interested and discuss the possible research ideas.
3. Do a literature review on the research idea.
4. Refine the research idea with the help of the researcher/consultant.

## 3. Collaborate with other Departments/institutions:

1. New technology creates many unanswered questions. By collaborating with other Departments/ institutions you will be able to develop excellent research ideas.
2. Discuss your idea with a consultant in your Department and see if your research idea is appropriate.
3. Review the literature.
4. Together with your consultant/mentor approach the relevant Department and discuss the research idea.
5. Refine your research idea.
6. Develop a clear memorandum of understanding with the other Department/ institution especially regarding data.

There are many other ways of developing a research idea. These are just a few examples that will help the majority of junior researchers. Any curious and critical thinker will find many other ways of developing research ideas. While you are going through the process of developing a critical mind, you will find it frustrating that some clinicians come up with many research ideas while you struggle to find a single good idea. The art of developing research ideas comes with time and you only need one good idea to start with. Use those around you to help develop your idea: be alert.

**TIP:** If you think or hear of a good research idea, write it down. It is surprising how quickly you can forget the idea.

Once you have found a good research idea it would be wise to apply the FINER criteria to it.<sup>1</sup>

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1 Thabane L, Thomas T, Chengln Ye, Paul J. Posing a research question: not so simple. Can J Anaesth 2009; 56:71-79.

F: Is it feasible?	Can it be done in the time frame available? Are the data or enough patients available? Are data from a pilot study available?
I: Interesting?	Does it interest you? Does it interest your mentor? Does it interest collaborators?
N: Is it novel?	What does the literature say? What is the opinion of your mentor? Are others doing it in your institution?
E: Is it ethical?	Will the study receive ethics approval? Are there ethical obstacles?
R: Is it relevant?	Will it add to the body of knowledge? What is your mentor's opinion? Will this change practice? Will this lead to more/new research?

Once you have identified your research idea it will be to your advantage to brainstorm the idea with an independent group of researchers. A presentation of your idea will help you refine your idea and address some of the concerns you might have after applying the FINER criteria.

**TIP:** Brainstorming at the start leads to the development of a more precise research question and saves time later.

You now have identified a good research idea and need to develop a precise research question (Step 4).

Before you develop your precise research question it is advisable to find a good mentor or two to help you.

## STEP 2

### *How do you find a good mentor?*

You need to find a good mentor if you are going to successfully complete your research project within the timeframe required. Many senior researchers still have mentors to help guide them through the maze of developing research questions, designing the correct study, finding the funding and writing the resulting article(s). All researchers understand the value of brainstorming a research idea and developing the precise research question. You are not on your own and all researchers will be willing to help you.

#### **What makes a good mentor?**

A good mentor is someone who is already an established researcher but more importantly someone who is enthusiastic in helping junior colleagues with their research. A good mentor is willing to spend time with junior colleagues to help them develop their present research project and a future career in research and academic medicine.

 **TIP:** Senior researchers are always looking for young colleagues who are interested in an academic career especially those enthusiastic about clinical research.

#### **Should you have more than one mentor?**

Senior mentors, while willing to aid junior colleagues, often have many commitments and it may be difficult to meet with senior mentors on a frequent basis. Getting an appointment can be quite a challenge.

Working with an additional junior mentor can be very fruitful. The junior mentors are normally more accessible, are able to spend more time developing the necessary research tools (forms, applications, CRF's, data analysis) and help writing the resulting article(s). Junior mentors will also be more than willing to help you, as your research will also help to promote their research/academic careers.

Having more than one mentor is helpful as this exposes you to different aspects of critical thinking and ways of completing your research project. Different mentors can open different doors of opportunity during your research project as well as after you have qualified. Occasionally, mentors may have differing approaches (all of which may be valid), which can confuse you as you are developing your ideas.

**TIP:** Do not have too many (>2) mentors. This can be very confusing.

## What is the function of a mentor?

The functions of a mentor would include:

1. Guiding you to develop critical thinking.
2. Helping you to develop a precise research question.
3. Critically reviewing your research proposal.
4. Guiding you through the research maze to enable a successful submission to the ethics committee.
5. Aiding you in the following additional aspects:
  - Critically reviewing the literature.
  - Developing the case report form (CRF).
  - Facilitating access to a biostatistician, data management expert and others as needed.
  - Representing your interests within the Department to ensure that the Departmental resources are available which could include financial, secretarial, data capturing etc.
  - Accompanying you to discuss the involvement of other Departments/institutions.
  - Helping with analysis of your data.
  - Reading your thesis/article/poster critically and making constructive comments.
  - Assisting you in selecting a journal to submit your article to.
  - Guiding you through the article submission process.
  - Helping you respond to reviewers' comments.
6. A good mentor will find ways to sponsor your attendance to a scientific meeting to present your findings.
7. Most importantly a good mentor will build your research capacity and career.

## How do you find a good mentor?

Finding a mentor can be very difficult, daunting and challenging. Here are a few suggestions on how to find a good mentor:

1. Word of mouth. Fellow registrars and young researchers will be able to tell you from their experiences who are good mentors that enabled them to complete their research.
2. If you have a good research idea discuss it widely with many of the consultants and you will find some of the enthusiastic consultants. Approach those showing enthusiasm for your project.
3. You could also do a PubMed search on the research your potential mentor has published to see if your research interests overlap.
4. Approach an established research group and enquire if there is a member willing to act as a mentor.

## How do you approach a potential mentor?

Approaching a mentor can be quite intimidating as you might feel the mentor is so knowledgeable and your knowledge is quite inadequate. It is important to remember that all mentors also had to learn how to do research.

1. One of the least intimidating methods of approaching a senior mentor is to send the mentor a brief e-mail explaining who you are and a brief explanation of your research idea. You would request an appointment to discuss your ideas with her/him. This gives the mentor an opportunity to think about your research idea and involve other researchers/consultants if the mentor thinks they will be beneficial to your research.
2. Another approach is to carefully listen to consultants during ward rounds and at clinical and academic meetings. Consultants often mention research ideas that you might be interested in and where they are looking for junior researchers to help with the research. Approach them immediately and express your interest to be part of the research project.
3. Finally approach colleagues working in established research groups and enquire which projects they are busy with and whether there is a subsection of their research you could be involved in.

## How do you find a junior mentor?

When meeting with your mentor raise the issue of a junior mentor. Senior mentors often have junior consultants or senior registrars who they would like to involve. For the junior mentor it is also an opportunity to develop capacity. Senior mentors will often just be too glad to be able to involve a junior colleague.

## How do you get the most out of your interaction with a mentor?

1. Always prepare prior to a meeting. It is a great help to the mentor if you send a short summary of your research idea. Make a short agenda of what you want to discuss.
2. A mentor cannot resist helping an enthusiastic junior researcher/registrar who is making progress with her/his research. It is important to show progress (even if it is a little) especially when you are doing a difficult (time consuming) clinical rotation.
3. After each meeting with your mentor, send her/him a short summary of the main points you have discussed and action points of your decisions during your meeting. Remember, mentors have many other things to think about and have good but short memories – refresh the memory with an agenda for next meeting and summary/action points of previous meeting.
4. Make a schedule of regular appointments to discuss your research.
5. If a glitch arises in the course of your research or you experience personal

problems, contact your mentor immediately. She/he understands that research is unlike clinical medicine and does not have the same predictable course. (See Introduction 4: Roadmap of research)

6. Stay focussed on your research. Mentors, like everyone else, love winners. Once you have found a good mentor (s) you have accomplished a big step forward in completing your research project. Be sure you keep your mentor(s) informed all the way along the research path.

 **TIP:** A good mentor is not only essential for your research project but can help you with your career.

## STEP 3

### *How do you write a review of the literature for your proposal?*

This is a very important part of your research study. A literature review is needed to develop your research proposal, refine your methodology and analysis and is essential for writing up your research findings. It is important to understand the difference between a literature review and a review of the literature as an introduction for a research study.

A literature review of a specific subject (as often published in journals) has to be a comprehensive review of that subject.

But when you are doing a review of the literature for your study, you start by doing a comprehensive literature review of your topic to explore the knowledge available and identify gaps in the literature so that you can develop your research question. Then you can proceed with the review of specific parts of the literature for your research study focusing on your research question.

It is important for you to realise that a review of the literature is not something that is done once-off and then left as completed. The whole time while you are writing your proposal and developing your research idea, you go back to the literature that you have already reviewed, read some more, refine your summaries and add more articles to your review. There must be a thread that can be followed through your review of the literature and link to your research question, your methods, your variables etc. Everything must link up and therefore, often when you write your method section for example, you will look back at your review of the literature to ensure that it reflects what you mention in the method section.

This step will concentrate on developing review of the literature for a research proposal.

In a review of the literature for a scientific research proposal you must demonstrate that you:

- Understand the context of the research and where it is being undertaken.
- Are able to identify what is known/not known about the research subject.
- Identify key definitions and variables already established in the literature.

- Critically analyse the limitations and difficulties in previous studies.
- Identify research opportunities in the field.
- Justify your research question.

In addition to the above, a review of the literature is also useful in discovering information that can be used in sample size calculations, appropriate methodology, data collection tools and analytical methods. Therefore remember it is an iterative process – you do your review of the literature, but then when you come to sample size calculation, you go back to review of the literature to see what other studies have used for sample size. The same with data collection tools, analysis etc.

This is a daunting task and takes lots of practice to get the correct balance between too much and too little information. Your mentor will play an important role in helping you and giving advice on key articles to read.

**TIP:** Listen to your mentor more than you argue with her/him.

## How you do a literature search?

### 1. Have a clear understanding of your research idea:

To do an effective literature search you must have a clear research idea. This will help you develop key words to use in your electronic search. A published review article on your research idea is a good starting place to look for keywords. If you find relevant references in the review article, you must find and read the original articles – not all reviews quote the originals correctly! Do not restrict yourself to keywords from the review article. An advantage of using a few important articles when you do your literature search, is to see if your electronic search comes up with these articles and some other articles: if not refine your key words.

**TIP:** Start by looking at current review articles on the subject (Set PubMed to advanced search and choose review articles).

### 2. Where do you look?

The most commonly used electronic databases are PubMed, Google Scholar and the Cochrane library. It would be worthwhile to spend some time learning how to use these databases effectively.

By setting limits in PubMed, you get a focussed search. In PubMed the limits can be set under Advanced search (10 tips for navigating PubMed<sup>1</sup>).

<sup>1</sup> McGill University Health Centre. 10 Tips for navigating PUBMED [http://www.muhclibraries.ca/files/2013/06/PubMed-tips\\_May2013\\_EN.pdf](http://www.muhclibraries.ca/files/2013/06/PubMed-tips_May2013_EN.pdf)

**TIP:** Remember to record your search strategy.

It can be frustrating if you have seen an interesting article and you cannot find it again. One search is normally not sufficient: search and re-search should be the dictum.

Some of the newest data are not available in the formal scientific literature. To find such data you have to search other sources (grey literature) e.g. the incidence of tuberculosis (WHO Tuberculosis report).

### **3. How far back should you look in the literature?**

You should be reviewing the current literature. It is normally recommended that you use articles no more than 2-3 years old. Let the good studies you find, guide you to ensure you read all the current literature.

In clinical research it is important not to forget older studies. Good research ideas could be based on knowing older studies and using new technology e.g. using MRI scan in TBM.

If you find a large number of articles quickly read through the abstracts to see which articles might be relevant to your study.

**TIP:** Find a recent good review article and make sure your search includes all the relevant articles. If you want to quote an article mentioned in a published review, you have to read the original article carefully.

### **4. How should you read the articles?**

The articles of interest should be critically read with emphasis on:

- Summary of the article.
- Key findings.
- Methodology used.
- How the article relates to my study.
- Accurate reference.

**TIP:** Remember PICOT (Population Intervention Comparator Outcome Time) when reading the articles. (See Step 4: How do I develop a research question?)

**TIP:** Keep good accurate written notes on each article that you read.

### **5. How do you file the articles you have read?**

You will need the articles to develop your proposal, implement your study, refine your analysis plan and write your article(s). You must therefore file the articles so that they can be accessed, as you need them.

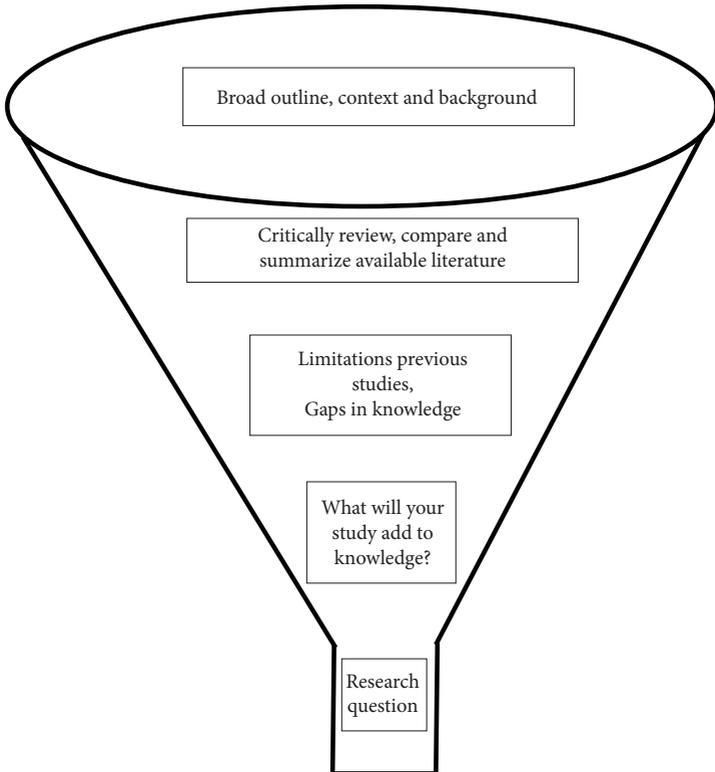
If you only have a few key articles you might want to just keep the hard copies. If you do a good literature search, you will discover a multitude of articles you need. It would be worth your while using an electronic reference manager. There are many commercially available reference managers (Papers, Endnote etc.). Mendeley reference manager is available as free software and is easy to use. (See appendix 2: Mendeley)

## How do you write a literature review for a research proposal?

An effective review will summarise all the current articles (2-3 years), critically review their content and point out the gaps in the literature requiring further research. The gaps then lead to your research question and what your study will potentially add to the literature.



Write a review in the shape of a funnel. Start with the broad issue (context) and narrow down (published studies) until you reach the most specific research issue which leads to your research question.



## How do you write the first draft?

**TIP:** Unless you are a genius and a cross between a person awarded the Nobel Prize for Science and a person awarded the Nobel Prize for literature, do not try to write your first draft in perfect language. First sit (or walk or ride your bicycle) and think about and then write down an outline of all the points you want to make. Once you have thought well, it is easier to write – but still do not allow yourself to get writer’s block because you cannot find the perfect word or sentence. Just write down your thoughts.

*“I don’t mind that you think slowly but I do mind that you are publishing faster than you think”.* Wolfgang Pauli, physicist, Nobel laureate (1900-1958).

This quote applies not only to publishing, but also to writing – do not write faster than you think!

*First paragraph:*

This paragraph should give a broad outline of the problem, the context in which the study is being done and the background to the problem.

**TIP:** Beware of overused statements: “One third of the world’s population is infected with tuberculosis”. This is common knowledge and does not grab the reviewers’ or readers’ attention – in fact, it is just boring.

**TIP:** Just like in clinical medicine where you have only 2 or 3 minutes to gain the trust of your patient, when you write, you have 2 or 3 sentences in the first paragraph, to grab the interest of the reader/reviewer.

*Second (and perhaps third) paragraph:*

This paragraph(s) narrows down to the published research in the area you are interested in. Here you critically review the available knowledge. Compare and contrast findings by groups of authors (and give references as 3-7) rather than mentioning each study separately. Combining the findings of various published studies requires careful synthesis and understanding of the available literature. It is often useful to make a template with a row for each reference you use and a column for each of the PICOT “categories”. Such a template often makes it much easier to group the literature together. These paragraphs show whether you have insight into and have really thought about the studies that you refer to.

*Third and fourth paragraph:*

This paragraph(s) now narrows down even further with a critical analysis of the limitations of previous studies or gaps/opportunities in the literature.

 TIP:

Look at previous published studies carefully and you will see that they usually mention their limitations in the last few paragraphs and often also mention future research ideas.

*Fifth and possibly sixth paragraph:*

This paragraph(s) should now make it absolutely clear exactly what your study is about as well as what it will add to the literature. Included in these paragraphs should be your research question.

## **What are common mistakes in writing the review for a scientific research proposal?**

*1. Too much data/information:*

If there is too much data/information, especially when there is no clear connection between the various studies reviewed, you will lose your reader and not build a logical train of thought. This especially occurs if you do not synthesise the findings of the different studies.

*2. Too little data:*

It is often incorrectly assumed that the readers know the field and scientific issues being discussed. Be careful not to make jumps in logic. You need a good balance between too much and too little data: rather err on the side of too much data.

*3. Unclear exactly what your study will contribute to the literature:*

Be very clear exactly what the gaps/limitations are in the literature and how your study will address these gaps/limitations.

*4. Confusing structure of the literature review:*

Think through very carefully the structure of the review. Make sure there is a common thread running through the review. Your review is part of your research proposal and not a stand-alone review. Avoid mentioning facts in your literature review that you never refer to again in the methods, limitations, analysis of your research proposal.

*5. Avoid personal anecdotes:*

This is a scientific review and anecdotes should be avoided. If you have completed a pilot study you might consider adding some of the possible outcomes but rather save this for the feasibility section of the proposal.

*6. Avoid duplication.*

*7. Get an early evaluation of your scientific review of the literature from your mentor.*

This will help you refine your review before you re-write it.

8. *Re-evaluate and re-write.*

Unluckily most of us have to re-write the review a number of times.

9. *And lastly* – remember that your literature review is a constant process – by the time your proposal has been approved by the Ethics Committee, the chances are good that new studies have been published since you wrote your proposal. Before you implement your study, ensure that you are still up to date with the literature and if you have kept a record of your search criteria and key words, this is easy! Keep up with the newest literature throughout your study.

10. *PUBMED and OVID can be programmed to give you automatic literature updates.*

 **TIP:** The C's to help you with your scientific review<sup>2</sup>:

**Cite:** Stick to cited articles or information sources, as they are your facts. Avoid personal opinion.

**Compare:** Compare different articles to each other looking for agreements and disagreement.

**Contrast:** Look for articles that disagree and contrast the strengths and weaknesses leading to research opportunities.

**Critique:** Identify what are the gaps in the literature and what are the research opportunities.

**Connect:** Synthesise what you have learned. How does this lead to your research question?

**Concise:** Keep your review to the point and avoid duplication.

**Construct:** Construct your review that it is orderly and systematic with a thread leading to your question (Funnel approach).

**Check:** Check that you have the newest information and re-check prior to writing your paper.

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2 Adapted from: Literature review: academic tip sheet.. Edith Cowan University. Australia  
[http://intranet.ecu.edu.au/\\_data/assets/pdf\\_file/0011/20621/literature\\_review.pdf](http://intranet.ecu.edu.au/_data/assets/pdf_file/0011/20621/literature_review.pdf)

# STEP 4

## *How do you develop a research question?*

Congratulations by now you have identified your research idea and hopefully found a mentor to facilitate your research. What follows is one of the most important aspects of all good research: developing the precise research question. The reason why this process is so important is that it determines exactly what you are going to research, which population, what methodology you will use, which variables you will examine and which outcome you will measure. By asking a precise research question you are then able to ensure that all the participants that need to be examined are included in your study. The process of defining the precise research question takes time and often needs to be refined many times.

Defining your research question is not an activity in isolation – the research question is the first step of linking your research idea to how you will do your research, which data you will collect and what you will measure/compare. A precise research question eliminates uncertainties, decreases the number of weaknesses of the study and forms the basis of a clear publishable article.

**TIP:** The basis of research is to compare. Purely describing something is not research.

Example: If you drink a glass of red wine and you say: “I am drinking a glass of red wine”, it is purely describing what you are doing and is not research. However, if you say: “I am drinking a glass of excellent red wine”, you are doing research, because how do you know the glass of red wine you taste is excellent? You compare it to other glasses of wine you have tasted and therefore you can make a statement that it is excellent.

Your research question will clearly identify the two essential elements of your hypothesis:

1. the key determinant and
2. the primary outcome.

These are the elements you will use when you decide on what type of study to do and to develop your two-by-two table (Step 5).

As an example: in a study comparing oscillation to conventional ventilation of HIV infected children suffering from PJP, the key determinant would be type of ventilation and the primary outcome would be death.

There are numerous aids to help you develop and define your research question and many are known by their acronyms: PICOT<sup>1</sup>, PESICO<sup>2</sup>, SPICE<sup>3</sup> etc. The acronym we have chosen to use in this manual is the PICOT criteria as this is widely known and used. The acronym PICOT stands for:

**P** = population (The exact population you are going to study, who are you including and excluding, is your population representative of the population you would like to apply your findings to.)

**I** = intervention (The intervention might be a drug, new technique, new test or treatment regimen etc. In clinical research you will often not implement a new intervention, but will measure the effect of various variables, which can be viewed as biological “interventions”, on the outcome.)

**C** = comparator (Which group of patients are you comparing to which other group? Premature babies born in hospital to those born outside the hospital, TBM treated medically to those treated surgically, HIV positive to HIV negative children etc.)

**O** = outcome (What is the outcome you want to measure? Mortality, duration of hospitalization, time to diagnosis, symptom free etc.)

**T** = time (Over what time period are you going to include research subjects in your study?)

 **TIP:** PICOT analysis is also valuable when you are critically evaluating an article to ensure that all the aspects are addressed in the article.

*Examples of how to use PICOT:*

**P:** The population refers to the study population (also known as a sample). If your study population are all premature babies admitted to a hospital and you go to the ward where such babies are usually admitted to find them, you might miss some premature babies admitted to the paediatric surgical ward, the overnight wards or those babies discharged over the weekend. By being more precise you can limit bias by ensuring the population you are investigating all have an equal chance of being included in your study. By being more rigorous you would then

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1 Thabane L, Thomas T, Chenglin Ye, Paul J. Posing the research question: not so simple Can Anesth (2009) 56:71–79

2 Schlosser RW, Koul R, Costello J. Asking well built questions for evidence base practice in argumentative and alternate communication. J Commun Disord 2007; 40: 225-228.

3 Booth A. Clear and present questions: Formulating questions for evidence based practice. Library Hi Tech. 2006;24:355-368

for example define the population to the premature babies born in the hospital between Monday morning at 08h00 and Friday afternoon at 16h00 admitted to a specific ward. You will have to carefully think about the above inclusion criteria to prevent bias.

**I:** If you do an intervention study, the intervention must be clearly defined. If you are studying oscillation as an intervention the indications for oscillation must be clearly defined. You might need to discuss the indications with the PICU team to make sure they are widely accepted and going to be uniformly applied. If the indications for oscillation are not clearly defined and applied this will lead to bias.

**C:** The group of patients you are going to use to compare to the group receiving the intervention needs careful thought. They need to be representative of the whole group from which those with the problem you are studying are coming from. Careful thought needs to be given to this group.

**O:** The outcome should be a hard outcome and clearly defined. In your oscillation study death would be a hard outcome. Time to extubation would depend on many variables e.g.: preference of the clinician, how busy the ICU is, day or night shift etc. This would be an interesting outcome but highly dependent on many other factors (known as confounding variables).

**T:** The time for including subjects needs to be carefully thought through. At night the admission ward where you are recruiting babies might be run by less experienced medical officers compared to experienced specialists during the day. Your outcomes could vary according to time of admission and not to your intervention.

You must be prepared to critically think about your research question, discuss it with colleagues and be prepared to revise your question. After a discussion with a senior colleague/mentor you might be surprised how much the exact research question (not necessarily your research idea) has changed and needs to be revised.

Clinical researchers will not only be interested in the primary outcome. You might not only be interested in the deaths among those receiving an intervention, say ventilation (oscillation vs. conventional ventilation) of HIV positive children treated for PJP, but would also be interested in many important secondary outcomes. Examples of secondary outcomes could include duration of assisted ventilation, duration of supplementary oxygen required, duration of hospitalization, survival one year after discharge, those diagnosed outside your hospital vs those diagnosed within the hospital, etc. All these aspects must be thought of when designing your research question to ensure that the data to answer these secondary outcomes are also included in the case report form (CRF). Remember

you might not be able to answer all the secondary outcomes that are interesting as the data might not be available or your study might not be powered to answer the question. If however you have not collected the data you will never be able to answer the questions.

**TIP:** Although it might be interesting to answer numerous secondary outcomes, collecting the extra data might not be feasible or practical. Moreover, it is not justifiable to consider that, if your primary question does not 'pan out', you can probably find another result that will be significant. This is not research, it is a 'fishing expedition'. Therefore think carefully and limit the number of secondary outcomes.

**TIP:** Your research idea might lead to numerous excellent and exciting research questions. Choose to do one that excites you and is feasible. You might be able to interest another researcher or registrar to do a separate aspect of the study. You will both gain from this collaboration. You might even be able to answer the rest of your research questions as a senior registrar or consultant.

**TIP:** Be prepared to revise the precise research question many times. It is worth the effort and will reward you later.

# STEP 5

## *What type of research study should you do?*

You must choose your type of research study based on practical as well as scientific aspects.

### **Practical aspects:**

Your study must be do-able (feasible) in the available time that you have. This usually means that you must either use already available data, or that you must link-up to an ongoing study with a “platform” onto which you can easily add a few additional questions. It also for example is not a good idea to start following up a group of children collecting data on them and then run out of time and resources. Now is a good time to look at the timelines in Introduction 3 “How much time do you need?” The worst thing that can happen is for you to start collecting new data and then to realise that you cannot get data on enough children or for a long enough time to make the study scientifically sound.

### **Scientific aspects:**

Studies are broadly divided into quantitative and qualitative science:

1. Qualitative studies focus on the analysis of social aspects of diseases and do not involve numbers or statistical methods.
2. Quantitative studies focus on numerical measurements and the data obtained are analysed using statistical methods.

This manual focuses exclusively on quantitative studies. If you want to do a qualitative study, you must get expert advice from and collaborate with social scientists.

Most quantitative studies have two components namely descriptive and analytical. However, to keep it simple, we classify quantitative studies into two main types of studies namely:

1. A descriptive study provides summary information on the data collected. This might be in the form of descriptive statistics such as frequencies, means, minimum or maximum values or graphs such as a bar chart. Case reports and case series are special types of descriptive studies and fall into this category. By far the most descriptive studies and case reports will not be sufficient for you to register at the HPCSA and therefore should not be considered.

2. Analytical studies in which variables are compared to an outcome and comparisons made between those who have a specific variable and those who do not have the variable. There are two types of analytical studies:
  - a. Observational (association or comparative) studies e.g. cross-sectional, case-control and cohort observational studies where a specific intervention is not implemented, but where variables (e.g. HIV status) are collected and the outcome (e.g. death) is measured and comparisons made between those with and those without the variable (HIV+ or HIV-)
  - b. Experimental (interventional) studies e.g. randomized control trial where a specific intervention (e.g. a new drug) is implemented and the outcome measured. These are usually prospective cohort studies and not something that junior researchers should do as their first study.

## Descriptive studies

An example of a descriptive study is a case report of a child with a specific condition but without comparing it to what is known in the literature and without stating why this child's presentation is different from what is known. Another example will be the description of how many children were admitted to Tygerberg Children's Hospital and how many of these were HIV infected and merely stating that 100 children were admitted of whom 15 were HIV infected. In this example there is no comparison with data from other hospitals, or with data from previous years or comparing the clinical outcome of the infected and uninfected children etc. The art of research is to develop a critical and inquiring scientific mind and to ask a question that will allow you to do a comparison and to calculate risks, ratios etc.

For a fun example and a real quick read just to see how a simple observation that teaspoons disappear in the tearoom, could be changed into a comprehensive and proper analytical research study. Look at this article published in the BMJ<sup>1</sup>

## Analytical studies:

An analytical study is a study where a deduction is made using a statistical method. An example of this will be to use the data of the 100 children admitted to Tygerberg Children's Hospital (as above) but to calculate and compare the proportion of children with TB in the HIV infected and HIV uninfected children. In this example HIV status is a single variable (the key determinant or independent variable) and TB status is the primary outcome (dependent variable). The two proportions say  $2/85 = 0.024$  (or 2.4%) in the HIV uninfected group vs  $2/15 =$

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1 Megan S C Lim, Margaret E Hellard and Campbell K Aitken. The case of the disappearing teaspoons: longitudinal cohort study of the displacement of teaspoons in an Australian research institute. *BMJ* 2005;331:1498-1500 or on [http://www.biostat.jhsph.edu/courses/bio622/misc/Disappearing\\_teaspoons.pdf](http://www.biostat.jhsph.edu/courses/bio622/misc/Disappearing_teaspoons.pdf)

0.133 (13%) in the HIV infected group are then compared with a formal statistical test. The deduction or inference is then made on whether this difference is significant or not.

Fortunately there are only a limited number of analytical study designs and in this step we will concentrate on observational studies where you as a young researcher will not implement a specific intervention, but will collect data and do comparisons/measure associations between a variable and an outcome.

The study design will determine the statistical methods used to analyse your research question. The study design provides a framework for carrying out the research in a systematic way and addresses the two essential elements identified when you developed your research question (Step 4) namely:

1. the key determinant and
2. the primary outcome

*There are four standard types of study design:*

- Cross-sectional design
- Case control design
- Cohort design
- Randomised control trial (not discussed in this guidance as this is not the design a young researcher should select for her/his first study).

There can be a great deal of confusion and discussion around exactly which design will be the best to answer a specific scientific question, even among highly qualified experts. You need to know the basics about study design and an easy way is to develop/draw a simple two-by-two table with 4 blocks ( see also Appendix 3), which will form the basis for your study design, sample size or power calculation and the most basic analysis.

		Know Outcome	
		Pneumonia	No pneumonia
Know Determinant	(HIV+)	a	b
	(HIV-)	c	d

The four categories found in the two-by-two table are:

- Those with the determinant and the outcome of interest (a);
- Those with the determinant and without the outcome (b);
- Those without the determinant and with the outcome (c);
- Those without the determinant and without the outcome (d).

For example, if your question is whether children who are HIV+ more often have pneumonia than children who are HIV-, you can use any of the three basic study designs all with specific advantages and disadvantages.

### Cross-sectional study design:

Relevant when the target population is studied at a certain time or during a specific period of time and when you know the determinant and the outcome at the same time.

		Know Outcome	
		Pneumonia	No pneumonia
Know Determinant	HIV+	a	b
	HIV-	c	d

You will for example make a list of all the children in the hospital on a specific day/for a specific period of time and from this list you will know the HIV status and whether each child had pneumonia or not and you will classify each child at the same time according to the determinant (HIV+ or HIV-) and the outcome (pneumonia or not pneumonia). There is no longitudinal component. A cross-sectional study differs from a case-control study in that it provides data on the entire population under study (all children in the hospital on a specific day or during a specific period of time), whereas case-control studies include only individuals with a specific outcome (the cases or those with pneumonia), with a selection, often a tiny minority, of the rest of the population (the controls or those without pneumonia).

Cross-sectional studies are important and often the first evidence of associations. For example, the first reports of the association between smoking and lung cancer and also the association between phototherapy and the improvement in neonatal jaundice, were from cross sectional studies.

*Advantages of cross-sectional study design:*

- Simple and easy to collect the data.
- Not expensive.

*Disadvantages of cross-sectional study design:*

- Chronological sequence of events cannot be observed - can only calculate prevalence of pneumonia and HIV status and infer whether there is an association between the two. One cannot determine causality.
- Dependent upon information already recorded with all its existing flaws if one uses already collected data.

*Statistics for cross-sectional study:*

- Calculate prevalence or proportion and also report precision in the form of confidence intervals.
- Should adjust for confounders that could explain part of the association found between the key determinant and the outcome.

**Case-control study design:**

**TIP:** This is the only way to study a rare condition.

The case population (e.g. children) is selected according to the rare outcome you want to study. For the example we will use a really rare disease, so let's study Nocardia pneumonia.

		Select on Rare Outcome	
		Nocardia Pneumonia	No Nocardia pneumonia
Determine whether determinant was present	HIV+	a	b
	HIV-	c	d

You can get access to the information of the children with this rare outcome that has been collected over a known period of time. You include all the cases (those with Nocardia pneumonia) and select the controls (those without Nocardia pneumonia) usually on a 1:3 ratio and collect the same information from the controls as well. The interest in a case-control study is usually a variable that represents exposure in some way. In our example this exposure could be HIV infection. Therefore for each child (cases with Nocardia pneumonia and controls

without *Nocardia pneumonia*) determine the exposure status (HIV+ or HIV-). If a larger proportion of the cases (*Nocardia pneumonia*) have the determinant (HIV+), then there is an association between the determinant (HIV+) and the outcome (*Nocardia pneumonia*) and the hypothesis is valid. The variables can again be cross tabulated in a 2x2 table.

Because you have to obtain cases and select relevant controls for a case-control study, you must think about the selection criteria very carefully and state these very clearly. The controls must be exactly the same as the cases, except for the primary outcome of the study. For example, you can select children who have *Nocardia pneumonia* and are in the hospital as cases and compare them to children without *Nocardia pneumonia* who are also admitted to hospital over the same period as the cases. The assumption is that children admitted to the hospital come from the same communities served by the hospital. Because there will be more children without the rare disease you can select more of them. A ratio of 3 controls for every 1 case is a good option. For example you would select 50 children in hospital who had *Nocardia pneumonia* and 150 children in hospital who did not have *Nocardia pneumonia* and look into their hospital files and determine which children were HIV+ and which were HIV-.

*Advantages of case-control study design:*

- Only practical study design to use for studying rare condition.
- Quick and relatively cheap.
- Sample size is economical.
- Easy to identify cases.
- Incident case will allow good planning.

*Disadvantages of case-control study design:*

- Cannot study the sequence of events and therefore cannot conclude whether or not a determinant is a cause.
- Cannot measure incidence.
- Difficult to ensure representative controls.
- Non-standardised methods of measurement if using already collected data.
- Data on exposure of interest not complete or not available on controls.

*Statistics for case control study:*

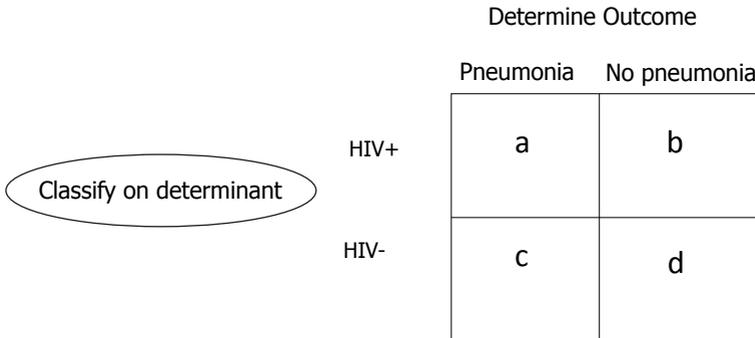
- Calculate prevalence or proportion of the exposure in the cases and the controls
- Calculate the odds ratio of disease in the cases and controls with 95% confidence interval

**TIP:**

When the sequence of events cannot be studied, it is not possible to determine causality. For fun go to <http://tylervigen.com/> to see how careful one needs to be about associations.

## Cohort study design:

The population (e.g. children) is classified according to the presence of the key determinant of the study at baseline into two groups (for example, HIV+ or HIV-) at the time the study is started, and then all the children are followed over time to determine the outcome (pneumonia or not pneumonia). The timeframe will depend on the expected incidence (of the outcome) in the two groups.



You can do a prospective cohort study by starting at a specific time and collecting information of all children admitted to the hospital and classify them as they are admitted into two groups as having the determinant or not (HIV+ or HIV-) and then follow them over time to see who will develop the outcome (pneumonia). The risk of doing a prospective cohort is that you may end up spending a lot of time and in the end not have enough children (not enough power due to a small sample size) to reach a conclusion or, you can classify a number of children but not be able to follow them up to determine if they develop the outcome (they move, they die, cannot be traced).

Another way of answering your question using a cohort design will be to do a retrospective cohort. For this design you use already collected data of all children admitted say in 2008 and classify them into those with and without the determinant (HIV+ and HIV-) and use the already collected data to determine the outcome (those who developed pneumonia or not pneumonia from 2008 until the time when you do your study). If more children who were HIV+ developed pneumonia than those who were HIV-, there is an association between the determinant (HIV+) and the outcome (pneumonia) and the hypothesis is valid.

### *Advantages of cohort studies:*

- Sequence of events can be observed.
- Incidence (Rate) can be calculated.
- Several determinants can be studied simultaneously.
- Standardised methods can be used to measure.

*Disadvantages of cohort studies:*

- Large population required especially when the outcome is uncommon or when several determinants are considered.
- Long time-scale.
- Expensive in resources.
- Drop-outs from cohort over time may bias results.
- Standard methods and criteria may drift.

*Statistics for cohort study:*

- Calculate incidence and precision.
- Calculate risk measures such as risk difference, risk ratios or hazard ratios if time to event is known.

## **International Standards for reporting studies:**

To ensure that reported studies comply with international standards there have been numerous statements and checklists developed. These guidelines have been developed for various study designs. There is even a guideline for reporting case reports. It is useful to look through the checklists of these guidelines to ensure that your study design complies with the requirements so that you can later easily publish your research.

We found the STROBE statement the most useful as this gives guidance for case-control, cohort and cross sectional studies.

*The following are just a few of the published guidelines:*

1. STROBE: Observational studies in epidemiology  
[www.strobe-statement.org](http://www.strobe-statement.org)
2. CONSORT : randomised case control studies  
[www.consort-statement.org](http://www.consort-statement.org)
3. CARE: reporting case reports  
[www.care-statement.org](http://www.care-statement.org)
4. PRISMA: systematic reviews and meta-analysis  
[www.prisma-statement.org](http://www.prisma-statement.org)
5. STARD: diagnostic tests  
[www.stard-statement.org](http://www.stard-statement.org)
6. SQUIRE: effectiveness of interventions to improve care  
[www.squire-statement.org](http://www.squire-statement.org)

There are many other available guidelines for genetic, economic studies etc.

## STEP 6

### *When do you need to involve a statistician?*

Once you have developed your research question and carefully thought about the methodology it is time to consult a biostatistician. You might think this is too early, as you have no data but the biostatistician will need to help you with the study design, a data analysis plan and calculating sample size for your study.

It is very distressing if after all your efforts of collecting the data you find that your results are not able to fully address your research question due to a shortcoming in your design or are inconclusive because your sample size was too small. These are important reasons why you consult before finalising your proposal and embarking on your study.

Even if your study is a descriptive study, an audit or a case series it is still worthwhile discussing the study with a biostatistician. For these studies we normally use descriptive analysis but doing comparisons within the studies enriches these studies. This is where the biostatistician will help.

Statistical programs are widely available for doing a sample size calculation or analysis. You can certainly use these but getting advice from a statistician will help you to avoid studies that are too small or too large, incorrect statistical analysis and embarrassment when your article is reviewed.

**TIP:** To ensure that you can have a good discussion with the biostatistician, read through studies that have done something similar to what you want to do and give good attention to the study design, samples size and analysis that those researchers have used.

**TIP:** You and the biostatistician are both novices! You are a novice since you are not a statistician and the statistician is a novice since he is not a clinician or basic researcher. Do not confront the statistician with the most technical stuff – keep it basic from him/her to get an understanding of what it is you want to do. Who, what where, when and how are you going to measure and obtain your data? The consultation between you and the statistician is a process to understand what each one of you is talking about.

**TIP:** To understand some of the concepts the statistician will be talking about the basic vocabulary (Appendix 4) is a useful resource. Print out and read the glossary of statistical terms prior to meeting the biostatistician.  
Link to statistical glossary  
<http://www.csm-oxford.org.uk/statistical-resources/statistical-glossary/>

**When you go and see the biostatistician you should have a clear idea of the following:**

1. The study design you intend to use. The biostatistician will be able to help you with the study design if you are uncertain.
2. The level of significance you require. This is normally set at  $p < 0.05$
3. The power required. This is termed a type II error and is normally set by convention at 90%.
4. The magnitude of the difference you expect between the 2 groups you are investigating. This can be very frustrating as this difference is often not known and this lack of knowledge is the reason for you doing the research. You will then have to use the published data or your clinical experience to make the educated guess. Often your mentor will be able to help you with this aspect. If you are investigating the difference in the complication rate that arises post operatively in patients that are HIV infected compared to those uninfected, the literature might indicate that the difference is 3 fold greater while your clinical experience indicates a 7 fold difference. With the aid of the biostatistician you might agree to set the magnitude of difference at 5 fold. (the larger the difference the smaller the sample size required)
5. Some idea of your analysis plan. What are the primary and secondary outcomes and what variables do you intend to collect?
6. What database do you intend to use. Some databases are easily compatible. You will save a lot of time if your database is compatible with the database used by the biostatistician.

Once you have discussed the primary outcome you might then discuss if you will be able to show a statistical difference for your secondary outcomes. The statistician might indicate that you have to enlarge your sample size to ensure statistical significance for secondary outcomes. You might then decide whether this is feasible or not.

In some cases it might be necessary to do a pilot study to collect some data to inform the calculation of the sample size. A pilot study can also be valuable in suggesting additional variables that should be collected.

**TIP:** See the biostatistician early. You cannot fix a flawed study after you have completed it.

You will need to visit the biostatistician again during the data analysis step.

### **What do you need for before you revisit the biostatistician?**

1. Clean your data to make sure your data is correct and that you do not have missing data or incorrect data. (See STEP 12)
2. Your final analysis plan.
3. What help you will require from the biostatistician when you write up/report you study. You may want him/her to help you with a specific analysis that might not be expected from you as a non-statistician.
4. Your expected timelines. You cannot expect the statistician to perform a miracle a day before you have to submit some report or conference abstract.

 **TIP:**

Always have a look at a summary of your raw data before you visit the biostatistician. You might see some interesting findings.

Once you have completed your first few drafts of your article remember to involve the biostatistician again to ensure that the description of the statistical analysis is correct. Remember the biostatistician needs to be included as an author on the paper or acknowledged in the paper for his/her help.

# STEP 7

## *Why do you need to write a proposal?*

- Your proposal is the document that states exactly the reason why you want to do the research and exactly what you are going to do.
- Your proposal is also the document that you will submit to the ethics committee and to Tygerberg Children’s Hospital or the Department of Health to get the necessary approvals and permissions to do the study.
- Lastly your proposal is the plan that you will follow during your research and you should constantly ensure that you still do what you originally stated you would do – this is what you will get ethics approval for. If during the course of your research, you want to change anything in your proposal (except the literature review) you HAVE to get permission from the ethics committee first.

### **A few important things to remember when you want to start writing your proposal:**

- Before you start writing your proposal you should already have:
  - Selected your mentor
  - Discussed your study with a biostatistician
  - Done your literature review – at least the first draft of the review
- It is jolly hard work to write a proposal (or in fact to write anything). The reason is that you have to be in a permanent state of critical thinking and of criticizing your own writing.

*“If any man wishes to write in a clear style, let him be first clear in his thoughts”.*

Johann Wolfgang von Goethe 1749-1832

- Your proposal should be the “critical path” of your research and should read like a story with a nice easy and logical flow to it. Do not distract from the flow by putting in too much detail– the detail should go into the appendices.
- To make things easy for you, we include an appendix with the outline of a proposal (Appendix 5) and a formatted template for easy use (Template 1). The proposal outline/framework and the template are standard and all the aspects in the outline and must be in your template proposal.
- The template has been formatted to make it easy to use. If you mess up the formatting – you are on your own.
- The wrong thing to do is to just take the template and start filling in all the different sections without thinking the whole time. The writing is the quick

part, the thinking takes much longer.

- Also included is a template of what you should include in your CV (Template 2).

*“I don’t mind that you think slowly but I do mind that you are publishing faster than you think”.* -Wolfgang Pauli, physicist, Nobel laureate (1900-1958). This is exactly the same quote as used in the Literature review (Step 3) – throughout your process of writing and publishing, remember to think and not go into auto-pilot writing style!

- Once you start writing remember:
  - Do not make up new abbreviations – use only globally accepted abbreviations and limit the number used.
  - Use consistent terminology – this is actually quite boring, but it is more important to write clearly than to write beautiful literature. Scientific writing is a new skill you have to develop. At school you were taught to write in descriptive terms and not to use (for example) the same word too many times. Your teacher probably told you that if you want to write a beautiful essay about nature to use different words to describe the vegetation – trees, plants, shrubs, flowers etc. In scientific writing you must define exactly what you mean by “a tree” and then ensure that if you talk about a tree, that your readers know that a tree is only a tree and not a shrub or a piece of vegetation or a flower. Use consistent terminology and define what it means. For example define for YOUR study what you define as pneumonia – is it a child with symptoms of pneumonia? Or a child with radiological features of pneumonia? Or a child with bacteriological confirmation of pneumonia? Define it once and then use the term consistently to mean only as you have defined it.
- Writing a proposal is not a one-direction activity – rather it is an iterative process. You start with the literature overview so that you know what knowledge is available and where the gaps are. Then you develop your research question/aim/hypothesis and read your literature review again to ensure that you in fact have addressed the knowledge aspects needed for your question/aim/hypothesis. Then you develop your methodology and once again you go back to ensure that now your literature review contains the necessary information from previous studies on the methodology relevant to your study and ensure that the question/aim/hypothesis still fit with the methodology. Often one has to adapt aspects of the literature review to fit the question/aim/hypothesis at this stage or adapt the methodology and especially the data collection to ensure that you will collect the correct variables to answer the question/aim/hypothesis.
- The points made in this step and appendix 5/template 1 can be viewed as a recipe – this step is the overall method while the appendix/template contains

all the ingredients and the detail of how to use the ingredients together (Some advice from the experience of cooks who have made many spectacular flops in the past and who now after many years, know what works: “Read the recipe for a quick overview, but buy the correct ingredients and exactly follow the instructions how to mix ingredients”. So we advise you to not make the same mistakes – rather use the appendix/template given in this manual).

*“Learn from the mistakes of others. You can’t live long enough to make them all yourself”.* (Eleanor Roosevelt)

- In your proposal you have to write which data sources you are going to use and how you will collect the data (see Appendix 7 for tips on data collection tools). However, the detail of the data, the variables, the data dictionary etc. should be added as appendices in your proposal.
- The proposal should follow a logical sequence and contain enough information to assure your mentor and the ethics committee of the need for the research, its scientific validity and your ability to do the research.
- Each proposal must have a budget – see Step 8 and template 3 which will give guidance regarding the budget which should be added as appendices to your proposal.
- Once you have written the whole proposal, it is a good idea to give it to a colleague to read and critically evaluate.
- Remember that your proposal should be so clear that anyone can understand and follow it easily.

*“We should not write so that it is possible for the reader to understand us, but so that it is impossible for him to misunderstand us”*(Marcus Fabius Quintilianus c. 35-100).

- Once you think your proposal is complete, you have to read it again a couple of times. This is really difficult and remember:

*“Hell – is sitting on a hot stone reading your own scientific publications”* (Erik Ursin).

Do not try to read only once or twice – read specifically for each of the aspects listed below:

- ▶ Read once for good science and flow, use PICOT and ask the following questions:
  - Does my literature review fit with the question/aim/hypothesis?
  - Did I define the study population including controls? (P and C from PICOT)
  - Did I clearly define the variables and the outcome? (I and O from PICOT)
  - Are my study methods, time period and data collection sufficient to answer the research question? (T from PICOT)

- Are there any biases?
- Are there any confounders?
- Will I be able to collect the data and finish in the time available?
- ▶ Read once for spelling and grammar and ask:
  - Did I use consistent terminology?
  - Did I use terms that I am not even sure what they mean? If so, delete these terms and use different terminology which you clearly define.
  - Are there parts that are duplicated?
  - Did I go off on a tangent that has nothing to do with my main research question/aim/hypothesis? If so, delete the tangents.
  - Are there clear headings and sub-headings?
- ▶ Read once to check references.
- ▶ Lastly, print out proposal and page through asking:
  - Does this look like a professional document?

Lastly *“Easy reading is damned hard writing”*. (Nathaniel Hawthorne 1804-1864)

## STEP 8

### *How do you write a research budget?*

Even though you will not necessarily apply for external funding, you should set up a full budget. When applying for external funding you have to account for your time with certain aspects/line items as “in kind” items – e.g. the time that you will spend on the study and on writing up the results etc. Setting up a budget is interesting as it illustrates how expensive research actually is. Each research study should have a budget to ensure that all the costs are covered: even simple research studies cost money (stationery, printing costs, secretarial help etc.) When drawing up a research budget, you must specify each item of expenditure required to conduct the study, even if the cost is covered “in kind” as above. You should also specify any additional funding required e.g. external hard drive. This helps to provide a realistic appraisal of the cost of undertaking the research.

### **Is there funding available for your research?**

Find out from your mentor about funding opportunities, especially small funding opportunities within the Faculty (e.g. Harry and Doris Crossley Funds). There are many opportunities for funding for short-term research assistants, travel and consumable items.

Your mentor will also indicate which costs the Division/ Department will help fund.

If you plan to publish your final article in one of the on-line open-access journals, there will be costs associated with the publication. Stellenbosch University supports open access journals and will fund the proportional publication cost for the Stellenbosch University authors.

### **What budget must you submit with your research proposal to the Ethics Committee?**

You must submit the following:

- A line by line budget on the template provided (Template 3). You can download the .xls template from [www.sun.ac.za/paediatrics](http://www.sun.ac.za/paediatrics) but be careful not to mess up the coding and formulae in the template.
- A narrative budget justification in which you motivate each line item in the budget.

## Advice on how to complete your budget:

Expenditure should, as far as possible, be given in units (hours, trips, kilometres etc.) For example, salaries can be calculated against full time equivalents or per hour according to qualifications.

These are the standard categories in a research budget and each category can have many line items:

- **Personnel**

This includes all staff who will work on the study. Think whether you have to budget for secretarial staff, data capturers, biostatistician, research assistant etc.? List all staff who will be involved in the study, either as full time equivalents or according to the time they will spend in the study. This is calculated as:  $\text{annualized base salary}/12 \text{ [}/\text{months]} \times \text{number of months appointed to project} \times \text{percentage effort (time allocation e.g. 0.2 or 20\% if one day per week is spent on the research)}$ . If you have to appoint additional staff like a research nurse, you should consult the human resources officer regarding job descriptions, level of experience required and salary levels. You should also remember that you have to manage all the staff on the research study and define their roles and responsibilities.

- **Travel and accommodation**

Travel should be planned in advance – e.g. presenting at a conference or travelling to sites away from campus to collect data. When applying for funding make sure what the research fund will allow. Some will not fund capital equipment, travel or staff. Adjust accordingly.

- **Equipment**

The budget should include all equipment required to undertake the project and should include costs related to the research “office” (laptop, printer, extra external hard drive for storage, filing cabinet etc.) as well as those related to research work (e.g. scales if you are going to weigh babies in their homes).

- **Materials**

Basic supplies e.g. stationery (paper, printer ink cartridges, folders, pens, lever arch files), consumables.

- **Other costs**

Ethics review – At Stellenbosch University this amounts to R3000. However, postgraduate students or studies funded by internal funds are exempt from this fee. Consider communications, internet costs, rentals, honorariums, training, contracting service providers.

Also consider the following:

- o Bulk printing of questionnaires, CRFs or consent forms.
- o Translation: If consent forms and questionnaires are to be used, these may need to be translated into local languages. Costs for translation

should be calculated and included.

- o Telecommunications: Consider funds for internet charges.
- o Training: If you need to train staff for the study, include costs for a venue and materials.
- o Overhead Administrative Charges: Most institutions have a standard overhead charge that is a fixed percentage of the total costs of running the research if external funds are used. At Stellenbosch University this is 17%. For internal (Stellenbosch University or Faculty funds) there are no overhead costs.
- o Audit: You do not need to budget for this as your study is small and the University will carry costs.



Develop a budget for your proposal as this will ensure your mentor helps you find the funding for your study. You should not have to pay for it.

# STEP 9

## *How do you ensure that your research is ethical?*

There are many textbooks and articles on the ethics of research – below we give you the basics and advise that you also read the few references in the footnotes.

When you start planning your research you have to determine the following:

### **Social value<sup>1,2</sup>:**

Your proposed research must have prospective value for the beneficiaries through improvement of their health or well being or adding to generalizable knowledge that may benefit beneficiaries in the future. The two major reasons why social value is important are to (1) avoid exploitation and (2) ensure responsible use of resources. You must clearly document who will benefit from the research and the importance of the health problem(s) that you want to investigate. Determine also how you will disseminate the information (see Step 13) to ensure that other persons with this health problem will benefit from your research.

### **Scientific validity<sup>1,2</sup>:**

The only ethical way in which you can do your research, is to develop a study with a scientific design, rigorous research methodology, including statistics, that will generate valid, reliable data. When you compare two therapies or interventions there should be clinical equipoise, meaning that you truly do not know which is the better therapy/intervention.

**TIP:** Any unscientific study is unethical.

### **Fair selection of your study population<sup>1,2</sup>:**

You must select a population that will meet the scientific study requirements of your study. Fair selection means that you select your participants according to the scientific goal and not because of privilege, vulnerability, availability or other factors unrelated to the study aim. For example, you cannot exclude an illiterate participant because the participant cannot read the informed consent. Under these circumstances you must use a witness to observe the full consent process.

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1 Emanuel, Ezekiel J., David Wendler, Killen J et al. "What makes clinical research in developing countries ethical? The benchmarks of ethical research." *Journal of Infectious Diseases* 189.5 (2004): 930-937

2 Emanuel, Ezekiel J., David Wendler, and Christine Grady. "What makes clinical research ethical?." *JAMA* 283.20 (2000): 2701-2711

At the same time you have to ensure that you exclude participants where the potential for harm exceeds the potential benefits.

### **Favourable risk-benefit ratio<sup>1,2</sup>:**

You have to carefully compare the potential benefits with the risks of your proposed study. You have to ensure that the benefits outweigh the risks and that the risks are acceptable within the context of the health risks. This is a multistep process, whereby you first identify all the risks involved, then you assess the potential benefits to the participants (remember that these benefits do not include unrelated benefits to the aim such as the payment of subjects or unrelated health care due to participation). The final step is to compare the risks with the potential benefit, and the potential benefits should outweigh the risks. Very often junior researchers are involved in studies that will lead to generalizable knowledge only, without direct benefit to the individual participant - if this is the case, you need to do a risk-knowledge assessment, which is often the case for non-therapeutic research<sup>3</sup>.

### **Informed consent:**

The main purpose of informed consent is to allow potential participants to decide whether to participate or not according to their own value system, preferences and interests. You show your respect towards your study participants' autonomy through the informed consent process. The informed consent document must accurately describe the objectives, procedures, the alternative treatment, as well as discuss both the potential benefits and the risks. You should provide a telephone number for yourself or one of the research team members for the participant to be able to contact you if there are queries or any emergencies related to the study. You have to use language that is understandable to the layperson and culturally appropriate. If you are dealing with children or mentally disabled persons your language needs to be even more simplified and you have to elicit both their assent, as well as their parent or legal guardian's consent. See Template 4 for examples of consent and assent forms for children.

### **Respect for recruited participants<sup>1,2</sup>:**

As part of respect for your participants you have to ensure confidentiality of their information. You have to document how you will ensure that confidentiality is protected throughout the research project and thereafter, in sharing the findings of your research project. You should create a unique study number for each participant which is linked to the actual patient/participant record and this generated list should be kept locked in a safe storage space. It is also important to link your raw data to this unique study number and analyse anonymously,

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<sup>3</sup> Weijer, Charles. "I need a placebo like I need a hole in the head." *The Journal of Law, Medicine & Ethics* 30.1 (2002): 69-72.

which means that the list with the linking to the actual name of the participant is not available during the analysis process. Part of respect for participants is also to ensure that they know that they may not give consent, or that they can withdraw from the research study without any influence on their health care (“no penalty”) at any time including the future. You need to also share your results during the course of the study or thereafter with your research participants (Step 13).

**TIP:** Remember that each section in your proposal links to the other sections – the ethics section must link to data management, communication of results etc. If you write in the ethics section that you will collect data in an ethical and confidential way, then you must give the detail of how you will do this, in the data management section.

### **Independent review<sup>1,2</sup>:**

Your research study must be reviewed by an independent ethics review committee. This is stipulated in the South African National Health Act<sup>4</sup> and ensures public accountability and also builds the trust of the community in you as a researcher. We all have diverse interests which let us embark on research and which may generate conflicts, which may influence our judgement.

### **Collaborative partnerships<sup>1,2</sup>:**

In the process of undertaking your research it is important to form partnerships with other researchers, policy makers and the community where you conduct your research. Involve these partners when you determine the importance of the health problem, the planning and conducting of the study, as well as integrating with the existing health system. Often you will have to assist in capacity building of especially the community you deal with that will assist them to become partners in the research process. Respect the culture and traditions of the community at all times.

## **Ethical principles including children**

There are several important guiding documents that you need to familiarize yourself with before embarking on research. Two important documents are the (1) Helsinki Declaration<sup>4</sup> and (2) National Health Act of South Africa no 61 of 2003 section 71<sup>5</sup>. The four important ethical principles are:

- respect for persons
- beneficence
- non-maleficence
- justice

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<sup>4</sup> World Medical Association. Declaration of Helsinki: Ethical principles for medical research involving human subjects. WMA Policy. Seoul: World Medical Association [Online] 2008 [access 2012, July 9]; Available: [www.wma.net/e/policy/pdf/17c.pdf](http://www.wma.net/e/policy/pdf/17c.pdf)

<sup>5</sup> National Health Act. South Africa. No 61. 2003 Section 71

The informed consent is the manifestation of respect for persons in research, the risk-benefit assessment is for beneficence/non-maleficence and fair selection is for justice. Children are particularly vulnerable since their ability to assent/consent is linked to their cognitive and developmental stage and a third party (usually their parents) are the decision-makers. You have to determine if the decision-maker for the child is truly acting in the best interest of the child and that the child also assents if cognitively able to. It is useful to use a checklist for paediatric research as found in “Research Ethics in Africa: a resource for research ethics committees” chapter 13 page 97<sup>6</sup>.

## When can you apply for a waiver of consent?

When you are using data that have already been collected and you do not have contact with the child or their caregivers you can apply for a waiver of consent from the ethics committee. A waiver of consent does not however mean that you do not need to abide by the confidentiality requirements and the children’s identity must be protected at all times.

**TIP:** If you are treating a very interesting patient you would consider writing up as a case report collect the consent from the parent and the assent from the child (if appropriate) as many journals will not consider your article if the consent is not sent to them. It can be very frustrating looking for the patient afterwards.

## How to submit to ethics (SU website)

The Health Research Ethics Committees of Stellenbosch University have a website dedicated to guide researchers in the submission of their research proposals for ethics review. Please go to the website to download the ethics application package that will guide you through the process. [http://sun025.sun.ac.za/portal/page/portal/Health\\_Sciences/English/Centres%20and%20Institutions/Research\\_Development\\_Support/Ethics](http://sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics)

You will also have to check the meeting and submission dates found on this website to guide you in time management of your research process. You have to submit an updated curriculum vitae with your application with a statement of your understanding of the research ethics guidelines as discussed in the Helsinki Declaration<sup>4</sup>. If you embark on research involving medicines or interventions, you will need to submit proof of a Good Clinical Practice course attended. Added to the Templates is an example of the consent forms you would require for research trials involving children (Template 4).

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6 Kruger M, Mokgatla-Mopolai B. In: Editors: M Kruger, P Ndebele, L Horn, Sun Media Publishers, June 2014. Chapter 13, Research Ethics in Africa: A Resource for Research Ethics Committees; p 97

# STEP 10

## *How do you implement your study?*

Implementation means how you go from developing your research proposal, the CRF and your data capturing forms to action.

### **REQUIREMENT:**

You must have ethics permission before you can implement your study and collect any data at all. This requirement also holds for a pilot study.

#### **TIP:**

In order to survive this research, you should implement your study:

- Within your timelines
- Within your budget
- Within the objectives of your proposal
- Ensuring the collection of high quality data

Right at the end of this step, you will also find some useful advice as to what to do once you have finished your research study. Basically you have to:

- Celebrate big time
- Write final report (after celebration)
- Store necessary documents

Before going over to action, you must ensure that:

### **You have clarified roles and responsibilities with your mentor**

In a nutshell – this is your study and you have the overall responsibility for the implementation of the research. You cannot delegate this. Your mentor must meet with you regularly and if she/he gets busy and forgets, it is your responsibility to make an appointment.

You must set deadlines and ensure that you stick to these. Deadline means exactly what it says – if you do not stick to the tight deadlines – you are dead. Your timelines are really tight (Introduction 3) and you will always feel you need more time – this is normal, but you have to develop the internal discipline to stick to your own deadlines otherwise you will run into problems finishing your research in time to register.

*“I don’t need time. What I need is a deadline.”* Duke Ellington 1899-1974

## **You have carefully planned the logistics before you start collecting data.**

It is good to remember that the easy part was to write the proposal – but it is very difficult to predict that you will be able to implement the protocol as you have written it on paper.

*“Prediction is very difficult, especially if it is about the future.”* (Niels Bohr)

- Therefore do a pilot study:
  - Ensure that you have permission from the Ethics Committee.
  - Remember that the data from the pilot cannot be used in your final analysis. Therefore use a different ward/timeline/group of children to try out your case report form (CRF)/questionnaire just to ensure that logistically what you thought out will work.
  - Ensure that you can in fact collect the data and store the data without the names and results appearing in the same document.

*“In theory, there is no difference between theory and practice; In practice, there is”.*  
(Chuck Reid)

- After the pilot study, adjust the CRF/questionnaire if needed and resubmit to Ethics Committee.
- Buy what you need.
- Print CRFs/questionnaires and make sure you have enough!
- Get the nurses in the ward where you will do your data collection on your side – explain study to them and get their buy-in.
- If you are going to work with a research nurse/assistant – appoint and train her/him.
- Decide together with your mentor how you are going to name and date all documents.
- Get your files (regulatory file and work file) sorted.
- Adapt timelines as needed.

## **Which files do you now need to keep during implementation?**

Keep a regulatory file and a work file for your study (lever arch files work well). The **regulatory file** is a file containing all the essential documents and correspondence of your study and must be stored long after you have completed your research study (Step 17 and appendix 6). This is a file to start right at the beginning of your research and to keep neatly and up to date on the shelf and

not to use for day to day work activities and not to use to scribble in. Appendix 6 contains an example of such a file. This is the file that you use to find your original ethics application, the reference to where your data are stored, your agreements with other colleagues etc. and is an accurate record of all the important documents and facts. And just take it from us who have made the same mistakes many times – by the time your manuscript comes back for revision there is a huge chance that you do not remember which was the final database and if you do not know this, then you are really stuck with replying to the reviewers. Once you have completed your study and published your thesis/article you will store this file long term together with your data.

Your **work file** will have some of the same documents as the regulatory file, but this file does not have to be neat or complete, and does not have to contain all the documents – this is your day-to-day work file in which you make notes, scribble, take with you to the wards etc. etc.

## Now that you are ready for action, what do you do?

*Stick to protocol:*

Ensure throughout the study that you still stick to the protocol. It is a good idea to build into your timelines specific times to check that you have not inadvertently deviated from the protocol. It is essential to keep meticulous records.

**TIP:** Quality data is more important than a large quantity of data.

*Collect and manage your data (also refer to Step 11)*

Most of you will use already collected data from hospital folders or special registers. If you appoint or work with a research nurse/research assistant/data manager/data typist to assist with the data, it remains your responsibility to ensure the quality of the work. You will need to train these colleagues to ensure that they all understand the study, all collect data in exactly the same way and that they stick to your timelines.

When you are ready to start retrieving the folders and transcribing the data onto your CRF, it is important to keep an accurate record of which folders you could NOT find. If you use a research nurse/assistant it is important that the two of you sit down and ensure that you understand exactly what is meant by each variable on the CRF. For example if one of the variables is “Lymphadenopathy” and the answer is “Yes or No” – then ensure that you agree on what lymphadenopathy means – is it any lymph node present? Or a lymph node larger than a specific size? Or a lymph node in a specific place? Or more than one lymph node? (See appendix 7 for some tips on how to develop your CRF)

**TIP:**

Defining your variables is very important even when you are working with experienced research assistants.

## Do you have to renew your ethics approval?

Once you have the initial Ethics Approval, make sure you address the recommendations (if any) and keep the original letter in your regulatory file and include the ethics number on all future correspondence.

Remember to send a progress report to the Ethics Committee every year and to apply every year for renewal of ethics approval. This process can take some time and a good guideline is to send your progress report and application at least 2 months before the ethics expiry date. An example of the progress report can be found in the Template 5 or can be downloaded from:

[http://sun025.sun.ac.za/portal/page/portal/Health\\_Sciences/English/Centres%20and%20Institutions/Research\\_Development\\_Support/Ethics/Application\\_checklist](http://sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_checklist)

**TIP:**

Check the website for updated forms.

## Do you have to send the ethics committee a final report?

When the research has been completed or is being closed out prior to completion, a final report is submitted to the Ethics Committee, study monitor and funder. A template to help you is included (Template 5).

# STEP 11

## *How do you manage your data?*

A few golden rules:

1. “Garbage in, garbage out”. If the quality of your data is poor, your results will suck.
2. Data management and the quality of the data are your responsibilities.
3. Throughout the research you must ensure that the data collection is done according to the protocol and that the quality of data is maintained.
4. Never store your computer and your back-ups in the same place – we have seen too many students loose both their computer and their back-ups.

If you manage your whole data process properly, you will ensure that appropriate data collection takes place; that data are entered into a suitable database; and, that the study has reliable, accurate data to analyse. All data should be handled and managed according to confidentiality and according to ethical standards. For good data management the following are needed:

- Carefully planned data forms (e.g. CRF or questionnaires).
- Data and sample flow algorithms and logistics.
- A data management plan.
- A data dictionary.
- Standard Operating Procedures (SOP) for collecting and storing data.

When you develop this section, “walk through” the different steps in your mind and think about logistics and about your budget:

- Will it work logistically?
- What resources do you need to do this? This might include:
  - Equipment (e.g. computer, printer)
  - Toner replacement; printer cartridges
  - Software or computer programs
  - Data collection tools (either paper based or electronic data capture devices like tablets)
  - Stationery (e.g. paper, envelopes, labels, barcodes, black pens, clipboards, files etc.)
  - Staff (data manager, database developer, data capturers)
  - Data storage and backups (electronic and hard copy)

## What database should you be using?

Most junior researchers will be tempted to use a spreadsheet. If you are using an Excel (.xls ) spreadsheet to collect your data remember the following:

- Never do calculations on your original spreadsheet – keep original ONLY for data entry and not for any calculations.
- Make sure the lines do not shift one up or one down – this can completely mess up all your data.
- Check the date formatting – often 12/01/2014 is changed programmatically to 01/12/2014 and this can really create havoc.
- Ensure that you code all missing data points (cross check with your data dictionary) as -1. Otherwise you run the risk of having .xls get a wobble and not distinguishing a true “0” from a missing data point as .xls may assign a “0” to a missing data point.

It is advisable to rather use a flat file data base (Epi6) or a relational database (Microsoft Access, Oracle etc.). Epi6 is available as freeware. Epi6 is a suitable database if you are collecting limited data and need one-on-one comparison. Epi6 is good for questionnaires, small audits and clinical studies. It is however not suitable for matching across different datasets. Relational databases are ideal for large datasets especially if many relationships are required to be examined in your research. The disadvantage of relational databases is they are complex and you will need help with the programming of your database.

 **TIP:** Remember to ask the biostatistician if the database you want to use is compatible with the database she/he will use.

## How do you maintain confidentiality and storage of high quality data?

There is a difference being the caring clinician (when you are the child’s doctor) who has access to all information about the child, and being a researcher when you are not necessarily the child’s doctor and you have to maintain confidentiality and not use the names of individuals when collecting and analysing data. However, often the only way to access data (e.g. when using data from hospital files) is to use the child’s name. The principle then is to use a unique study number for each child and not to have the name and study results in the same document, electronic spreadsheet or database. Usually the only place where you will have a name of the child is on list 1 (as below) and on the consent form (if you use one)

Three lists are needed to ensure confidentiality (See also Appendix 7):

1. A list with child’s name, surname and unique ID
2. A list with unique ID and unique study code (no name, no result).

3. A list with unique study code (no name, no unique subject ID), and columns for results.

In some instances, personal identifiers (names, dates of birth, address, etc.) may be required to perform record linkage e.g. if you want to link a child's CXR result with the laboratory result. If this is necessary, the procedures to carry it out must be described along with processes to ensure that, after linkage is complete, personal identifiers are removed.

You must describe the exact manner in which you (or anyone else) will access data and steps taken to ensure confidentiality.

## How do you ensure good quality data?

You must ensure consistency of the data – data must always be collected and captured in exactly the same way. The best way to do this is to develop Standard Operating Procedures (SOPs) for managing the data – this must include step-by-step instructions on how you will collect the data during the study and must include details of how to handle missing data. You will most probably not be able to collect all your data in one session and one thing you can be sure of is that when you return to your research after a rotation in ICU, you would have forgotten exactly how you collected the data. The instructions in the SOP must be so clear that you will be able to restart collecting data (after your ICU rotation!) in exactly the same way as before. This SOP will also help when you finally write up your results for publication and will ensure that the study is reproducible if other groups want to do the same study.

Try to avoid collecting data that you will not use. Ensure throughout your research that you limit the number of missing data points – missing data will create a huge problem when you come to the analysis stage.

It is a good idea when calculating sample size to plan for missing data – usually statistical methods can to a certain extent compensate for missing data. A much bigger problem is if you have inaccurate data – no statistical package can compensate for this. Therefore it is important to ensure that good quality data are collected and that you have a system to regularly check the data.

**TIP:** Regularly read your proposal (Step 7 and all its appendices and templates) that has been approved by the Ethics Committee and ensure that you in fact collect and manage your data as written in your proposal and that you use the forms as submitted to the Ethics Committee.

## **Guidance on filling in a CRF or questionnaire:**

- Maintain a log of all hospital files that you looked for, those that you could find and those that you enter on CRF. This sounds like a boring thing to do, and it is, but it is really important as later when you have to set up your flow diagram (appendix 8) and you do not know how many hospital files you were looking for and how many you could not find, you are really in a fix that you cannot correct at that late stage.
- Do not enter patient names; use unique identifiers.
- What you write on the CRF must be exactly the same as what is in the source documents (hospital files). Do not interpret what you think is in the hospital file, or what you want to be in the hospital file.
- Write legibly.
- Use a black pen (never use a pencil as anyone can rub your writing out and write something else there).
- Filling in the little blocks on a CRF is a little bit like voting – you have to fill in the block so neatly that there is no doubt as to what you filled in – it is very frustrating later when you want to type the CRF into your database, if you cannot figure out which block you meant to fill in.
- How do you correct a mistake on the CRF?
  - Never use correction fluid
  - Never erase or obscure original entry
  - Ensure an audit trail exists for all entries
  - Strike through, correct, initial and date

## **What about using electronic data entering (Ipads etc.)?**

- This is the future of data collection.
- These interactive systems can be programmed to detect errors while entering.
- Data entry screen is made to resemble a data form.
- If you want to use one of these gadgets, get an expert to do the programming.
- Remember to backup, backup backup. You do not have hard copies if something goes wrong!

## **What rules should be followed when entering your data into a computer?**

Once data collection has started, data entry should also commence.

It is advisable to have dual entry of the data, in other words two people capture the same data separately on identical databases – each person has his/her own copy of the database. The reason for this is that humans make errors; the 10% error rule. It is well accepted that there is approximately a 10% error in entering data. With dual entry and comparing the 2 datasets the error rate drops dramatically.

## Dual entry to reduce transcription errors

- Generates two separate files by two data entry operators
- These two datasets are then compared to detect data entry discrepancies between the two and by checking the source documents, data entry errors can be greatly reduced.

*Example of the validation process using dual data entry*

Dataset 1 is captured by data capturer 1 and dataset 2 is captured independently by data capturer 2. For validation of the data, dataset 1 is compared with dataset 2 and all discrepant answers are listed. In this example gender is captured in dataset 1 as 0 (male) and in dataset 2 as 1 (female).

Dataset 1		Dataset 2	
UniqueID	1224	Unique ID	1224
Sex	0	Sex	1

The next step is to check the source document (e.g. CRF) and mark the correct item on the validation document. The last step is then to establish which dataset (1 or 2) has the least errors and to make all the corrections for the final database on this dataset.

After data have been captured, the dual entries corrected and validated and all queries resolved, the database should be locked and a copy of the locked database stored safely.

## What if dual entry of data is not possible for your study?

The standard to strive for is dual entry. Often with small studies this is not feasible or the funding is not available. If this is the case in your study you must print out your data and carefully analyse it to reduce incorrect data (see step 12).

## How do I secure my data once I have entered it into my computer?

- Ensure a security system to prevent unauthorized access.
- Identify who is authorized to make changes.
- Design a system that allows changes to be tracked.
- Record every change to a file, no matter how small.
- Keep track of changes to files by saving new version.
- Use file naming conventions. An example would be the name of the file

followed by the date and initials of the person who worked on the file.  
(Jaundice 14-08-05 jm).

## **What about network security, physical security and computer security?**

- Keep confidential data off the Internet.
- Restrict access to computer and room where data is kept.
- Restrict access to computer(s) containing data.
- Keep virus protection up to date.
- Don't send confidential data via e-mail.
- Use passwords on files and computer.

## **How do you manage your electronic data?**

The importance of regular backups of electronic data cannot be over emphasised. We all preach this but every now and then, one of us forgets and ends with a minor (or major) disaster.

Always keep at least three copies of all your data:

- Original.
- External hard drive at local site.
- External hard drive at a remote location. This is really important as a number of young researchers regularly lose their data because they kept their external hard drive in their laptop bag. It has also happened that there have been a fire or burst water pipe in the room where data was stored.

Always use a reliable back-up medium for example:

- Departmental or University Server.
- Tape backups, External hard drives.
- CDs or DVDs are NOT recommended.
- Thumb drives are not recommended as they get lost quite easily.

Create a back-up schedule – below is an example:

- Daily – keep the most current back-up off-site.
- Weekly back-ups (keep for at least a month).
- Monthly back-ups (keep for 6 months).
- Quarterly back-ups (keep for year).
- 6-monthly backups (keep for 5 years).

It is essential to very carefully store the final database that you use for analysis. Most of us as senior researchers have been in the terrible position that we get the reviewers' comments back on a submitted article and we want to rerun

an analysis and guess what? We cannot find the database that we used for the analysis – be cleverer.

Principle for a locked database

- The locked database should never contain patient names.
- Locked database should be stored safely (including at least 2 back-ups stored in different locations).
- The original locked database should never be used for analysis, a copy is made to work on; if the original database is used and a mistake is made or the database becomes corrupt, it may be impossible to analyse the data.

## **What about the regulatory aspects of your study?**

You must keep a neat regulatory file (Appendix 6) for auditing purposes, including an audit by the Ethics Committee and therefore all correspondence and reports to Ethics Committee must be stored in the regulatory file and must be available on request. You must keep all the important and essential documentation of the research study (the study protocol and amendments, applications to the ethics committee, serious adverse event reports and all other correspondence relating to the study). You must keep this regulatory file up to date throughout your research study and it must be stored safely after you have completed your research study.

A few practical tips for maintaining the dreaded regulatory file:

- Use the outline provided (Appendix 6).
- Add additional tabs and/or documents to each section as needed.
- Keep the file current and up-to-date.
- Store the file in a safe and secure location, but accessible at all times.
- Participant-specific documentation and information, e.g. signed consent forms and completed case report forms, should not be kept in the regulatory file and should be filed separately.

# STEP 12

## *How do you prepare your data for analysis?*

The more time you spend making sure you collect good quality data, the less time you have to spend on preparing your data for analysis.

This is where you suddenly discover the value of the careful preparation of your data – remember that dreaded data dictionary and the extra time you took to define your variables and put in ranges and validations? If you have been meticulous with the definitions, ranges and validations and you have collected the data carefully, then preparing your data for analysis is very easy. If for example you validated that the weight of a child cannot be more than 80 kg, or that the temperature cannot be higher than 43°C, then you should not have any crazy values.

However, even if you have been very careful, there will be errors in the database – either due to incorrect collection of data (which is almost impossible to fix at this stage) or due to errors in transcribing data from the CRF onto the database (which can be corrected). It is well accepted that there is approximately a 10% error in biological data. This is why all data needs to be cleaned.

### **What do you clean?**

It will never be possible to clean all the data. Therefore focus on the errors that are not simply small variations but errors that will influence the main results of your study. These include:

- your key determinant and your primary outcome variable (look at your 2x2 table).
- variables that will influence your whole population (e.g. sex and age).
- dates.
- weight (if recorded).
- duplicate records.
- biologically impossible results.

In all studies involving children, dates are extremely important as you will use date of birth and date of admission to calculate age and in most childhood studies age and growth parameters (e.g. weight for age) are important variables –either as a determinant or as an outcome variable.

**TIP:**

Plot the distribution of your data: you will see if you have outliers

## How do you clean your data?

You start by looking at your data with a critical mind and by doing some very simple checks.

- Check that the date format is correct.
- Check that a true “0” and a missing value are not the same “0”. You can avoid this by coding missing values as -1 and then you will know that all cells with a -1 in is a missing value.
- If you add up a column of data, and you get zero, or an answer that simply does not make sense, you know you have a problem with your data.
- If you try to calculate age by using the date of birth of the child and the admission date to hospital and you cannot get it to work, you know you have a problem with your data.

## How do you do descriptive statistics?

This is not difficult – you simply do the following:

- Define the normal range and distribution shape of each variable.
- Make summary tables for all variables.

For all your categorical variables (these are the variables with yes/no answer, or male/female etc.) you must make a table and calculate frequencies and proportions. There are easy step by step Youtube clips available – have fun!!

<http://www.youtube.com/watch?v=8nCEDCV6VXg>

For all your continuous variables (these are variables like age, weight, length) you must make a table and calculate mean and standard deviation, or median and range.

And here you go with Youtube again (this time in Irish instead of American English): <http://www.youtube.com/watch?v=62i1fqKhNhg>

## What do you do after you have done the descriptive statistics?

Again this is easy and you only have to do two things:

- Read the article on Data Cleaning by Jan van den Broeck et al<sup>1</sup> and look specifically at figure 2 and think (only think!) what to do about your data.
- Make an appointment with your biostatistician and discuss the data with her/him.

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<sup>1</sup> Jan Van den Broeck, Solveig Argeseanu Cunningham, Roger Eeckels, Kobus Herbst. Data Cleaning: Detecting, Diagnosing, and Editing Data Abnormalities. PLoS Medicine, October 2005 | Volume 2 | Issue 10 | e267

# STEP 13

## *Who do you communicate your results to?*

Principle 36 of the current Declaration of Helsinki<sup>1</sup> which guides research on humans, states that:

“Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.”

So, once you have collected data, you have no option but to make it publicly available and the best way to do this is to publish your study in an accredited medical journal.

*“If it is not written down, it did not happen.”*

There are various other ways in which you should disseminate your results:

- **Communication to the Scientific World:**
  - o Presentation to Department of Paediatrics and Child Health (this might also include presentation at Faculty Academic Year Day).
  - o Presentation to all collaborative Departments/stakeholders.
  - o Write and publish a manuscript in an accredited medical journal.
- **Communication to Ethics and other committees:**
  - o Final written report to Ethics Committee and any other committee who needs report.

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<sup>1</sup> World Medical Association. Declaration of Helsinki: Ethical principles for medical research involving human subjects. WMA Policy. Seoul: World Medical Association [Online] 2008 [access 2012, July 9]; Available: [www.wma.net/e/policy/pdf/17c.pdf](http://www.wma.net/e/policy/pdf/17c.pdf)

- **Communication to the public and stakeholders**
  - If there is a forum for presenting research findings to for example the Hospital or clinics where the research was done, it is good to do a presentation at this forum preferably before you submit the article to a journal.
  - If there is no forum for presentation to the health authorities, and your results are not favourable towards the Department of Health, you should send a summary of the results and/or a copy of your article to the Department of Health to inform them about your findings. It is unfair to publish an article with poor health services/outcomes and let the Department of Health read about it in a journal or worse, in the newspaper.
  
- **Communication with participants:**
  - This is of course difficult if you use already collected data and do not have access to the participants. But you should always think whether there is any way in which you can communicate the findings to the people whose data you used.

# STEP 14

## *How do you write an article?*

Writing is hard work and takes time. Few have the talent to write effortlessly but all can learn to write a scientific paper. To get your article published it must be of scientific merit, topical, submitted to an appropriate journal, be written in the correct format and the reviewers answered correctly. In other words you must know the publication game. This step will attempt to help you write your article according to the “rules”.

**To write successfully the following are helpful:**

1. Start early. You can write the methods before analysis of the data.
2. Set aside a time to write. Take regular breaks, as writing is mentally tiring.
3. Have the most important articles you are to cite available.
4. Think clearly about the message you want to convey. Stick to the message.
5. Make sure all the collaborators agree with the message.

There are many articles and books to guide you on how to write successfully. This is just a brief synopsis of many articles and our experience. (See useful references for one-page articles on each step)

## **Who should be an author on your paper?**

Who should be an author has been clearly set out by the International Committee of Medical Journal editors ([www.icmje.org](http://www.icmje.org)).

To be an author requires:

1. Making a substantial contribution to the design of the study, acquisition, analysis or interpretation of the data AND
2. Writing or critically revising the drafts and article AND
3. Approval of the final version AND
4. Agree to be accountable for all aspects of the work.

There is no place for guest authorship or politically correct authorship. The new recommendation expects all authors to be accountable for the accuracy and integrity of all the aspects of the article. If something goes wrong you cannot use the excuse that you were not involved in that part of the study.

Decide early in the study who will be authors and what their contribution will be to the study. Initially many will be interested in your study but as the hard work and critical thinking required by research arrive, they fall by the wayside.

## **How do you choose a journal?**

Choose the journal in which you would like to publish your article. Your choice will depend on the message you are trying to get across and to whom you want to give this message (your audience). If you have an oncology patient with an unusual lung mass you would frame the message slightly differently if you were writing for an oncology journal than for a pulmonology journal. The next choice is whether you want to publish in an on-line journal, or in a traditional journal.

There has been a proliferation of on-line journals many of which are highly respectable journals. The advantage of on-line journals is that your article gets published quickly, if you can get past the editor and the reviewers and that the article is then freely available on-line for all people who want to read your article. Something to keep in mind is that on-line journals have a publication fee – Stellenbosch University will pay the pro-rata amount for the proportion of authors who are from the University.

Another factor that plays a part in choosing a journal is the journal's Impact Factor (IF). You should aim at the journal with the highest impact factor that is read by the audience you are aiming the article at. But be realistic – the chances of you publishing your first article in the New England Journal of Medicine with a very high impact factor (IF 54.4), is more or less zero.

Look at which journals have published similar articles or research and look at the references you are using in your literature review – these journals will normally be interested in your research subject.

Your mentor will help you choose the journal most likely to publish your paper. Decide on, write down and ensure all co-authors agree with 3 journals in order of preference. If the one journal rejects your article you know which is the next to go for without agonising or having major discussions with your co-authors again.

## **Follow an unconventional sequence of activities when writing**

Most scientific journals follow the IMRAD (Introduction, materials/methods, results and discussion) format. While you have to stick to this format, we strongly advise that you do not start with Introduction, then methods etc. We advise that you follow a different sequence of writing as explained below.



TIP:

While your final paper will contain this format, do not write the sections in this order.

The review of the literature which you have written for your scientific proposal (which will need to be updated) will form the basis of the introduction for your paper. Do not start your paper by refining your literature review. Start your paper by writing your research question/aim. This forms the basis of your whole paper and every section must relate to this and to this only. Once you have clearly written down your research question/aim, you can write the materials/methods section. The materials/methods section is normally the easiest to write, followed by the results section (where you will need help from the biostatistician). The introduction should be written once you have written the research question/aim, methods and results. The most difficult part of writing the introduction is to refine the literature review from your proposal and to leave out all the vague parts that do not directly relate to your research question/aim, methods and results. The discussion is the toughest to write. Write the abstract last.

## Research question/aim:

This is the most important part of your paper and everything must relate to this. It is often useful to look back at your initial 2x2 table and refresh your memory regarding your question, your key determinant and your primary outcome.

## Materials and method:

This is your research study's recipe. It must accurately describe exactly what you have done, how you have done it and how you have analysed your data. This section must be written in the past tense. You must find a balance between giving enough detail to allow another researcher to repeat the exact same study, and being brief enough as you cannot cover all the fine technical aspects. A major portion of your methods section will be in your research proposal. It is initially easier to describe the method section in great detail and then edit it later.



TIP:

Do not copy and paste it from your research proposal, as the tenses will be wrong.

Remember PICOT? Well, back to it as it is essential to include all the PICOT criteria:

*Population:* This includes your study design, data sources as well as the setting where the study was performed including the context (e.g. high burden TB region). Patients that were studied and the inclusion and exclusion criteria used. A flow diagram is very useful to explain this and is often required by the journal (appendix 8). Sometimes the flow diagram fits better in the methods section, and

sometimes in the results section. You also have to describe your sample size and how you ensured that your study was not biased.

*Intervention:* Intervention or new diagnostic used.

*Comparator:* If an intervention or new diagnostic was used you must indicate what it was compared with. Most junior researchers do not embark on an intervention study as their first research study and then your key determinant is used as your comparator.

*Outcome:* What was the primary outcome investigated and what was the outcome definition used.

*Time:* When was the study performed? By convention this is given near the beginning of the methods section.

If the method(s) have previously been well described in a scientific publication, a brief description of the method with a reference will suffice.

You also have to describe the data management and the statistical methods used to analyse the results of your study, as your conclusions are dependent on the correct analysis.

Ethics permission should finally be included. If there are specific ethical considerations, it should be mentioned e.g. how you maintained confidentiality or that a waiver of written informed consent was obtained as you used already collected data from hospital records. Permission from the hospital or health authority to do and publish the study is normally included in the acknowledgements.

## **Results:**

The results section should mirror the methods section. For each part in the methods section there must be a corresponding result. In the result section you just give the results and do not comment on them (that belongs in the discussion).

 **TIP:** If your study was a cricket match, in the results section you would only give the score, each batsman and bowler's contribution but no comment on how lucky they were etc. The commentator's comment on how lucky the batsman was or whether he was better than someone else, will go into the discussion section.

The results are normally written in the following order:

- Description of the population studied. You must account for all the children that possibly could have been included in your sample (including excluded subjects). Flow charts are very useful for this purpose (see appendix 8).
- The results of your primary outcome. This would include the variables that influenced the primary outcome.
- Results of your secondary outcome(s).
- Finally write about the unexpected results.

Useful points to remember in reporting your results:

- Use Tables/Figures if you have a lot of data and highlight the findings in the text.
- Do not duplicate data given in Tables/Figures in the text.
- Use linking sentences in the text to draw attention to the Tables/Figures. (“The characteristics of the HIV infected and uninfected children are given in Table 1”)
- Do not only give the p values but also give the odds ratios / risk ratios with their 95% confidence intervals or ranges as applicable.
- Restrict the numbers to one decimal point e.g. 10.5 not 10.532597.
- Report percentages together with absolute numbers (50% (10/20) children).
- Use the term statistically significant rather than significant, as they do not mean the same.
- Do not blame the poor data by writing “xxx did not reach statistical significance”. Rather write “... was not statistically different from xxx”.

## Using Tables and Figures:

Editors have limited space in their journals so an effective way of reporting large amounts of data is to use a Table or Figure. It is often easier for the reader (editor and reviewer) to get a grasp of the results of your study by examining a good table(s) or figure(s).

A good table or figure must have the following characteristics:

- The table together with its heading should be able to be read without reference to the paper and be self-explanatory.
- The title of the table/figure should clearly indicate what the data is in the Table/Figure.
- The legend is used to explain abbreviations used in the table and what the symbols indicate (\* =  $p < 0,05$ ) (# = children with bacterial pneumonia).
- The Tables and Figures must be clear and easy to read.
- The Table/Figure must be in the format required by the journal (.tiff .jpeg etc.)
- Tables and Figures are inserted after the references and each table and figure must be on a separate page.
- Ensure that the numbers in the tables make sense and reflect what you mention in the text. Reviewers do quick checks on this, and mistakes indicate

that you have not been careful (that in fact you have been sloppy) and can cast doubt on the quality of your work.

## Discussion:

This is the most difficult part to write but is not impossible if you follow these suggestions:

In the first paragraph you describe your primary outcome followed by the secondary outcomes substantiated by statistics. In other words you answer your research question but substantiate your answer.

**TIP:** Back to the cricket match – this is the section where the commentator (that is you) interprets the results on the scoreboard and interprets the results by making reference to other players in this cricket match (in your case other data of your study) or to previous cricket matches (or in your case previously published studies).

In the following paragraph(s) you critically compare your findings to those available in the literature. You will point out what your study adds to the subject. You can consider why the findings of the other studies differ from your study.

If you have interesting secondary outcomes these are discussed in the next paragraph or two. Do not over-emphasise these findings, as your study was probably not designed/ powered to answer them.

The next paragraph or two you discuss the strengths, limitations and difficulties of your study and compare your limitations to those in the literature.

In the final paragraph you briefly summarise your findings and point out the clinical significance of these findings.

Points to consider when writing the discussion:

- Do not over-emphasise your findings. Your study will not prove but rather demonstrate, show or suggest (be modest).
- Do not go off on a tangent (on your pet subject) that is not substantiated by your data and that does not relate to your research question/aim/hypothesis.
- You may point out interesting findings that were not significant but do not draw any conclusions from this data.
- Do not try and sell other interesting observations you may have made but are not included in the results section.
- Do not duplicate your results in the discussion.
- Do not add new findings that were not given in your results.
- Read the discussion over to make sure it follows a logical theme.

*How to start writing the discussion:*

Follow the above recipe but first only write one key word or thought in each of the suggested sections of the discussion.

It is easier to now expand on the key words or thoughts.

## **Now for the Introduction:**

It is now time to insert your funnel shaped introduction leading to your research question with your primary and secondary outcomes.

You must carefully recheck your introduction to ensure that new articles published since you wrote the introduction for your research proposal are included.

Ensure that the theme of your article is carried through from the introduction to the discussion.

## **Title:**

You have probably been dreaming of the title of your article for months. Your title should have all the key elements of your article in it but not be too long. It should be interesting enough to draw the editor and readers' attention. Writing the title is not as easy as it seems. A useful aid to developing a title is to write down the key elements of your study and then develop a title from these elements. It is seldom that the title of your article is exactly the same as the title of your research proposal.

## **Authors:**

See first section of this step as to who should be an author on your article.

When you write the final version of your article, ensure that all authors' names, affiliations and titles are correct. You should be the first author and your mentor the last/senior author.

## **References: surely not a problem?**

If you have been using a reference manager it is relatively easy to complete the references.

Carefully examine the references to ensure:

- That the correct reference is included.
- That you have actually read the primary reference and have correctly quoted from it.
- That the spelling of the authors, title of the article and journal is correct.

- That when you are ready to submit your article recheck that the references have not moved.
- That the numbering of your references has not changed after inserting the introduction – correct the numbering if needed.

It is very irritating for a reviewer to find faults in the references as this indicates that the author is sloppy and should not be taken seriously (and the reviewer will very likely wonder: “What else in the study is sloppy?”)

## Who should be included in the acknowledgements?

This is the time to thank those who helped you. Include acknowledging the health authorities for allowing you to perform the study and publish the paper.

## What next?

Even though you have been in constant discussions with your mentor, it is now time for you to give your article to your mentor for critical review. Do not feel despondent if it is returned looking like a blood bath from all the red ink or track changes. This is quite normal and it takes most of us 5-7 drafts to get the article to such a stage that we can submit to a journal.

How can you keep the bloodbath to a minimum?

- Read the article for logic of thought and structure.
- Then re-read the article for language and spelling.
- Then make sure the numbers in the article add up. Are all the participants accounted for? Especially check your tables for correct data.
- Then check your references.
- Ask a colleague to critically read it for you. (Rather do not ask your partner as this could spell the end of your relationship).
- Then re-write the article again.

**TIP:** When writing scientifically, avoid unnecessary words and write clearly rather than beautifully.

**TIP:** Do not use jargon e.g. do not write “the aetiological factor” – rather write “the cause”. If you write about children, write about “boys and girls” rather than about “male and female participants”.

**TIP:** Do not use unnecessary words. E.g. write “history” and not “past history” and write “unique” and not “very unique”. And for a sentence describing the study population write “There were 120 children, of whom 60 were boys” rather than “The 120 participants were divided into two groups consisting of 60 boys and 60 girls”.

## How to manage your mentor's suggestion?

Your mentor is there to help you and probably likes you. Your mentor is not the enemy. So sit down and carefully read your mentor's suggestions/criticism. If you think your mentor is wrong you have more likely than not expressed yourself incorrectly.

Now it is the time to carefully address every single one of the mentor's suggestions and improve your manuscript.

This will probably require you to re-write the article. (Now you have written it 4 or 5 times: you are getting there.)

Return the manuscript to your mentor as well as all the other authors. Give them a reasonable time in which to reply (1-2 weeks).

Time to start writing the abstract.

## How do I write an abstract?

The recipe for writing an abstract is:

- One or two short sentences stating the context/background.
- One sentence stating the research question.
- One or two sentences stating the methods.
- One or two sentences stating the most important findings including statistical significance. Start with the answer to your research question.
- One sentence modestly stating the clinical significance of your study.

Many journals require a structured abstract and will give you exactly the sub-headings to use.

*Points to consider in writing the abstract:*

Check the word count of the abstract. Online submissions (all journals) do not let you exceed the word count.

Make sure the abstract can be read as a stand-alone and makes sense. Remember the majority of readers will only read your abstract. You have to draw them to your article via the abstract.

Make sure your abstract has the following elements:

- Why you did the study?
- What did you do?
- What did you find?
- What does it mean?

**TIP:** If a journal gives you sub-headings to use, and the number of words to use in your abstract, they actually expect you to use these and best advice is to do so!

## Ready for submission?

Now that your mentor and fellow authors have returned your article you need to make the corrections, add the abstract, re-read and re-check the article and return to all the authors with a shorter deadline than the previous deadline.

In the mean time you can get all the instructions together for submission. Make sure the Tables/Figures meet the requirements of the journal etc.

You are now ready to submit. But remember that with online submission, it often takes quite a long time ( a hour or two) to fill in all the necessary information needed by the journal and it can be quite frustrating if the journal requires information that you do not have. So make sure when you go onto the website and you have all the information (e.g. some journals need the qualifications of all the authors) before you start the submission process.

Lastly, your article may never be submitted to more than one journal at a time.

**TIP:** After you have pressed the “submit” button, make sure that you know where your final locked database used for the analysis of your article is and that you have made a copy of the database. It is very frustrating when you get the reviewers’ comments and you have to do some more analyses and guess what? You do not know or cannot find the correct database and you get different values from the results submitted – trust us – it happens!

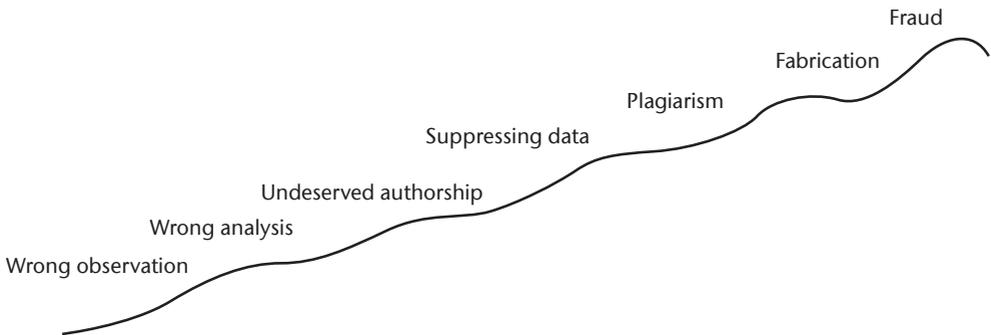
# STEP 15

## *Plagiarism: surely not me?*

Plagiarism has received a lot of attention recently but it has been present for centuries. In 1804 Francious Bidault's PhD thesis at the University of Paris was plagiarised from a publication by Thomas Baumes: "Treatise on Icterus or Jaundice of newborn infants"<sup>1</sup>.

Now, with the explosion of on-line medical journals, many of these for profit, scientific fraud and plagiarism are proliferating. It is worthwhile to read the article in *Science*<sup>2</sup> on how easy it is to get scientific fraud published.

Also worthwhile to note how far down the "slippery slope"<sup>3</sup> to or high up the highway to fraud, plagiarism falls.



*The Highway to Fraud. Adapted from <sup>3</sup>.*

1 Hansen TWR. Pioneers in the Scientific Study of Neonatal Jaundice and Kernicterus. *Pediatrics* 2000;106(2):1-7

2 Bohanon J. Who is afraid of peer review? *Science* 2013; 342; 60-65.

3 Nylenda M, Simonsen S. Scientific misconduct: a new approach to prevention. *Lancet* 2006; 367:1882-1883.

There are many forms of plagiarism that vary from ghost writing, duplicate publications, intentional copying to scientific fraud.

All of us, when writing our manuscripts and articles, are tempted to perform unintentional plagiarism – especially if we read an excellent article and we ourselves cannot find good words to use to say exactly what another author has written.

Intentional plagiarism is when we copy an idea, statement or a sentence from an article we have not cited. So to prevent plagiarism we need to take note of the available guidelines.

*You can prevent plagiarism by:*

1. Making sure you have read and abide by the University guidelines on plagiarism ([www.sun.ac.za/english/legal/documents/plagiaat\\_Nov2010\\_eng.doc](http://www.sun.ac.za/english/legal/documents/plagiaat_Nov2010_eng.doc))
2. Register for Turnitin on the University website (see appendix 9)
3. Scan your proposal, manuscripts and articles through Turnitin before submission. If you do not scan your article, others will.
4. Cite, cite, cite.

Plagiarism is a very complex subject and every author has a responsibility to ensure that this does not occur. One of the dangers of accepting guest authorship is that you could be found guilty of plagiarism and scientific fraud, as you were not involved in the process of research and writing the article.

Self-plagiarism is a particularly difficult issue. If you are quoting yourself, which you often do in the methods section, you must cite the article.

# STEP 16

## *How do you respond to the reviewers of your article?*

### **How long is a reasonable time to wait for a response?**

A number of journals allow you to track the progress of your article through the review process. On submission of the article, the journal will send you a number to use for tracking your article. This is helpful to see where your article is stuck.

A reasonable time to wait before enquiring about your article is 2- 3 months.

### **What should you remember prior to reading the reviewer comments?**

There are 3 facts to remember before you open and read the comments from the editor and the reviewers:

- No article is perfect no matter how long you have worked on writing it. You will have to revise portions of it. Everyone has to revise his or her articles.
- Most reviewers and editors are actually interested in improving your article. So most reviewers and editors are on your side if you have an interesting article.
- Peer review means exactly that: review by one of your peers. Peer review is not always a review by an expert. It is important to accept this fact.

### **What should I do when reading the comments from the editor and reviewers?**

You are either going to be very happy (your article provisionally accepted with minor revisions) or very cross (your article requires major revisions or is rejected). If your article has been provisionally accepted on condition that you respond you have a good chance of getting the article published. You now have to develop your reply to the reviewers.

## What tips are there to replying to the reviewers?

One of the best articles published with tips on replying to the reviewers had the following advice<sup>1</sup>:

1. Get mad then get over it.
2. Consider what the editor's letter really says.
3. Wait, gather your thoughts.
4. Even if the reviewer is wrong it does not mean you are right.
5. Choose your battles wisely.
6. Never pit one reviewer against the other.
7. Be grateful for the editor's and reviewer's time.
8. Restate the reviewers comment(s) when responding.
9. Be prepared to cut text.
10. Do not submit to another journal without revising your manuscript.

To these tips we would add the following:

1. The editor is always right.
2. Be polite when responding.
3. Discuss the review with all the authors; take advice.
4. If the reviewer(s) misinterpreted your statements the most likely reason is that you did not write clearly.
5. Address each point the reviewers make. Address does not necessarily mean that you agree with the reviewer or accept their recommendation(s).
6. If you differ from the reviewer and do not accept a recommendation for changes you have to argue your point academically/scientifically and not emotionally or personally.
7. Absolutely avoid personal comments.
8. Write a well thought through letter to the editor. Do not fight with the editor. Remember point number 1.
9. If you have a good paper never give up, it will be published.
10. Even though we all hate criticism, use this process as another learning opportunity to improve your writing skills.

## What do you do if the article is accepted with minor revisions?

If the editor indicates that your paper is accepted with minor revisions – celebrate! Your paper will be published. Accept the changes the reviewers request and re-submit with a letter indicating exactly how you have responded to each of the reviewers suggestions and a letter to the editor thanking him /her. Do this quickly so that the editor does not have a chance to forget the article.

---

<sup>1</sup> Annesley TM. Top 10 tips for responding to the reviewer and editor comments. *Clinical Chemistry* 2011; 57:551-554.

## **What do you do if the editor's letter suggests that the article is possibly accepted but needs major revision(s)?**

This is the response that most authors receive (>80%). Do not think the editor or reviewer is against you. In most cases if you respond in detail to each of the recommendations made by the reviewers, your article should be accepted. Do not send it to another journal before answering the present one.

Read the letter carefully as well as the reviewers' comments to make sure you know exactly what the editor and the reviewers want.

Send the letter to your fellow authors without any comments (they probably have received an electronic copy already).

Re-read the letter after a day or two to make sure you understand the revisions required.

Discuss the letter with your fellow authors and devise a plan how to respond. Sometimes responding takes a lot of time. You might even have to re-analyse some of your data (remember the last TIP step 14 to safely store your final database?) or do an extensive literature search.

We recently wrote an 11-page response to a 7-page article and eventually got it published!

Take your time, do not rush. You must and will get it right. Discuss your reply with your fellow authors.

Write a covering letter to the editor on resubmission.

Follow all the rules of the journal for re-submission.

If you have answered all the reviewers' comments carefully, and you are lucky you can sometimes get a letter of acceptance within a week ( our record is 6 hours).

## **Now you know what to do, but how do you respond to the comments made by the reviewers?**

The easiest way is to copy the whole letter from the editor and reviewers onto a word document and then address each recommendation/query in a detailed respectful way. (See Appendix 10 for example of a reply to the editor /reviewer.)

## What do you do if your article is rejected?

The rejection can follow 2 courses. The one is a desk rejection by the editor who feels the article is not suited to the journal. There are no accompanying reviewers' comments so you have not learned about the strengths and weaknesses of your article. Reconsider your title and abstract to make sure you are selling your article. Choose the next journal on the list and submit the article.

The second type of rejection follows the comments and recommendations by the reviewers. It does not help fighting with the editor. Unless a reviewer has made a serious mistake the editor is going to back the reviewers. Read the reasons for the rejection carefully. Put the article aside for a day or three and then follow the process required for a major revision. After the article has been revised and all the authors agree with the revised version it is ready to resubmit to the next journal on your list.

Please do not resubmit without careful consideration of all the reviewers' points. Save yourself the pain of getting another unfavourable review.



All articles of scientific merit will get published: do not give up.

# STEP 17

## *How do you store your data once the study is completed?*

### What do you need to store and for how long?

Your data (electronic and hardcopy), data sharing agreement and your regulatory file need to be stored. The question is for how long? The rules state that all research documents must be stored for 15 years.

#### **Data:**

Apart from your regular data back-ups you have to store your final database. Ensure that you know which one was your final database. One of the worst things that can happen is that you submit your article for publication, the reviewers send some remarks and you have to look at your data again and you cannot remember which database was the final one. This can lead to hours of extra and unnecessary work and a lot of frustration

#### **Paper documents:**

The following must be stored safely and for 15 years:

- All research data, including the CRFs, questionnaires and consent forms.
- Regulatory file (example of index Appendix 6).
- Data sharing agreement or MOU with other colleagues (example Data Sharing Agreement Appendix 6).

All paper documents must be kept for 15 years. Long term storage requires a lock-up facility which is preferably safe from natural disasters like floods, fire and other destructive elements, for example rats and moths. As a further precautionary mechanism against water damage from burst water pipes or floods, never store data directly on the floor, always store it on shelves.

Data and documents should be stored in a logical format for later retrieval e.g. by community or by date or by unique identifier. The consent forms and the linking lists which contain names should always be stored in a separate locked filing cabinet.

## How not to store your data!!!!

Do you recognise Prof Gie sweeping the floor after a flood on 2nd floor one Friday afternoon in 2009? Data forms stored on the floor were water-boarded and destroyed!



The Department of Paediatrics and Child Health has a cabinet for the secure storage of research data and forms.

## Requirements on completion of the research study

After the final report is submitted to the Ethics Committee, and your study published, all documentation must be stored for a minimum period of 15 years. This should be stored in the department where you did your research and are enrolled as a postgraduate student. You and your supervisor will have to ensure that the necessary space is allocated and that your data is retrievable if necessary in the next 15 years.

## How do you dispose of your data after the required storage time?

You have to ensure that you inform the custodian of the storage facility when the data should be destroyed. You have to do it yourself or need to proactively arrange for this to take place in a confidential manner by the custodian. A good memorandum of understanding (MOU) should be in place when the data is stored for the first time. A good idea is to clearly indicate the following on the storage box:

- Name of study
- Name of investigator and mentor
- Funded by
- Type of documents
- Do not destroy before 2029 (or the date 15 years after completion)
- Additional information

# APPENDIX 1

## *Timeline*

There are various aids to developing a timeline.

### **On.Track electronic time manager:**

Available to postgraduate students and mentors registered at Stellenbosch University is an electronic timeline (On.track). This is a project management tool that enables students to complete their research study or thesis in the allocated time. This is a useful tool.

Registering for On.track is simple on this website:

<http://www0.sun.ac.za/ontrack/login.php>

- Register using your SU username and password
- Fill in your details
- Assign a mentor to your account
- Fill in your registration date
- Fill in your planned completion date

There is a video available on line at the Stellenbosch University Postgraduate and International student website to guide you through registration.

An example of a more traditional way of representing your planned timeline:

2013	April	May	Jun	July	Aug	Sept	Oct	Nov	Dec
Finalisation of research protocol	Draft 1 10 April 2013	Draft 2 10 May 2013	Draft 3 7 June 2013	Draft Final 5 July 2013					
Submit documents for Ethics approval [Set up Database]									
Obtain Health Department permission									
Implement work plan									
Preparing scientific reports, Presentation of the results									
Submission of manuscript to scientific journal									2014

What about a time line for a young researcher to complete their study within one year?

This is not a suggested timeline to follow but gives you an idea if you want to complete your study within 1 year of how tight the schedule has to be.

- Month 1: Consider your research idea  
Review the literature  
Approach a mentor
- Month 2: Develop your research question  
Consult with a biostatistician  
Write your research proposal  
Present your proposal to the Departmental committee
- Month 3: Submit your research proposal to the Human Research Ethics Committee (HREC)  
Develop your data collection tools.
- Month 4: Get a reply from the Human Research Ethics Committee  
Respond to any queries from the HREC
- Month 5-8: Collect your data
- Month 9: Clean your data set  
Analyze your data set
- Month 10: Write the first draft of the article/thesis  
Respond to the suggestions from your mentor
- Month 11: Complete the writing of the article/thesis  
Submit your article thesis
- Month 12: Respond to the examiner's/reviewer's comments  
Resubmit  
Graduate!!!!!!

# APPENDIX 2



**MENDELEY**

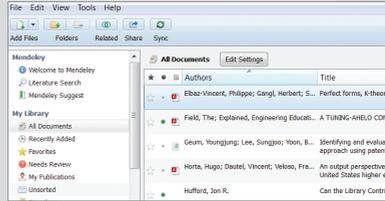
Quick Reference Guide



# How to use Mendeley in 4 steps



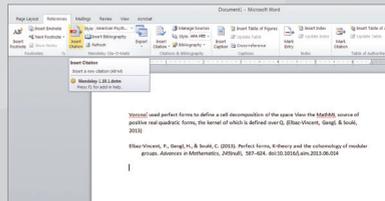
1. Download articles directly from platforms like ScienceDirect.



2. Store an article in your library, sort it and have it with you wherever you are, online and offline.



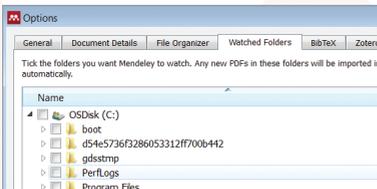
3. Highlight, annotate and share articles with your research team members.



4. Create references in new papers and select a citation style with one click.



## 1. Download articles directly from platforms like ScienceDirect.

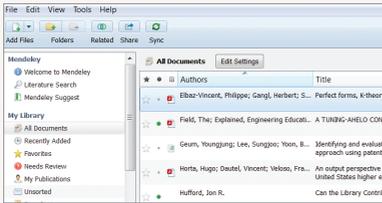


There are many ways to get articles into your Mendeley library. Try one of these popular methods:

- **Import from your reference manager:** Use the import function under the 'File' tab in Mendeley desktop.
- **Use the web importer:** Get the web importer from the 'Tools' bar in Mendeley desktop and import articles directly.
- **Use the watch folder:** Create a folder on your own computer and set up Mendeley to watch this folder using the settings under the 'File' tab. Each PDF saved to that folder will be automatically imported to your Mendeley library.
- **Search Mendeley:** Use either 'Papers' on the web version or 'Literature Search' in Mendeley desktop.



## 2. Store an article in your library and use it wherever you are, online and offline.

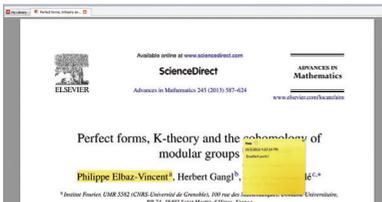


Once documents are in your Mendeley library, you can organise them using an iTunes-style folder management approach.

- Create folders to keep various research interests separate from one another.
- Add tags to make it easy to find articles.
- Use the 'Sync' button so that changes you make in your desktop version of Mendeley are automatically carried over to your web and iOS versions (and vice versa).
- 'Mendeley suggest' presents you with interesting articles in your field based on the contents of your library.
- Use 'Account usage' in your Mendeley web version to keep track of how much of your free 2GB storage space you have available.



## 3. Highlight, annotate and share articles with your research team members.

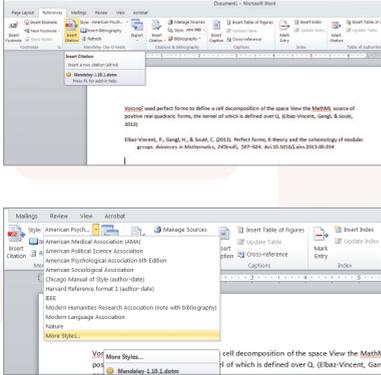


Create private groups on Mendeley desktop or web versions, or join public groups. Basic Mendeley allows you to create private groups with up to 3 members per group.

- Use drag-and-drop to add articles to your groups.
- Annotate and highlight articles in your library and share them with your private group(s). Then, group members will be able to see your edits and add their own annotations and highlights.
- Join public 'Groups' in the web version of Mendeley.
- Team plans are also available. A Team Plan allows you to create an unlimited number of private groups with up to 50 people, and get unlimited group library space.



## 4. Create references in new papers and select a citation style with one click.



Mendeley helps you easily create and format citations in papers you are writing.

- Install the **Mendeley Citation Plugin** found under 'Tools' in the desktop version of Mendeley.
- Once installed, the plugin is visible in the 'References' tab of the MS Word menu bar.
- You can now easily:
  - Insert citations (always click 'Cite').
  - Insert a bibliography at the end of your paper or chapter.
  - Choose from over 6,500 citation formats and change the citation style with one click of a button.



## Remember to personalize!

**Dr. Victor Henning**  
Co-Founder, Mendeley & VP Strategy, Elsevier  
Amsterdam, Netherlands

**Research field: Psychology - Cognition**  
Emotions, Decision Making, Theory of Reasoned Action, Internet Movie Picture Economics

**Publications**

▼ Journal Article (6)

Victor Henning, Thorsten Hennig-Thurau, Stephanie Feiereisen (2012) Giving the Heart, 705-781. In *Psychology & Marketing* 29 (10).  
Download PDF (3.84 MB)

Victor Henning (2012) 研究者コミュニケーションを根本から変える。文書管理の革命 情報流通の将来 (Revolution of the reference management tool and its huge pot communications: The future of scholarly communications described by CEO of *Journal of Information Processing and Management* 55 (4).  
<http://japanlinkcenter.org/CIW-JST...>

Kris Jack, James Hammenton, Dan Harvey et al. (2010) Mendeley's Reply to the *Procedia Computer Science* 1 (2).

We hope you enjoy working with Mendeley, the free reference manager and academic social network.

Remember to **create your own personal profile** and keep it current by uploading your papers to promote your work and to be found by other researchers.

If you need more help using Mendeley, have a look at:

[www.resources.mendeley.com](http://www.resources.mendeley.com)

10.2013

# APPENDIX 3

## Appendix 3 Two by two table (2x2)

		Disease or Outcome	
		Yes	No
		Pneumonia	Pneumonia
Determinant	Yes HIV+	a	b
	No HIV-	c	d

From the 2x2 table, you can calculate

		Outcome	
		Yes	No
		Pneumonia	Pneumonia
Determinant	Yes HIV+	a	b
	No HIV-	c	d

- Proportion(s) =  $a/(a+b)$  e.g. the proportion of children with pneumonia in HIV+ children
- Risk Ratio (RR) =  $\text{Proportion1} / \text{proportion2}$  e.g. the RR of pneumonia in HIV+ children compared to HIV- children given by  $(a/a+b)/(c/c+d)$
- Risk Difference (RD) =  $\text{Proportion1} - \text{Proportion2}$  e.g.  $(a/a+b) - (c/c+d)$
- Odds1/given HIV+ = # with outcome/# without e.g. Odds for pneumonia in HIV+ children =  $a/b$
- Odds2/given HIV- = # with outcome/# without e.g. Odds for pneumonia in HIV- children =  $c/d$
- Odds ratio (OR) =  $\text{Odds1}/\text{Odds2} = ad/cb$

# APPENDIX 4

## *Glossary to help you when reading papers and visiting the biostatistician*

This is not meant to be a course on biostatistics but rather explanations of terms you might encounter at various stages of your study: planning, analysis and reporting..

**TIP:** It would be to your advantage to have a look at these short explanations prior to your first (and subsequent) meetings with the biostatistician, as this will facilitate the deliberations.

The biostatistician will in the course of the discussions use other statistical terms that you might not understand but you will at least be able to follow most of the discussion without asking for an explanation of every term.

We have included two links:

1. To an alphabetic statistical glossary from the **Centre for Statistics in Medicine (CSM)** based at Oxford. This glossary covers most of the concepts that you will encounter in your study.

Examples from this glossary are:

*Categorical variable*

A variable whose value ranges over categories and has no numerical value, such as: red, green, blue.

*Clinical significance*

A statistically significant result does not necessarily imply that it is useful in a clinical setting (does the treatment reduce a patient's blood pressure by a worthwhile amount? Does it help the patient?). Clinical significance is a matter of judgement taking into account the clinical importance and applicability of the results

*Number needed to treat (NNT)*

This is one measure of a treatments clinical effectiveness. It is the (average) number of people you would need to treat with a specific intervention (e.g. aspirin for people having a heart attack) to see one additional occurrence of a specific outcome (e.g. prevention of death).

### *Validity*

Validity is the degree to which a measurement truly reflects what it claims to measure. When critically appraising a paper it is important to assess whether any known biases could have affected the results (internal validity).

### **Link to statistical glossary**

<http://www.csm-oxford.org.uk/statistical-resources/statistical-glossary/>

2. To the **BMJ Statistics Notes**, which is, a series of short papers that outline a specific statistical analysis. These notes have been written for clinicians and researcher to help them understand the statistical reasoning behind a specific analysis.

Examples of the notes are:

- One- and two-sided tests of significance BMJ 1994;
- The cost of dichotomising continuous variables BMJ 2006;
- How to obtain the P-value from a confidence interval BMJ 2011.

### **Link to the notes:**

<http://www.csm-oxford.org.uk/publications/bmj-statistics-notes/>

The notes are also available from the BMJ directly

# APPENDIX 5

## *Outline/framework for research proposal*

Title page	
	Study title
	Registrar name and surname
	Mentor name and surname
	Co-investigator(s)
	Contact details for all of above
Summary	
Literature review	
Defining the research	
	Research question
	Hypothesis
	Aims and objectives (for descriptive study)
Study Methods	
	Study setting
	Study design
	Target and study population
	Sampling
	Sample size and power
	Variables, definitions and data sources
	Data collection
	Data management
	Data analysis plan
Ethical considerations	
	Ethical considerations
	Submission to Ethics Committee
	Submission to other committees for permission to do study
Strengths and limitations	
Communication and Dissemination	
Study management	
	Roles and responsibilities
	Study timelines
	Regulatory aspects (if linked to a study with specific regulatory requirements)
References	
Appendices	
	Researcher's curriculum vitae
	Data collection tools e.g. case report form (CRF) and Data Dictionary
	Consent Forms
	Budget and budget narrative
	Timelines

# APPENDIX 6

## *Regulatory file and what should be stored long-term*

There are certain documents that you have to store long term. Here are examples of some of these documents.

### Regulatory file example:

1.	Index
2.	Title Page: Study Title Name of Registrar/ co-investigators Name of Mentor Ethics Committee Approval Number Other Approval Numbers
3.	Protocol/proposal <ul style="list-style-type: none"><li>• This must contain your CRF/questionnaire</li><li>• The initial proposal and ALL subsequent drafts and amendments</li><li>• All drafts must contain a draft date and number</li><li>• The application for ethics approval is attached to the final protocol/proposal</li></ul>
4.	Consent Form & Information Sheets
5.	CVs: <ul style="list-style-type: none"><li>• Your CV</li><li>• Your mentor's CV</li></ul>
6.	Investigator Declarations: The Ethics Committee may request a statement on financial or other competing interests with respect to the study, which may present a potential conflict of interest for the investigators Ensure that you know what the rules are
7.	Ethics: Approval letters and reference numbers. Include ethics renewals. Progress reports and annual renewal confirmation
8.	Other Approvals Department of Health application forms and approval letters
9.	Final database name and where stored
10.	Data Share Agreement
11.	Incidents/Adverse Events
12.	Budget and Expenditure Reports
13.	Standard Operating Procedures (if any)
14.	Manuscripts submitted/Publications/Presentations/Posters

# Data (or sample) sharing agreement example:

Date.....

**Agreement between:**

Your name

Department Paediatrics and Child Health, Faculty of Medicine and health Sciences, Stellenbosch University and Tygerberg Children’s Hospital, South Africa

**and**

Name of Research investigator

Contact details

Name of Research Institution

**Conditions of data transfer:**

1. Reason for data transfer: (Brief summary below including list of analysis to be done and outcomes. Full proposal should be attached as appendix and must be submitted for Ethics Approval)
2. Data transferred between the above institutions will be kept confidential and will not be copied, sent or made available to other institutions.
3. Any additional analysis of the data (not listed above) must be pre-approved by the submission of an additional protocol describing the proposed study.
4. It must be accepted that the data will change from time to time and therefore the recipient institution must enquire about updates before final analysis and publication.
5. If there is a data sharing agreement, then all research done on the data must be viewed as collaborative research.
6. All manuscripts arising from the analysis of the data must be reviewed by a collaborative researcher in the institution where the data originated and you (and your mentor and probably some of your colleagues at Stellenbosch University) should be authors.
7. Queries used to select the data must accompany the data to inform the collaborator of what data has been sent.
8. Stellenbosch University cannot be held responsible for errors occurring in the data.
9. On completion of the study all the transferred data must be destroyed. Similarly, when a new version of the data is issued the old version should be destroyed.
10. First and Senior authorship must be agreed upon, prior to the initiation of the study.

**Agreed by:**

**Host Institution:**

Executive Head,  
Department Paediatrics and Child Health  
Stellenbosch University

Data manager or co-investigator

Name:

Name:

Date:

Date:

The above signature does not necessarily entitle the right to co-authorship

**Agreed by Collaborative institution:**

Head of Department

Research investigator

Name

Name

Date:

Date:

The above signature does not necessarily entitle the right to co-authorship

# APPENDIX 7

## *Data Collection Tools*

### **Data sources:**

Data sources are the places/documents you will use to collect your data from. Mostly you will use hospital or clinic folders with the data already collected by someone else. This is known as routinely collected data.

Sometimes you will start collecting data right from scratch – this is a much more lengthy process and you never know whether you will have enough children to enrol into your study.

For each variable, it is important to specify the data source that the variable will be collected from. For example, you may use the hospital folder to obtain information about the child's hospital stay and then also use the child's road-to-health card to obtain information about birth weight, immunization status, weight gain and the mother's HIV status during pregnancy.

### **Variables:**

Variables are the pieces of information (data) that are collected in a research study in order to address the research question. There are two main types of variables:

#### **Categorical variables**

- **Nominal:** These are named categories where one category is no worse than the next. For example sex is either male or female; outcome can be either death or survival. There is nothing in-between
- **Ordinal:** These variables are ordered, with gradation over the category. For example, HIV disease staging as WHO Stage 1, 2, 3 or 4.

#### **Numerical variables**

- **Discrete variables:** The data consist of whole numbers and the values do not overlap in any way. For example, a child could only have had 1,2,3,4 previous pneumonia episodes. A child cannot have had 1.5 episodes of pneumonia.
- **Continuous variables:** The data may have a value anywhere along a

continuum. For example, age could be said to be 6 months but is truly 6.546348..... etc. And by the time this number is written, the age has already moved on several decimal points. For this reason, continuous variables are 'rounded' to a specified level.

It is important to indicate the type of variable because the statistical analysis differs based on the type of variable. This is discussed further in the Steps on involving the biostatistician and data analysis.

You should always collect variables at the highest level of detail possible. For example rather use either the date of birth or the age rather than using age group (eg 0-2 years, 3-10 years, 11-15 years... etc.), The data can be collapsed into categories for analysis at a later stage if required, but if you collect data in an age group, you can never "un-collapse" it.

## **Definitions:**

Once you have decided which variables you are going to collect, you have to define each variable carefully and accurately.

## **The data dictionary:**

You have to develop a data dictionary – this will ensure that you think logically about the structure and the format of data that you are going to collect and will ensure that you collect good quality data. It is much better to collect data right from the beginning into the format that will be used for analysis. For example data on male or female should be collected as nominal categorical variables (convention is male= 1 and Female = 2 and not as M or F).

The data dictionary should contain at least the following information for each variable that you are going to collect:

- Variable name
- Variable definition/description
- Format / type (character, integer, date or free text)
- Length
- Value / format / range (permitted values)
- Logic checks (e.g. root vs. nested question: cannot have number of pregnancies completed if sex was recorded as male)
- Missing values (e.g. -99=Unknown) – make sure that the symbol used for the unknown value is not a value that can occur in the real data for that or any other variable.

Variable Name	Variable Description	Type	Length	Coding/Format	Range/ Value	Logic Checks
PID	Patient ID = Unique Identifier	Integer	4	May not be null	0001;9999	No duplicates
Q01_DOB	Date of Birth	Date	10	DDMMYYYY Unknown=01011800	< or = today	Must be before Date of Interview If Unknown – enter age
Q02_Age*	Age	Integer	3	Months	>0; (if child < 216)	If DOB entered – default value = 999
Q03_Ward	Ward name	Integer	2	1= Gground 2= F1 etc. 15= PICU	0-15	May not be 0
Q04_Sex	Gender	Integer	1	1= Male 2= Female 3= Unknown	1-3	May not be 0

\* Note: Good example of why you have to do a data dictionary and set the coding/format/values and ranges – if you collect data on the age of each child, decide whether you collect age in months which will be good for the young children and babies but then an 18 year old will be 216 months! So consider whether it will be best to collect age in months or years. What you do not want, is to have values filled in and you are uncertain whether the values represent months or years.....and this has happened to most researchers who collect ages on children.

You must set the length and an acceptable range for each variable– this is very important and will influence the quality of the data collected as well of course the results.

You can collect information either as numbers or as text. It is not advisable to collect free text data and it is much better to use codes or numbers.

## CRF

You have to develop a CRF and submit to the ethics committee irrespective of whether you are going to use paper to collect your data or whether you are going to use an electronic data capture device. If you decide to use an electronic data capture device, make sure you have an expert to programme your CRF/ questionnaire onto the device.

Often the data that you are going to use in your study, have already been collected and is known as the source data – these are the data variables in the child’s hospital folder, road-to-health card, or is available from the laboratory. You may wish to collect additional data.

All the data that you are going to use from the source data or which you are going to collect, must be documented on a case report form (CRF) and the variables collected on the CRF, must appear in your data dictionary.

The CRF should be simple and contain all the variables required. The data collected should be guided by the variables required for the study rather than the data available in the source document.

The questions in the CRF should follow a logical sequence. For example, data that is available at the start of a hospital file (e.g. demographic information such as age and sex) should be collected early in the CRF whilst data on HIV status or all the tests the child had to diagnose pneumonia should be collected towards the end of the CRF. If you collect data from multiple data sources, you should group the questions according to the data source used.

We strongly advise that you pilot the CRF before you start using it in the study. After all the years of developing CRFs, we yet have to develop a CRF that does not require adaptation after piloting it.

But remember that you can only pilot the CRF after obtaining ethics approval. The pilot should be undertaken on a similar population to that used in the study but data from the pilot cannot be used in the analysis of the study. You should use the pilot data to calculate ‘dummy’ outcomes as this will also help to ensure that all the required variables are being collected.

Once study data collection commences, the CRF must be routinely monitored to improve accuracy and ensure completeness. A data collection Standard Operating Procedure (SOP) should be developed that sets out all of the pertinent issues: from selection of records to be reviewed, to collection of data elements, to handling of missing records or data, to checking the CRF for completeness and other quality assurance checks.

## **Guidance for developing a CRF:**

- Do not collapse variables.
- Collect information exactly as it is recorded in the source document. Avoid having to interpret information from the hospital file. For example, if you want to know whether a child gained weight during his/her hospital stay, set up the CRF in such a way to record the weight in Kg together with a date, rather than interpreting “did the child gain weight”?
- Collect the highest level of detail possible. For example collect the exact dates when the child was admitted and the date when treatment was started rather than how many days did it take to start treatment – this can be calculated from the dates.

- Collect date of birth and date of admission and calculate exact age, rather than collect age as 3 yr.
- Ensure that all possible responses are included in a question. For example, do not have only “Yes” / “No” categories - include the response categories ‘No record’, ‘Not done’ and ‘Not applicable’ where appropriate. The use of an option ‘Other’ should be kept to a minimum as this requires a substantial additional effort in post-coding once data collection has been completed. The range of response categories can often only be finalised once the CRF has been piloted.
- Do not include any open ended questions.
- Decide for which questions there can only be a single response, and which questions can have multiple responses.
- Line up check boxes on right hand side of page for easy completion. This greatly reduces missing some boxes.

**Example**

With a single response variable, only one response is possible in the different categories as shown in the following examples:

*Sputum culture results (tick only ONE box):*

- 1. Positive .....
- 2. Negative .....
- 3. Contaminated .....
- 4. Taken but no result available .....
- 5. No record of culture taken .....

Some variables allow for *multiple responses* to the question. For example:

*Tests done to make diagnosis of pneumonia (tick one or more boxes).*

- 1. Sputum Culture.....
- 2. Blood Culture .....
- 3. Chest XRay .....
- 4. No record of tests done .....

For continuous variables, categories cannot be specified. However, a format should be selected to help standardise data collection. For example:

Date of admission (DD/MM/YYYY)..... //

CD4 count (cells/ul) on admission.....

Weight (kg with 2 after decimal point) on admission..... .

Some data e.g. laboratory results may be available in electronic format and this makes data collection very easy. If you want to use electronic data, ensure that you discuss this carefully with the head of the laboratory and discuss roles, responsibilities and authorship. Request that the data be provided in a format that will be easy to import into your study database.

## Confidentiality:

Three lists are needed to ensure confidentiality (See also Step 11):

1. A list with subject name, surname and unique subject ID

List with child's name, surname and unique subject ID	
Name/Surname	Subject ID

2. A list with unique subject ID and unique study code (no name, no result).

List with unique subject ID and unique study code (no name, no result).	
Subject ID	Study code

3. A list with unique study code (no name, no unique subject ID), columns for results.

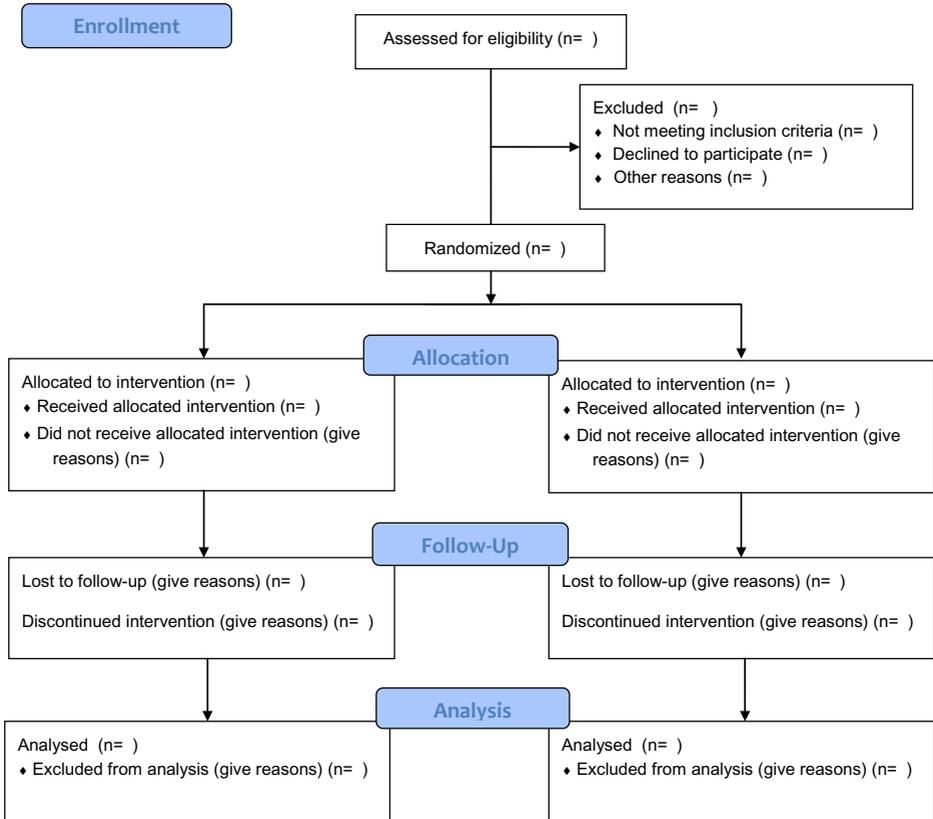
List with unique study code (no name, no unique subject ID), and column for results	
Study code	Results

In some instances, personal identifiers (names, dates of birth, address, etc.) may be required to perform record linkage e.g. if you want to link a child's CXR result with the laboratory result. If this is necessary, the procedures to carry it out must be described along with processes to ensure that, after linkage is complete, personal identifiers are removed.

You must describe the exact manner in which you (or anyone else) will access data and steps taken to ensure confidentiality.

# APPENDIX 8

## CONSORT Flow Diagram<sup>1</sup>



<sup>1</sup> [www.consort-statement.org](http://www.consort-statement.org)

# APPENDIX 9

## *How to use Turnitin to diminish plagiarism*

You have to be a registered postgraduate student at the Stellenbosch University to be able to use this facility. (you need your username and password)

If it does not allow you please contact the Postgraduate and International student division to ensure that you are registered.

The screenshot shows the SUNLearn homepage. At the top right, it says "You are not logged in. (Login)". The main content area is divided into several sections: "NAVIGATION" with links for Home, Contact us, Site news, and Courses; "COURSE CATEGORIES" listing various disciplines like Medicine and Health Sciences, Military Sciences, Engineering, etc.; "Facilitator Training" and "Password help" buttons; "Student Training" and "Contact Us" buttons; "LATEST NEWS" with a recent update about Turnitin downtime; and a "CALENDAR" for August 2014. A large graphic in the center reads "Assignments... HET JY GEWEET" followed by several large red question marks.

Go to the top right and login  
Use your username (rpg1) and password.

The screenshot shows the SUNLearn user interface after login. The user is logged in as Anita Fourie. The main content area displays "COURSE OVERVIEW" for the "Robert Peter Gie Training Module" and a notification: "You have assignments that need attention". Other sections include "NAVIGATION" with a breadcrumb trail, "ADMINISTRATION" with profile settings, "CLOCK" showing the server time, and "MY PRIVATE FILES" which currently has no files available. A list of "ONLINE USERS" is also visible, including Nm Pugin, Jr Van Niekerk, V Roeloffse, Zander Juan Rossouw, Samantha Di Bona, B Fick, Ja Dorfling, Eugenie Lamprecht, and Sybrand Hagan.

You are now login  
Click on Robert Gie training module

The screenshot shows the SUNLearn interface. At the top, there is a breadcrumb trail: "My home > My courses > Training Courses > Robert Peter Gie Training Module". On the right, it says "Turn editing on" and "You are logged in as Anita Fourie (Logout)". The main header is "SUNLearn". On the left is a "NAVIGATION" menu with a tree structure: "My home", "Site home", "SUNLearn", "My profile", "Current course", "Robert Peter Gie Training Module", "Participants", "Badges", "General", "Topic 1", "Topic 2", "Topic 3", "Topic 4", "Topic 5", "Topic 6". The main content area shows "News forum" and three "Topic" sections, each with a "Turnitin" icon. On the right, there are three boxes: "SEARCH FORUMS" with a search input and "Go" button; "LATEST NEWS" with "Add a new topic..." and "(No news has been posted yet)"; and "UPCOMING EVENTS" with "There are no upcoming events", "Go to calendar...", and "New event..."

Click on Turnitin under Topic 1

The screenshot shows the SUNLearn Turnitin interface. The breadcrumb trail is "My home > My courses > Training Courses > Robert Peter Gie Training Module > Topic 1 > Turnitin". The header is "SUNLearn". On the left is a "NAVIGATION" menu with a tree structure: "My home", "Site home", "SUNLearn", "My profile", "Current course", "Robert Peter Gie Training Module", "Participants", "Badges", "General", "Topic 1", "Turnitin", "Topic 2", "Topic 3", "Topic 4", "Topic 5", "Topic 6", "Topic 7", "Topic 8", "Topic 9", "Topic 10", "My courses". Below the navigation menu is an "ADMINISTRATION" menu with options: "Assignment administration", "Edit settings", "Locally assigned roles", "Permissions", "Check permissions", "Filters", "Logs", "Settings", "Restore", "Advanced grading", "View gradebook". The main content area is titled "Turnitin" and says "Dear Turnitin students here is". It has a "Grading summary" section with a table:

Participants	1
Submitted	0
Needs grading	0
Due date	Tuesday, 11 August 2015, 10:15 AM
Time remaining	1 year 6 days

Below the table is a "View/grade all submissions" button. There is also a "Submission status" section with a table:

Submission status	No attempt
Grading status	Not graded
Due date	Tuesday, 11 August 2015, 10:15 AM
Time remaining	1 year 6 days

At the bottom of the submission status section is an "Add submission" button and the text "Make changes to your submission".

Click on "Add submission" at the end of the page.

## SUNLearn

NAVIGATION

My home

- Site home
- SUNLearn
- My profile
- Current course
  - Robert Peter Gie Training Module
    - Participants
    - Badges
    - General
    - Topic 1
      - Turnitin**
      - Topic 2
      - Topic 3
      - Topic 4
      - Topic 5
      - Topic 6
      - Topic 7
      - Topic 8
      - Topic 9
      - Topic 10
- My courses

ADMINISTRATION

- Assignment administration
- Edit settings

### Turnitin

Dien Turnitin skakels hier in

All files uploaded will be submitted to the plagiarism detection service Turnitin.com

#### File submissions

Maximum size for new files: 20MB, maximum attachments: 20 - drag and drop not supported

↓ Add Create folder

Files

Save changes Cancel

Add file by clicking on Add  
Then remember to click on “Save”

## SUNLearn

NAVIGATION

My home

- Site home
- SUNLearn
- My profile
- Current course
  - Robert Peter Gie Training Module
    - Participants
    - Badges
    - General
    - Topic 1
      - Turnitin**
      - Topic 2
      - Topic 3
      - Topic 4
      - Topic 5
      - Topic 6
      - Topic 7
      - Topic 8
      - Topic 9
      - Topic 10
  - My courses

### Turnitin

Dien Turnitin skakels hier in

#### Grading summary

Participants	1
Submitted	0
Needs grading	0
Due date	Tuesday, 11 August 2015, 10:15 AM
Time remaining	1 year 6 days

[View/grade all submissions](#)

#### Submission status

Submission status No attempt

The submission will be available in a few hours  
Click on View/grade submissions

# APPENDIX 10

## *Author's response to the editor/reviewers*

### **Guidelines:**

- Always change technical errors.
- Always correct reference errors.
- Always add additional references suggested by the reviewers.
- Always change sections unclear to the reviewer.
- Always change comments made by both reviewers.
- Always be polite.
- Always argue scientifically and systematically.

### **Process:**

- If the comments involve minor changes, discuss these with your mentor and get going in preparing the documents to submit.
- If the comments involve major changes, then discuss with your mentor and co-authors. Sometimes a strategy for answering comments or for doing additional analysis should be discussed and agreed upon by all authors.
- Prepare documents for re-submission.
- Circulate these documents to all the authors and ask for their comments within a short period of time.
- Resubmit the documents within the grace period granted by the editor.

### **You must prepare at least the following 3 documents:**

1. Letter to the editor.
2. Document with response to reviewers.
3. Manuscript with track changes. Check requirements from the journal.

Some detail about these documents:

#### **1. Letter to the editor**

The letter should include the following:

- Thank the editor for reviewing the paper.
- Write a brief summary of the changes that you have made to the article (major changes).
- You can ask the editor's opinion regarding differences between reviewers (major differences).
- The letter should be brief (Half a page or less).

## 2. Document with response to reviewers.

- Reply to reviewer 1.
- Thank the reviewer and give a brief (1 paragraph) summary of the changes.

Now copy the comments the reviewer made and respond to these comments one by one.

Examples:

Comment 1.

This is an interesting article on the management neonatal hyperbilirubinemia in a low income country and would be a valuable addition to the literature.

*Response:*

*We thank the reviewer for this kind comment*

Comment 2:

It is unclear which neonates were included in each arm of the intervention.

*Response:*

*To ensure clarity of which neonates were included in the intervention arm and the control arm of the study we have now included a flow diagram (Figure 2) in the article. Reference to Figure 2 is included in the manuscript (page 2 line 15).*

Comment 3:

The scientific value of the article would be enhanced if the authors had long term data on the outcome of the neonates included in the observational arm of the intervention.

*Response:*

*We agree with the reviewer. Unfortunately the study was conducted in a region of the province where the long term follow up of these children was not possible due to logistical constraints. We have carefully considered this and are planning a long-term follow up study to try to address this important issue. We have included this as a weakness of the study in the discussion (p6 line 13).*

Comment 3,4,5,6 etc.

Reply to Reviewer 2,3,4

## 3. A manuscript with track changes and one without track changes (see journal requirements).

# TEMPLATES

The templates that follow are available on the Department of Paediatrics and Child Health website.

[www.sun.ac.za/paediatrics](http://www.sun.ac.za/paediatrics)



Use the formatted templates freely for your application but do not fiddle with the formatting.

# TEMPLATE 1

This template is a framework to help you write down your proposal, in a way that will be acceptable for submission to the ethics committee in terms of sections and sub-sections.

It is not a template to be used before you have put a lot of thought into your research question, or before you have discussed your study with a biostatistician or before you have selected and discussed your research with your mentor

The template has been formatted to make it easy to use. If you mess up the formatting – you have to un-mess it again on your own!

You can download the template from the website [www.sun.ac.za/paediatrics](http://www.sun.ac.za/paediatrics)

## TITLE PAGE

### Registrar Research Proposal

#### STUDY TITLE

**REGISTRAR NAME** Type name here

**MENTOR:** Type your mentor's name here

**DEPARTMENT** Type name of PI/s employing  
department and institution

**Address** Type contact details here

**Telephone**

**Fax Number**

**E-mail Address**

**CO-INVESTIGATOR/S** Type name/s here if any

**DEPARTMENT** Department of Paediatrics and Child  
Health

**Address** Type contact details here

**Telephone**

**Fax Number**

**E-mail Address**

**PARTNER ORGANISATIONS** Type names of organisations if any.

**FUNDING REQUESTED** If any

**DURATION OF PROJECT** Type number of months

**Start date** DD MM 20YY

**End date** DD MM 20YY

*Update the following information each time you submit a draft to your mentor:*

**DRAFT NUMBER:** Type draft number here (1, 2, 3, Final)

**DATE OF SUBMISSION:** DD MM 20YY

## **CONTENTS**

### **SUMMARY**

### **FULL PROPOSAL**

- 1. REVIEW OF LITERATURE**
- 2. DEFINING THE RESEARCH**
  - 2.1. RESEARCH QUESTION
  - 2.2. HYPOTHESIS
  - 2.3. TWO-BY-TWO TABLE (START WITH THIS BUT YOU CAN LATER DELETE)
  - 2.4. AIMS AND OBJECTIVES
- 3. STUDY METHODS**
  - 3.1. STUDY SETTING
  - 3.2. STUDY DESIGN
  - 3.3. TARGET AND STUDY POPULATION
  - 3.4. SAMPLING, SAMPLE SIZE AND POWER
  - 3.5. VARIABLES, DEFINITIONS AND DATA SOURCES
  - 3.6. DATA COLLECTION
  - 3.7. DATA MANAGEMENT
  - 3.8. DATA ANALYSIS PLAN
- 4. ETHICAL CONSIDERATIONS**
- 5. STRENGTHS AND LIMITATIONS**
- 6. COMMUNICATION AND DISSEMINATION**
- 7. STUDY MANAGEMENT**
  - 6.1. ROLES AND RESPONSIBILITIES
  - 6.2. PROJECT TIMELINES (SEE APPENDIX 5)
  - 6.3. REGULATORY ASPECTS
- 8. REFERENCES**
- 9. APPENDICES**
  - APPENDIX: CV (TEMPLATE 2)
  - APPENDIX: DATA COLLECTION TOOLS AND DATA DICTIONARY (APPENDIX 7)
  - APPENDIX: CONSENT FORMS (TEMPLATE 4)
  - APPENDIX: BUDGET AND BUDGET NARRATIVE (STEP 8 AND TEMPLATE 3)
  - APPENDIX: TIMELINES (APPENDIX 1)

## **SUMMARY**

This is a short summary (usually 1-2 pages) of the project proposal and is only written after the rest of the proposal has been completed. Do not use abbreviations or insert tables, figures or references into the summary. The summary should contain the following sub-headings:

**Background/Literature review:**

**Research questions, hypothesis, objectives:**

**Methods including all the major aspects:**

**Ethical considerations:**

## FULL PROPOSAL – Check how long this should be and stick to the guidelines

### 1. REVIEW OF LITERATURE

See Step 3

### 2. Defining the research

#### Research question

See Step 4

Frame the research question in terms of the problem (outcome) and factors influencing the problem (determinant).

#### Hypothesis

State the hypothesis (statement of association)  $H_a$ : There is an association between *determinant* and *outcome*.

State the null hypothesis (statement of no association)  $H_o$ : There is no association between *determinant* and *outcome*.

Example of research question, hypothesis and null hypothesis:

If the research question is: Is a child who is HIV+ more likely to have pneumonia than a child who is HIV-?

This is transformed to an hypothesis as follows: There is an association between being HIV+ and having pneumonia.

The null hypothesis is: There is no association between being HIV+ and having pneumonia.

The hypothesis is made up of two factors - the main variable namely HIV status and the main outcome namely pneumonia.

Statistical methods are used to either prove or refute the null hypothesis.

#### Two-by-two table (if you do a comparative study)

See also Step 5

It is a good idea to include your two-by two-table showing key determinant and outcome during the initial phases of proposal development to assist you with clear

and disciplined thinking and developing the various components of the proposal. Once the proposal is completed, the 2x2 table can be deleted.

The two-by-two table is an easy way to think clearly about the association between the main variable and the main outcome.

The outcome variable (the problem you wish to study e.g. pneumonia) is placed at the top of the table and the exposure variable (the key determinant e.g. HIV status) at the left side of the table. The table is constructed such that the worst event (HIV+ and pneumonia – the result ‘yes / yes’ to the presence of the two variables) is in the upper left box and the best event (HIV- and no pneumonia – the answer ‘no / no’ to the presence of the two variables) in the lower right box. It is important to get into a habit of placing them this way to avoid confusion when seeing the results of the statistical analysis and to interpret the results of the study in the correct

### **Aims and objectives (if you do a descriptive study)**

List the specific aim / purpose / goal of the project. Identify the objectives that will be required to achieve this aim. Include secondary objectives where required.

### **3. Study Methods**

This is the recipe for your research and enables you to write down and discuss with your mentor exactly what you want to do. It also enables anyone reviewing the research (like the ethics committee) and later when you publish your results, to repeat the study in another location or time. In this part of the research proposal, it is essential to be comprehensive and precise and you have to define each term used, describe exactly how the data will be collected and managed and how it will be compared to make a scientific conclusion.

#### **Study setting**

Describe the place where the research will be undertaken – in Tygerberg Children’s Hospital, or in a specific clinic or in Brooklyn Chest Hospital etc. Describe briefly what type of management and care is normally given to the children that you will include in your study. By reading this section, someone outside the situation (in another country, in another hospital) should be able to understand the study setting and how it is similar or differs from their own setting. For example would the management, care and diagnosis of HIV and pneumonia and the type of children admitted to the hospital be the same in Tygerberg Children’s Hospital, Brooklyn Chest hospital, Paarl Hospital and Great Ormand Street Hospital? In order for the reader of your published article to understand the context and setting of your research, it is important to describe the setting accurately and in detail.

## **Study design**

Describe the study design e.g. cross-sectional study, cohort study, case control study and provide the rationale for selecting this type of study design. (Step 5)

## **Target and study population**

See Step 7 and remember PICOT

Describe the target, accessible and study populations. List the inclusion and exclusion criteria for participation in the study. If you study the association between HIV and pneumonia, the target population is all the children in the whole world. You can of course not study all these children because you have access only to the children in (for example) Tygerberg Children's Hospital (the accessible population). You will then select to include (for example) all children of a certain age over a certain period in Tygerberg Children's Hospital who had an HIV test done and who have information on whether or not they have pneumonia (the study population). It is essential to remember that your results and conclusion will be true only for the children selected for your study from Tygerberg Children's Hospital (study population) and not for all the children in the whole world (target population)

It is important to clearly state which children will be excluded and to ensure that you will not bias the study by excluding certain children

## **Sampling**

If you want to select a sample from the study population you have to discuss this with a biostatistician before you finalise your proposal. It is not good enough to state in proposal "a biostatistician will be consulted".

The biostatistician will help you to describe the sampling frame and how the study sample will be drawn. You have to discuss with the biostatistician which assumptions should be used in calculating the sample size.

Use your time with the biostatistician as a learning opportunity.

## **Sample size and power**

For this section you need to talk to your statistician. See Step 6

## **Variables, definitions and data sources**

See Step 11 and Appendix 9.

In this section you describe what you will collect. Mention the most important variables that you will collect in the proposal. As an appendix list all the variables that will be collected and for each, classify the type of variable, define the variable precisely and indicate the source from which that variable will be collected (case report form (CRF), questionnaire, data dictionary).

## **Data collection**

See Step 11 and Appendix 6

In this section you describe how you will collect the data. You basically have two options:

- Paper questionnaire/case report form (CRF)
- Electronic data capture device (like a tablet).

Clearly state if you are going to do any additional tests or anything that is not standard of care.

Clearly define each variable.

The detail of the variables you are going to collect, the CRF, the data dictionary should be added as appendices.

## **Data management**

See Step 11 and Appendix 6

Describe the process of collecting, capturing, storing and preparing the data for analysis. Indicate how ethical standards specifically how the confidentiality of data will be maintained.

Discuss data flow logistics and any standard operating procedures that will be developed. Indicate what database will be used. Indicate how data will be backed-up and stored.

## **Data analysis plan**

Discuss this with the biostatistician and indicate the planned analysis of the study population, the statistical tests that will be used and indicate whether an analysis of sub-population will be undertaken and any potential confounders identified.

## **4. ETHICAL CONSIDERATIONS**

See Step 9

Remember to check for:

- all possible ethical issues.
- informed consent? If so, include a 'Participant Information Leaflet' and 'Consent Form' as an appendix to the proposal.
- If no informed consent – then state justification for this and formally request a waiver of informed consent from the ethics board / committee.
- Indicate who the custodians of the records are, and that permission to use the data will be sought from them.
- State which Ethics Committee you will submit to.

- Submission to other committees for permission to do study – e.g. Tygerberg Hospital or Provincial Health research Committee.

## **5.        *STRENGTHS AND LIMITATIONS***

Read carefully through whole proposal and for almost each sub-heading indicate the strengths and limitations based on knowledge already available, research methodology; data used (particularly when routine data is used); cost of the research; potential importance in creating new knowledge or advice on patient management.

## **6.        *Communication and Dissemination***

See Step 13 and clearly indicate how research results will be disseminated.

## **7.        *STUDY MANAGEMENT***

### **Roles and responsibilities**

Indicate the key personnel involved in your research and the roles and responsibilities of the investigators and other personnel.

### **Study timelines**

See Introduction and Appendix 1

### **Regulatory aspects**

Mention that you will keep a regulatory file

If you link onto a federally funded (US\$) study through your mentor, then find out about the regulatory aspects of the parent study.

## **8.        *References***

Use the Vancouver Style of referencing. References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses or superscript.

## **9.        *Appendices***

# TEMPLATE 2

## Researcher's curriculum vitae

You can download this template from website xxx

<b>1. Surname:</b>	<b>Nationality:</b>
First name (s):	Sex:
<b>2. Summary</b>	
Write a bio-sketch of your professional experience and current position, excluding details included in other sections	
<b>3. Degree(s) (subjects, university or school, year)</b>	
<b>4. Posts held (type of post, Institution/Faculty/department, date)</b>	
<b>4. Publications</b>	
<b>5. Grants held</b>	

# TEMPLATE 3

## Budget

Study period:

Study Title:

Categories		Item	No of Units	Unit Cost	Amount in ZAR
<b>Personnel</b>					
eg:	Study Nurse	FTE			0.00
	Research Assistant	FTE			0.00
	Data Capturer	FTE			0.00
	Clinical Assistant	FTE			0.00
<b>TOTAL PERSONNEL COST</b>					<b>0.00</b>
<b>Travel &amp; Transportation</b>					
eg:	Provincial Travel	trips			0.00
	District Travel	km			0.00
	Car hire for travel to remote areas	days			0.00
	Accommodation	days			0.00
<b>TOTAL OF TRAVEL &amp; TRANSPORTATION</b>					<b>0.00</b>
<b>Equipment</b>					
eg:	Scale/Stadiometer	unit			0.00
	Computers, printers, external harddrives	unit			0.00
	Office furniture, filing cabinet, desks, chairs	unit			0.00
<b>TOTAL OF EQUIPMENT</b>					<b>0.00</b>
<b>Materials</b>					
eg:	Stationery	unit			0.00
<b>TOTAL OF MATERIALS</b>					<b>0.00</b>
<b>Other Costs</b>					
eg:	Honorarium - Statistician	per hour			0.00
	Honorarium - Data management	per hour			0.00
	Printing	lumpsum			0.00
	Telephone & IT Cost	lumpsum			0.00
	Catering for training	lumpsum			0.00
	Hire of venue for training	lumpsum			0.00
<b>TOTAL OF OTHER COSTS</b>					<b>0.00</b>
<b>TOTAL BUDGETED EXPENSES</b>					<b>0.00</b>

# TEMPLATE 4

## Consent and Assent for Children

These templates are available on the website – please check that they have not been adapted before you you're your proposal to Ethics Committee.

[http://sun025.sun.ac.za/portal/page/portal/Health\\_Sciences/English/Centres%20and%20Institutions/Research\\_Development\\_Support/Ethics/Application\\_checklist](http://sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_checklist)  
Due to constraints of space we have chosen to only show the English format. On the website there are Afrikaans and iXhosa examples.

Assent for Children

### CHILD ASSENT TEMPLATE<sup>1</sup>

**NB! DELETE THIS PAGE BEFORE ADAPTING THE TEMPLATE TO YOUR PROJECT!**

Please note:

1. Children who are able to understand the basic concepts of research should be given the opportunity to assent to a research study. Generally children between the ages of 7 to 17 should assent to research. This is not a fixed rule and some children younger than 7 may well have sufficient insight and understanding to give assent for a study.
2. If they refuse assent then this refusal should be accepted, even if the parents have consented. There may be exceptional cases where this rule may not apply. The HREC should be consulted.
3. This template is specifically for 7-12 year olds and can be adapted to suit adolescents.
4. If you are including a wide range of children in your project you will need 2 different versions of assent, one for younger children and a more detailed one for adolescents.
5. You can adapt the template to suit the needs of your specific project including deleting sections which are seen as not applicable/appropriate.
6. This assent document must be used in conjunction with a parental Information Leaflet and Informed Consent form, which should obviously cover the project in more depth and detail.
7. Once your project has been approved and you have a reference number, you should replace the information in the 'footer' with your own information e.g. Project No..... Assent template Version 1.1; Date 10.08.09.

---

<sup>1</sup> With thanks to Anel Kirsten for graphics and layout.



## PARTICIPANT INFORMATION LEAFLET AND ASSENT FORM



**TITLE OF THE RESEARCH PROJECT:** *Insert the title of your project. Simplify it if necessary.*

**RESEARCHERS NAME(S):**

**ADDRESS:**

**CONTACT NUMBER:**

### What is RESEARCH?

Research is something we do to find new knowledge about the way things (and people) work. We use research projects or studies to help us find out more about disease or illness. Research also helps us to find better ways of helping, or treating children who are sick.

### What is this research project all about?

*Explain your project in simple child friendly language. Adapt the information to the age of the children that you plan to include.*

## Why have I been invited to take part in this research project?

*Answer this question in simple language*

## Who is doing the research?

*Identify yourself and explain who you work for and/or why you are doing the project*

## What will happen to me in this study?

*Describe what the participant will be expected to do. Describe all procedures using simple terms and explain any technical or medical terms.*

## Can anything bad happen to me?

*Explain any possible risks to the child, using simple terms. If something might be painful, state this in the assent. Explain that the child should inform his/her parents if they are sick or in pain as a result of being in the study.*

## Can anything good happen to me?

*Only describe known benefits to the subject. You may include any possible future benefits to others. If there are no known benefits, state so.*

## Will anyone know I am in the study?

*Explain in simple terms that the subject's participation in the study will be kept confidential, but information about him/her will be given to the study sponsor. (NOTE: This information may not be applicable in assent forms for very young children).*



**Who can I talk to about the study?** *List those individuals the subject can contact (including their contact details) if he/she has any questions or has any problems related to the study.*

**What if I do not want to do this?**

*Explain to the participant that he/she can refuse to take part even if their parents have agreed to their participation. Explain that they can stop being in the study at any time without getting in trouble.*

Do you understand this research study and are you willing to take part in it?

 YES NO

Has the researcher answered all your questions?

 YES NO

Do you understand that you can pull out of the study at any time?

 YES NO

\_\_\_\_\_  
Signature of Child

\_\_\_\_\_  
Date

# PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR:

ADDRESS:

CONTACT NUMBER:

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

**This study has been approved by the Health Research Ethics Committee at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.**

### **What is this research study all about?**

- *Where will the study be conducted; are there other sites; total number of participants to be recruited at your site and altogether.*
- *Explain in participant friendly language what your project aims to do and why you are doing it?*
- *Explain all procedures.*
- *Explain any randomization process that may occur.*
- *Explain the use of any medication, if applicable.*

### **Why have you been invited to participate?**

- *Explain this question clearly.*

### **What will your responsibilities be?**

- *Explain this question clearly.*

### **Will you benefit from taking part in this research?**

- *Explain all benefits objectively. If there are no personal benefits then indicate who is likely to benefit from this research e.g. future patients.*

### **Are there in risks involved in your taking part in this research?**

- *Identify any risks objectively.*

### **If you do not agree to take part, what alternatives do you have?**

- *Clearly indicate in broad terms what alternative treatment is available and where it can be accessed, if applicable.*

### **Who will have access to your medical records?**

- *Explain that the information collected will be treated as confidential and protected. If it is used in a publication or thesis, the identity of the participant will remain anonymous. Clearly indicate who will have access to the information.*

## **What will happen in the unlikely event of some form injury occurring as a direct result of your taking part in this research study?**

- **Clarify issues related to insurance cover if applicable. If any pharmaceutical agents are involved will compensation be according to ABPI guidelines? (Association of British Pharmaceutical Industry compensation guidelines for research related injury which are regarded as the international gold standard). If yes, please include the details here. If no, then explain what compensation will be available and under what conditions..**

Will you be paid to take part in this study and are there any costs involved?

**No you will not be paid to take part in the study but your transport and meal costs will be covered for each study visit. There will be no costs involved for you, if you do take part.**

Is there any thing else that you should know or do?

- **You should inform your family practitioner or usual doctor that you are taking part in a research study. (Include if applicable)**
- **You should also inform your medical insurance company that you are participating in a research study. (Include if applicable)**
- **You can contact Dr ..... at tel ..... if you have any further queries or encounter any problems.**
- **You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.**
- **You will receive a copy of this information and consent form for your own records.**

### **Declaration by participant**

By signing below, I ..... agree to take part in a research study entitled (insert title of study).

#### **I declare that:**

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) ..... on (*date*) ..... 2005.

.....  
Signature of participant

.....  
Signature of witness

**Declaration by investigator**

I (*name*) ..... declare that:

- I explained the information in this document to .....
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter. (*If a interpreter is used then the interpreter must sign the declaration below.*)

Signed at (*place*) ..... on (*date*) ..... 2005.

.....  
Signature of investigator

.....  
Signature of witness

***Declaration by interpreter***

I (*name*) ..... declare that:

- I assisted the investigator (*name*) ..... to explain the information in this document to (*name of participant*) ..... using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) ..... on (*date*) .....

.....  
Signature of interpreter

.....  
Signature of witness

## CONSENT FORM FOR CASE REPORTS<sup>2</sup>

### For a patient's consent to publication of information about them in a journal or thesis

Name of person described in article or shown in photograph: \_\_\_\_\_

Subject matter of photograph or article: \_\_\_\_\_

Title of article: \_\_\_\_\_

Medical practitioner or corresponding author: \_\_\_\_\_

I \_\_\_\_\_ [insert full name] give my consent for this information about MYSELF OR MY CHILD OR WARD/MY RELATIVE [insert full name]: \_\_\_\_\_, relating to the subject matter above ("the Information") to appear in a journal article, or to be used for the purpose of a thesis or presentation.

I understand the following:

1. The Information will be published without my name/child's name/relatives name attached and every attempt will be made to ensure anonymity. I understand, however, that complete anonymity cannot be guaranteed. It is possible that somebody somewhere - perhaps, for example, somebody who looked after me/my child/relative, if I was in hospital, or a relative - may identify me.
2. The Information may be published in a journal which is read worldwide or an online journal. Journals are aimed mainly at health care professionals but may be seen by many non-doctors, including journalists.
3. The Information may be placed on a website.
4. I can withdraw my consent at any time before online publication, but once the Information has been committed to publication it will not be possible to withdraw the consent.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of requesting medical practitioner/health care worker:

\_\_\_\_\_ Date: \_\_\_\_\_

<sup>2</sup> Adapted from *BMJ Case Reports* consent form.

# TEMPLATE 5

## Progress report

Website:

[http://sun025.sun.ac.za/portal/page/portal/Health\\_Sciences/English/Centres%20and%20Institutions/Research\\_Development\\_Support/Ethics/annual\\_project\\_reapproval](http://sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/annual_project_reapproval)

The following statement is on SU FMHS website:

**Progress report:** According to its Standard Operating Procedures (SOPs) and the South African Department of Health Research Ethics Guidelines, HREC must review all approved ongoing research projects at least annually. Researchers must submit a progress report for each project at least two months before current HREC approval expires. If the required information is not received by the deadline date, the application may not be reviewed and reapproved in time, leading to noncompliance with HREC SOPs and suspension of the study until the protocol is recertified.

We include a template of the progress report here – please check website to ensure that form has not been updated.

### GUIDELINES FOR COMPLETING PROGRESS REPORTS

(NB. Please delete this Page and the next page before you print out and submit your progress report.)

1. Ethics approval is valid for one year only. A progress report is an application for renewal of ethics approval and must be submitted annually, well before the ethics approval expiry date, so that the progress report can be reviewed and the project re-approved prior to the expiry date. No research may continue without this process and re-approval. NB! Six monthly progress reports may occasionally be requested if the HREC deems the project to be of particularly high risk.
2. All clinical trials falling under the jurisdiction of the MCC must submit a progress report to the MCC six monthly and should provide the REC with a copy of this report. However a site specific progress report must be submitted annually, for ethics reapproval, using this format.
3. The progress report should contain sufficient information to allow the

reviewer to conduct a substantive and meaningful review of the progress of the project, including any challenges or problems encountered.

4. For multi-centre studies the information in the progress report must pertain specifically to SU sites.
5. An updated complete protocol, incorporating all approved amendments should be submitted approximately every three years unless there have been no, or minimal changes to the project. If so, state this in the progress report.
6. Copies of published abstracts, may be submitted as attachments, and may replace text required in Section G, if appropriate and self-explanatory.
7. The Serious Adverse Event (SAE) Summary and Protocol Non-compliance Summary are applicable mainly to clinical research studies with an experimental design. If not applicable to your project then these pages need not be included and can be deleted.
8. All investigators whose projects are funded by US government federal funds (NIH, CDC etc.) must comply fully with OHRP requirements for continuing review. These can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm>

Main points to be included are:

- the number of participants recruited;
- a summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure);
- a summary of any withdrawal of participants from the research since the last Research ethics committee (REC) review;
- a summary of any complaints about the research since the last REC review;
- a summary of any recent literature that may be relevant to the research and any amendments or modifications to the research since the last REC review;
- any relevant multi-center trial reports;
- any other relevant information, especially information about risks associated with the research; and
- A copy of the current informed consent document and any newly proposed consent document.



HEALTH RESEARCH ETHICS COMMITTEE 1 & 2  
PROGRESS REPORT  
(To be completed in typescript)

A. REPORT TYPE

Final

Annual (i.e. application for renewal of ethics approval)

Reporting Period: From dd/mm/yy to dd/mm/yy

B. PRINCIPAL INVESTIGATOR

Surname				Initials			Title		
Department									
Present position					E-mail				
Telephone no.	(w)			Cell			Fax		

C. PROJECT

Title					HREC Ref No		
Approval date			Start date			Expected date of completion	

C. FUNDING - HOW IS THIS PROJECT FUNDED?

1. Industry	4. NIH/US Gov
2. Internal	5. Other International Grant
3. Self	6. External SA Grant

D. PARTICIPANTS (SU SITES ONLY)

Expected number of participants (total)	
Number of participants enrolled with verbal/written informed consent	

<b>Number of participants enrolled with an approved waiver of informed consent (e.g. records examined)</b>	
<b>If this is a laboratory based study: Number of blood/other samples collected/examined</b>	
<b>Number of participants withdrawn. (Provide details in G.)</b>	
<b>Number of participants already completed</b>	

**F. SERIOUS ADVERSE EVENTS AND PROTOCOL NON COMPLIANCE (PLEASE ATTACH DETAILS)**

<b>Number of SAE's for reporting period</b>		<b>Total SAE's</b>	
<b>No of protocol deviations for reporting period</b>		<b>Total Protocol Deviations</b>	

**G. SUMMARY OF PROGRESS TO DATE (APPROXIMATELY 500 WORDS)**

--

Date of project completion (applicable on final reports only)

**H. THE FOLLOWING DOCUMENTS ARE ATTACHED: (NB PLEASE REFER TO THE POINTS IDENTIFIED IN BRACKETS IN THE GUIDELINES ON PAGE 1)**

▪ Current Informed consent documents (8)	
▪ Updated version of the protocol incorporating previously approved amendments (5)	
▪ Summary of serious adverse events (7)	
▪ Summary of protocol deviations with explanations (7)	
▪ Relevant multi-centre trial reports e.g. DSMB reports.	
▪ Published article or abstract(s)	

.....  
Signature of principal investigator

.....  
Date





# REGULATORY DOCUMENTS

1. Stellenbosch University regulations Guidelines for MMed research assignments
  - Guidelines for MMed research assignments
  - Submission of MMed research assignments
  - Assessment of MMed research assignments
2. HPCSA documents for registrar research

**STELLENBOSCH UNIVERSITY**  
**FACULTY OF HEALTH SCIENCES**

**PROVISIONS FOR**  
**RESEARCH ASSIGNMENTS OF**  
**STRUCTURED MASTER’S PROGRAMMES**

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**INTRODUCTION**

The provisions set out in this document tie in directly with two sets of formal provisions governing master’s degrees:

1. those under “Rules for Higher Degrees” in Part 1 (General) of the University Calendar; and
2. those given in the Faculty of Health Sciences’ Calendar (Part 12).

Therefore, please read the brochure **in conjunction with** the two sets of formal provisions. Keep this document handy for **future reference**. In what follows below, unless the context otherwise indicates, “he” and the related forms “him” and “his” are used in their generic sense – that is to say, inclusively of the corresponding meanings of “she” and “her”.

The term “assignment” is the only officially accepted term for denoting the product of research for a structured master’s study.

The following objectives apply for such research:

“Candidates in all fields of structured master’s study are required, as part of the final examination, to complete an assignment or a publication(s) to the confirmed satisfaction of the relevant Postgraduate Programme Committee and the head of the division, and in which evidence is provided that the candidate is able to:

- ⇒ plan research;
- ⇒ apply the literature study to the research;
- ⇒ apply elementary statistical principles;
- ⇒ conclude a project; and
- ⇒ draw meaningful conclusions.”

In order to achieve these objectives, the candidate must therefore demonstrate that:

- he has developed an ability for independent critical judgement;
- he is able to discuss both existing and newly acquired knowledge in a rational and objective manner; and
- the research contributes to existing knowledge.

## **FORMAT OF ASSIGNMENT**

The candidate must furnish the following declaration on the first page of the assignment after the title page, and sign and appropriately date it:

### **“Declaration**

I, the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

**Signature:** .....

**Date:** .....

**OR**

## “Verklaring

Ek, die ondergetekende, verklaar hiermee dat die werk in hierdie werkstuk vervat my oorspronklike werk is en dat ek dit nie vantevore in die geheel of gedeeltelik by enige universiteit ter verkryging van ’n graad voorgelê het nie.

**Handtekening:** ..... **Datum:** .....

**The assignment may be submitted in one of the following two formats:**

1. A completed manuscript for a (preferably subsidy-bearing) peer-reviewed scientific journal (i.e. that appears on the list of the approved scientific journals of the Department of Education) with the candidate as first author, **or**
2. A full-length assignment.

**Option 1 must comply with requirements of the relevant scientific journal, while option 2 must fulfil the following minimum requirements:**

- a **Declaration** of the nature and extent of the contributions of the candidate and of collaborators;
- a **Table of Contents** with accurate page references;
- an **Abstract** in both English and Afrikaans;
- an **Introduction**, preferably not more than one page in length, briefly defining the topic of the research;
- a **Literature Review**, which focuses on the specific, demarcated area, elucidating the topic of the study and which may culminate in a **problem statement and/or hypothesis**;
- the **Aim of the Investigation**, which arises logically from the literature review and which may serve as the **motivation** for the study;
- the **Methodology** and **Materials** (experimental animals, patients, tissue culture, therapeutics, etc.);
- the **Results** or findings after statistical processing (where applicable), elucidated by clearly comprehensible tables, diagrams, graphs, etc., with appropriate annotations;
- the **Discussion**, in which the results are succinctly argued and interpreted in the light of the literature review;
- the **Conclusion**, in which the findings, the interpretation thereof, and unresolved issues are concisely summarised. The chapter may close with a set of

**recommendations** suggesting new approaches, clinical applications and/or further research projects; and

- the **Bibliography** in accordance with any acknowledged style.

**Research must be consistent with the following definition:**

1. On the basis of clearly formulated problems and through the methodical gathering and systematic processing of data, all efforts must be made to gain insights through which:
  - the body of scientific knowledge can be expanded; and/or
  - the application possibilities of theoretical knowledge can be scientifically developed; and/or
  - techniques, systems, processes or methods for practical use can be developed or improved in a scientifically planned and well grounded way.
2. The research component of the master's programme is defined as:
  - a. an independent and cohesive component of activities in a master's programme (it must be a cohesive component of activities in order to obviate the inclusion of any unconnected activities – especially those that cannot be directly linked to the student's "clearly formulated problem or problems" – as part of the research component);
  - b. research that exists independently from any taught modules in the programme;
  - c. research that takes place under the guidance of a supervisor;
  - d. research that comprises 20%–25% of the total credits of the programme; and
  - e. research in which the candidate can be expected to
    - i. gain insights by means of methodical gathering and systematic processing of data and by way of clearly formulated problems, through which basic scientific knowledge can be expanded, application possibilities of exploiting knowledge scientifically or techniques and technology can be developed or improved scientifically;
    - ii perform autonomously, professionally and ethically while conducting the research;
    - iii communicate the results of his research in an academic or professional way; and
    - iv produce an academically acceptable assignment on the activity.
3. "Research component" further implies that part of the master's programme where the outcome is such that it fulfils the "level descriptors" of level 8 (PG3) of the draft New Academic Policy, specifically requirements f: "an ability to present effectively and

communicate the results of research to specialist and non-specialist audiences using the resources of an academic/professional discourse; the production of a dissertation or research report which meets the standards of scholarly/professional writing” and g: “a capacity to manage learning tasks autonomously, professionally and ethically.”

## EXAMPLES OF TYPES OF RESEARCH

1. Laboratory-based research relating to the candidate’s discipline.
2. Prospective preclinical or clinical research.
3. Goal-directed retrospective research, based on information available in data banks or files.
4. Epidemiological research.
5. Health service system research.
6. A thorough, critically assessed literature review that has already been accepted for publication in a (preferably subsidy-bearing) peer-reviewed scientific journal with the candidate as first author. This (as with the other options) must still be undertaken in terms of a preplanned protocol (submitted as such beforehand) that accurately specifies matters such as the aim, methodology and procedure, and the work must make a scientific contribution to the subject area concerned, for instance by being presented in the format of a meta-analysis. Such an application must be well motivated.
7. Qualitative research.
8. Research on instruction/teaching.

## CANDIDATE

1. Each candidate is required to submit the documentation specified below to the **head of the division** concerned:

The **protocol** of research not exceeding five A4 double-spaced pages of typescript and specifying the following:

- the proposed place of research;
- the topic and the scope of the proposed research;
- a concise literature review;
- the aim of the proposed research and/or a statement(s) of the hypothesis(es);
- the materials and methodology;

- the projected results, where possible;
- ethics of the research;
- the budget, available finances and experimental materials; and
- a **complete application** for submission to the Committee for Human Research for the evaluation of the ethics and registration of the research project (obtainable from the Research Development and Support Division (Tygerberg Campus)). All protocols must be approved by postgraduate programme committees for quality assurance purposes before heads of departments or divisions sign them off to be submitted for ethical approval. For this purpose, programme committees may use their own subcommittees for research.

**Candidates experiencing difficulties with the compilation, format and/or formal organisation of the protocol should approach the head of the division for assistance.**

2. **NB: ALL** research projects for master's assignments **MUST** receive ethical approval from the Committee for Human Research **BEFORE** the project may begin. The Committee for Human Research handles all "low-risk" projects according to a swift disposal procedure. The candidate must submit all the necessary application documents to the secretary of the Committee for Human Research, with a letter signed by the candidate's supervisor and head of the division to declare that the research is being conducted for the purpose of obtaining a degree and that the swift disposal procedure is requested. The chairman of the Committee of Human Research may provisionally approve the project, after which the project may commence. The Committee for Human Research must, however, review the provisional approval at its subsequent meeting. The Committee for Human Research may ratify or set aside the provisional approval, in which case the project may be halted, until such time that the ethical problem has been satisfactorily resolved.
3. To be considered for the timely completion of the appointment of examiners, the candidate must inform his study leader in writing of his intention to submit his assignment at least four months before the intended submission date.
4. To be considered for the timely completion of the examination process, two copies of the assignment must be submitted for examination as follows (master's theses and doctoral theses have other faculty-specific submission dates that are not applicable here):
  - with a view to the December graduation ceremony: before 1 October
  - with a view to the March graduation ceremony: before 1 December
  - with a view to the fulfilment of the requirements for the degree in June: before 1 April

The supervisor must give permission for handing in of the assignment for examination.

The examiners must have **not less than one month to assess the assignment**. The reports of the examiners (from the head of the division) and the recommendation of the executive head of the department must be presented to the Assistant Registrar (Tygerberg Campus)

at least 10 working days before the deadline for the submission of final marks for further handling. Failure to follow these guidelines may jeopardise the awarding of the degree in question to the candidate at the next graduation ceremony.

5. The candidate is responsible for the costs of duplication of the assignment.
6. The candidate is responsible for submitting two copies of the final assignment, one to the head of the division and the other to the supervisor, no later than the date determined annually by the university for the handing in of final marks in June or November.

### **HEAD OF THE DIVISION**

1. The head of the division or his delegate (for example, the supervisor) is responsible for the monitoring and further handling of the protocol and for the administrative arrangements necessitated by this function.
2. The head of the division is moreover required to familiarise himself with all the formal provisions and requirements of dealing with the protocol, the research, the submission of the assignment, and its assessment.
3. The approval and appointment of a supervisor are the responsibilities of the head of the division, who has to ensure that the supervisor can cope with the number of students entrusted to him. The onus is on the head of the division to decide how this requirement is to be met, taking into account the special demands and alternatives of the discipline in question, as well as different approaches and the capacities of supervisors.
4. The head of the division is responsible for the appointment of examiners, in consultation with the supervisor, and for obtaining their consent to participate. Thereafter he is required to submit the names via the Committee for Postgraduate Education to the Faculty Board. (See point 5 under Supervisor.)

### **SUPERVISOR**

Besides being familiar with the information above, the supervisor has to acquaint himself with the contents of the following provisions:

1. The supervisor must consider his availability when accepting candidates for postgraduate study. If some subsequent event radically affects his availability, with a concomitant effect upon postgraduate programmes, arrangements must be made with the head of the division concerned, and every student thus affected should be informed accordingly in writing, whereafter alternative arrangements must be made. Such instances should be reported to the Committee for Postgraduate Education.
2. In cases where the nature of the topic or research methodology requires expertise in more than one area, consideration must be given to involving a co-supervisor(s) with the appropriate qualifications and experience.

3. Where deemed appropriate, the supervisor must ensure that the required equipment and the laboratory, computer and library facilities are available or accessible.
4. The supervisor assumes responsibility for the originality, scientific merit and standard of the research work that is to be performed.
5. The supervisor should take the initiative for the appointment of examiners by the head of the division, in consultation with the Programme Committee (A person is independent if he was not involved in the realisation of the assignment in any way. An internal independent examiner is a person who is on the university's or associate's staff establishment, but who is independent in terms of the abovementioned. An external examiner is a person who is not on the university's staff establishment and who should also be independent. Extraordinary professors and honorary professors of the university do not qualify as external examiners.); and should restrict his interaction with the examiners solely to the originality, scientific merit and standard of the research work.
6. The supervisor must further acquaint himself with all the provisions in respect of the handling of the protocol, the research, the submission of the assignment and the examination thereof.
7. Feedback on the progress of the study should be given on an annual basis and in writing by the supervisor to the head of the division and the Postgraduate Programme Committee of the division.
8. All work handed in should be handed back to the candidate with comments by the supervisor within a reasonable time.
9. Both the supervisor and the student can approach the Vice-Dean (Teaching) of the Faculty of Health Sciences should disagreement between the supervisor and student arise for whatever reason. The input of the Vice-Dean (Research) of the faculty can also be obtained, where applicable. Should the Vice-Dean (Teaching) not be able to solve the problem, the matter can be directed to the Committee for Postgraduate Education.

### **CODE OF CONDUCT FOR THE RELATIONSHIP BETWEEN SUPERVISOR, CO-SUPERVISOR AND STUDENT**

The following set of guidelines is proposed as a code of conduct for ensuring that the nature of the relationship between the supervisor and the student is conducive to successful postgraduate studies at the university:

1. The candidate (with the necessary input from the supervisor) undertakes to remain up to date with regard to the infrastructure and related rules of the specific division.
2. The university undertakes not to select a student for a specific project unless the faculty gives prior written confirmation that the project can be undertaken. Responsibility for the required funding and applicable infrastructure will be specified.

3. The candidate, with the help of the supervisor, will acquaint himself with the guidelines for keeping a record of research according to what is generally acceptable within the relevant division.
4. The candidate must confirm that he has the necessary computer skills or the appropriate support to complete the project satisfactorily.
5. The necessary preparatory study as required by the university should be completed within an agreed period of time.
6. A work programme must be compiled for the candidate, in collaboration with the supervisor, within a reasonable period of time after the start of the project (usually not exceeding 60 days). This programme must indicate deadlines, for example, for the submission of a project protocol, the completion of a literary review, the completion of specific chapters and the submission of progress reports. Times of absence (study leave, university vacations, etc.) must also be noted.
7. Regular and predetermined contact sessions between the candidate and the supervisor during the academic year must be arranged.
8. When the project nears completion, the candidate must make the necessary submissions according to the specific requirements for graduation within the specific discipline. (Specific reference is made to point 4 on page 6, to ensure that there is sufficient time for the rounding off and examining of the assignment, taking into account the different graduation ceremonies in December and March of each year.)
9. The candidate undertakes, as agreed upon with the supervisor, to deliver the relevant outputs (e.g. publications, patents, academic papers). The candidate must acquaint himself with the conventions regarding authorship that are relevant to the specific division. Should the candidate not complete the task within the time agreed upon, the university reserves the right to appoint a writer to prepare the project for publication – in such a way so as not to disadvantage the copyright of the candidate.
10. The candidate may not have any direct contact with examiners before or during the examination process, except in the case of an oral examination.
11. Where applicable, the candidate and the supervisor must acquaint themselves with the regulations applicable to intellectual property within the relevant environment.

**If a co-supervisor is also involved, the following guidelines for the relationship between the co-supervisor and the student apply:**

1. The co-supervisor should be appointed in time so as to be involved in the development of the protocol. A co-supervisor may be appointed at a later stage if the current co-supervisor needs to be replaced due to unforeseen circumstances.
2. The co-supervisor should comply with the code of conduct as compiled by the Faculty of Health Sciences and also with the guidelines regarding the methodology of the research process.

3. The co-supervisor should be directly involved in the planning and supervision of the research project. The comments of a co-supervisor are not limited to content and/or methodology, but it is expected of him to provide general comments on the progress of the research project.
4. The co-supervisor should at any time be able to deputise for the supervisor.
5. The co-supervisor should submit an annual report on the candidate's progress to the relevant Postgraduate Programme Committee, who will communicate this to the Committee for Postgraduate Education. A check list can be used for this purpose with comments and the recommendation of possible remedial support if problem areas have been identified. Caution should be taken against unnecessary bureaucratic processes.
6. Both the co-supervisor and the student can approach the Vice-Dean (Teaching) of the Faculty of Health Sciences should disagreement between the co-supervisor/student and the supervisor arise for whatever reason. The input of the Vice-Dean (Research) of the faculty can also be obtained, where applicable. Should the Vice-Dean (Teaching) not be able to solve the problem, the matter can be directed to the Committee for Postgraduate Education.

**Responsibilities of the supervisor:**

- To be acquainted with procedures and regulations;
- To establish a stimulating research environment;
- To establish a relationship between the supervisor and the student;
- To advise on the choice of project, planning, protocol and ethical principles;
- To discuss issues related to intellectual property and publishing;
- To provide training in research;
- To consult with the student, continuously monitor progress and provide structured feedback;
- To remain aware of the student's situation and needs;
- To arrange for study guidance during periods of absence;
- To advise the student in respect of funding and bursaries;

**Responsibilities of the student:**

- To be familiar with the university's regulations regarding postgraduate study and to comply with such regulations;

- To undertake research with commitment;
- To develop initiative and independence;
- To keep thorough records of all research findings;
- To establish a relationship with the supervisor;
- To obtain feedback by means of reports and seminars and to apply such feedback;
- To do a literature review and remain aware of new relevant information;
- To benefit from the research environment;
- To inform the supervisor of non-academic problems;
- To prepare and write the assignment;
- To prepare and write publications, patents and reports;
- To know the faculty-specific closing dates for the submission of assignments for examination; and
- To have no direct contact with examiners before or during the examination process, except for the purpose of an oral examination.

## EXAMINERS

1. Two independent examiners (in other words, who have not been involved in the planning and conducting the study), one of whom should be an external examiner, must be appointed by the head of the division in consultation with the supervisor and the Programme Committee. Exceptions to the rule must be well supported and must be presented to the Committee for Postgraduate Education for consideration.
2. The **examiners** must be suitable persons, who are capable of passing an objective judgement. The head of the division, in consultation with the Programme Committee, is required to submit the names via the Committee for Postgraduate Education to the Faculty Board for approval. (See also point 4 under Head of Discipline.)
3. The assignment, together with a copy of the guidelines for assessment and a copy of the standard (pro forma) report form, must be submitted by the head of the division (and not the supervisor) to the examiners for assessment. The examiners must return the completed standard report form to the head of the division together with a more detailed report (if considered necessary).
4. **The examiners must be allowed a period of one month for assessing the assignment.**
5. The report form for examiners must cover at least the following aspects:

- adequate demarcation and conceptualisation of the field of research and of the research topic;
  - adequate command of the relevant research methodology;
  - adequate command of the relevant literature;
  - clear, systematic and logical presentation of the material;
  - proper documentation and substantiation of the results of the research;
  - acceptable linguistic and stylistic editing; and
  - the question whether the assignment makes an original contribution to knowledge in the subject area concerned.
6. The examiners are required to submit their recommendations to the head of the division in the following format:
- acceptance recommended without amendments; or
  - acceptance recommended with proposed amendments to the satisfaction of the supervisor or examiners (indicate appropriate block); or
  - acceptance not recommended and must be re-submitted and re-examined.
7. The marks assigned by the internal independent examiner and those given by the external examiner both contribute 50% to the final mark for the assignment. The calculation of the final mark for the assignment is subject to other relevant regulations in the existing regulations in this document on assignments for master's degrees.
8. A mark is allocated after the first round of examination by the examiners, which will also be regarded as the final mark. In the case where a student initially fails and then undergoes re-examination, the final examination mark awarded cannot be higher than 50.
9. In cases where the assignment is not recommended by one or more of the examiners, the Committee for Postgraduate Education must appoint an ad hoc committee to review the reports of the examiners and to report back. The ad hoc committee must consist of two examiners and two members of the Committee for Postgraduate Education. After the ad hoc committee has dealt with the reports, the supervisor must carry out the decisions of the ad hoc committee before reporting back to the Committee for Postgraduate Education. It is left up to head of the division to lay down policy as to when, during the programme, the assignments are to be submitted so that remedial steps will be practicable.
10. The written reports of the examiners, together with covering comment, must be submitted by the head of the division via the executive head of the department to the Assistant Registrar (Tygerberg Campus) for further handling.

## 11. **Manuscripts for scientific journals**

- 11.1 In instances where a completed manuscript has been submitted to a (preferably subsidy-bearing) peer-reviewed scientific journal (i.e. which appears on the list of approved scientific journals of the Department of Education), but has not yet been accepted for publication, **external** examination is required. (The previous provisions concerning examiners also apply here.)
- 11.2 In instances where the manuscript **has already been accepted for publication** by a (preferably subsidy-bearing) peer-reviewed scientific journal (i.e. which appears on the list of approved scientific journals of the Department of Education), assessment by examiners similar to that of assignments of structured master's programmes are required to award a mark, with the proviso that the candidate must be the first author. The manuscript, with proof of acceptance by a subsidy-bearing peer-reviewed scientific journal, must be presented to the head of the division for final approval and disposal.

## 12. **Format of assignment**

- 12.1 Since the preparation and the submission of a manuscript/assignment form part of the final process of examination, no publication (for example, a master's thesis) submitted for the award of another degree (for example, MSc) can be presented again in partial fulfilment of the requirements for one of the structured master's programmes.
- 12.2 The research and preparation of a manuscript/assignment must occur fully or partially within the period of registration for the structured master's programme, but may be based on research previously conducted.

23/05/2011

## RECOMMENDATIONS

### FOR SUBMISSION A STRUCTURED MASTERS RESEARCH ASSIGNMENT IN THE FORMAT OF A JOURNAL ARTICLE (PRE- PEER REVIEWING MATERIAL, I.E., THAT HAS NOT YET BEEN ACCEPTED OR PUBLISHED) FOR ASSESSMENT

1 The following can be submitted together with the manuscript:

- 1.1 The title of the journal and a copy of the journal requirements
  
- 1.2 Additional information on the study not contained in the manuscript, including:
  - 1.2.1 A more comprehensive literature review than that normally included in a journal article.
  - 1.2.2 Should the publication format not allow for a comprehensive description of the methodology used, such a description should be provided. If more than one manuscript are submitted for assessment it might be necessary to include a separate description of the overarching methodology used.
  - 1.2.3 Photographs, figures and/or tables that can not be included in the publication format.
  
- 1.3 Generally the Results, Discussion and Conclusion sections of the manuscript should be adequate to enable assessment. If necessary, addenda can be provided to any or more of these sections to provide the examiner with additional information.
  
- 1.4 An article that has been accepted finally for publication in a peer reviewed journal that preferably qualifies for a subsidy from SU, is sufficient to be submitted as MMed assignment. The changes that the journal's reviewers requested must have been made and the article must be accompanied by the editor's note stating that it was accepted finally. Alternatively, the final article, as it appeared in the journal, or the galley proofs of the final version may be submitted.

The examiners' guideline in such a case shall be to review only the scientific merits of the research before allocating a mark (which may not be below 50%).

## 2 Criteria for marking

If the above guidelines are followed, it should be possible to use the proposed “Assessment Sheet for Research Assignments of Masters Programmes” (Addendum 1) also for assessment for assignments submitted in publication format.

**UNIVERSITY OF STELLENBOSCH**  
**Faculty of Health Sciences**  
**Guidelines**  
**Assessment Sheet for Research Assignments of Structured**  
**Masters Programmes**

<b>Programme:</b>					
<b>Title of Thesis/Research Assignment:</b>					
<b>Student name and number:</b>				<b>Assessor:</b>	
				<b>Moderator:</b>	
<b>Date received:</b>		<b>Date back:</b>		<b>Mark:</b>	
<b>Assessor's General View of the Assignment:</b>					
<b>Rating Scale:</b>					
	<b>Excellent</b>	<b>Good</b>	<b>Satisfactory</b>	<b>Needs some more work</b>	<b>Needs much more work</b>
<b>INTRODUCTION</b>					

Background and context					
Literature review					
Formulation of Research question and Hypothesis					
Formulation of Aim and Objectives					
<b>2.1 METHODOLOGY</b>					
Appropriateness					
Student's understanding of methodology					

Detail in which described (i.e. sufficient detail to allow replication of study?)					
Clear distinction between quantitative and qualitative methodology					
Sampling methodology					
Inclusion and exclusion criteria					
Description of statistical analysis to be used					
Understanding of statistical methodology					
Appropriateness of statistical methodology					
<b>RESULTS</b>					
Extent to which the results address the research question and main and secondary objectives					
Clarity and logical description of results					
Insight into and understanding of the output of statistical analysis					
<b>DISCUSSION</b>					
Contextualisation of findings with current knowledge and literature					
Logical and					



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## MEMORANDUM

From: Mr JE Coetzer  
Faculty Secretary

☎: 021 - 938 9204

E-mail: [jco@sun.ac.za](mailto:jco@sun.ac.za)

TO: ALL EXECUTIVE DEPARTMENTAL HEADS AND HEADS OF DIVISIONS  
RE: ASSESSMENT AND APPROVAL OF ASSIGNMENTS FOR STRUCTURED  
MASTER'S PROGRAMMES  
DATE: 11 July 2013

1. I refer you to the approved guidelines and procedures for the assessment of assignments for structured master's programmes.
2. **The following six points in the process of examining the assignments are of particular importance:**

Two independent examiners (in other words, who were **not** involved in the planning and execution of the study), of which one should be an external examiner, should be nominated by the Head of the Division in consultation with the supervisor and the Programme Committee.

The examiners should be suitable people who can pass an objective judgement. The names should be submitted by the Head of the Division to the CPT and Faculty Board for approval, via a report of the relevant Post Graduate Programme Committee.

The guidelines for assessment and a standard (pro forma) report form are sent by the Head of the Division (not the supervisor) to the examiners together with the assignment that is sent for assessment. The examiners must send back the completed standard report form, together with a more detailed report (if regarded as necessary) to the Head of the Division.

Examiners should be allowed a period of grace of one month for the assessment of the assignment.

In cases in which the assignment is not recommended, the Committee for Postgraduate Training (CPT) must appoint an *ad hoc* committee to check the examiners' reports and report back. The *ad hoc* committee shall consist of the two examiners and two members of the CPT. After the *ad hoc* committee has dealt with the reports, the supervisor must implement the decisions of the *ad hoc* committee before reporting back to the CPT. It is up to the Head of the Discipline to determine policy on when the assignments should be handed in during the programme so that remedial steps are in fact possible.

The assignment itself, as well as the written reports of the examiners, must be submitted with covering comments by the Head of the Division, via the Executive Head of Department to the Deputy Registrar (Tygerberg Campus) for further processing.

3. Regarding 2.3 above, the guidelines for assessment and the standard (pro forma) report form are attached hereto for use.
4. Kindly bring this information to the attention of all the staff and students concerned.
5. I trust that you will find this information to be in order.

Thank you for your attention.

**HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA**  
**SUBCOMMITTEE FOR POSTGRADUATE EDUCATION AND TRAINING**  
**NEW REQUIREMENTS FOR THE REGISTRATION OF SPECIALISTS IN**  
**SOUTH AFRICA**

**NOTING:**

1. The Standards Generating Body (SGB) Subcommittee of the Medical and Dental Board has completed the process of aligning the qualification for specialists and subspecialist with the Higher Education Qualification Framework (HEQF) of South Africa;
2. The SGB subcommittee of the MDB has defined the purpose, rationalé, prior learning, international comparability, assessment, moderation, criteria for assessors, and exit level outcomes and associated assessment criteria for clinical disciplines, pathology disciplines, surgical disciplines, and subspecialities;
3. The failure of many training programmes to comply with the requirement for integrated assessment, including portfolio assessment, formative assessment, continuous assessment, summative assessment, and assessment of research.
4. The current failure of many specialists to meet the exit outcomes of the current criteria for specialist qualification, especially the exit outcome 3 which is related to the need to 'undertake and complete a relevant research study';
5. The variation in the assessment of exit outcomes 1 and 2, which are related to professional knowledge, skills, and competence, with some being examined in a local examination (the MMed route) and others taking a national examination (the College route);
6. The need to align the requirements for the registration of specialists in South Africa with the SGB standards of the MDB;

**RESOLVES THAT EVIDENCE OF CONTINUOUS INTEGRATED ASSESSMENT DURING TRAINING IS REQUIRED FOR REGISTRATION AS SPECIALIST IN SOUTH AFRICA:**

1. **Evidence of continuous integrated assessment during training is required for registration as a specialist in South Africa.**
  - 1.1 The nature of integrated assessment will be defined by the SGB subcommittee of the MDB from time to time.
  - 1.2 The Head of Academic Department of the training institution is responsible for providing evidence of integrated assessment of each candidate in their programme.

2. **Completion of a national curriculum and national professional examinations of exit level outcomes 1 and 2 will be required for registration in South Africa.**
  - 2.1 The national core curriculum and professional outcomes for each specialist will be set by the Subcommittee on Postgraduate Education and Training (Medical) (PETM) for each specialty according to requirements of the SGB subcommittee of the MDBP.
  - 2.2 Candidates in each specialty will be required to undertake a national professional examination through a national examining body which is constituted by representatives of the training institutions and professional societies, such as The Colleges of Medicine of South Africa;
  - 2.3 The outcomes of the professional examinations may be used as credits for Parts I and Part II of the Mmed degree, by the universities.
  - 2.4 The national examining body, which will be appointed as an agency of the MDBP, will abide by the SGB requirements of the Board;
  - 2.5 The national examining body will be accredited by the PETM, in collaboration with the Committee of Medical Deans, on a 5 yearly basis at their cost as part of the quality assurance process of the SGB subcommittee of the MDBP in collaboration with the Committee of Deans or institution.
  
3. **Completion of a research component will be a requirement for registration as a specialist in South Africa.**
  - 2.1 All specialist trainees will be required to complete a relevant research study, under the supervision of the Head of Department or nominee;
  - 2.2 The assessment criteria of the research study would be that appropriate theoretical knowledge is demonstrated; a research protocol is compiled according to required norms; and a progress report on the research project is given on a regular basis; and that research results are reported in a format of a dissertation according to acceptable scientific norms.
  - 2.3 The research study will be allocated a minimum of 60 credits in terms of the SGB.
  - 2.4 The research study, which will be assessed at university level, may be used as a credit for Part III of the MMed degree.

**SUBCOMMITTEE FOR POSTGRADUATE EDUCATION AND TRAINING (MEDICAL), 20 JANUARY 2010**

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# USEFUL REFERENCES

These are just a few references to help you with the research:

1. How to find a research question  
Thabane L, Thomas T, ChengIn Ye, Paul J. Posing a research question: not so simple. *Can J Anaesth* 2009; 56:71-79.
2. Tips for navigating PubMed  
McGill University Health Centre. 10 Tips for navigating PUBMED  
[http://www.muhclibraries.ca/files/2013/06/PubMed-tips\\_-May2013\\_EN.pdf](http://www.muhclibraries.ca/files/2013/06/PubMed-tips_-May2013_EN.pdf)
3. Cleaning your data before analysis:  
Jan Van den Broeck\*, Solveig Argeseanu Cunningham, Roger Eeckels, Kobus Herbst. Data Cleaning: Detecting, Diagnosing, and Editing Data Abnormalities. *PLoS Medicine*, October 2005 | Volume 2 | Issue 10 | e267
4. How to write an article:  
These are a series of articles published in the *Journal of Clinical Epidemiology*. Each aspect is one page long and a very good summary of what to do.
  1. Effective writing and publishing scientific papers-Part 1: how to get started.  
<http://dx.doi.org/10.1016/j.jclinepi.2013.01.002>
  2. Effective writing and publishing scientific papers-Part 2: title and abstract.  
<http://dx.doi.org/10.1016/j.jclinepi.2013.01.005>
  3. Effective writing and publishing scientific papers-Part 3: introduction.  
<http://dx.doi.org/10.1016/j.jclinepi.2013.01.004>
  4. Effective writing and publishing scientific papers-Part 4: methods.  
<http://dx.doi.org/10.1016/j.jclinepi.2013.01.003>
  5. Effective writing and publishing scientific papers-Part 5: results.  
<http://dx.doi.org/10.1016/j.jclinepi.2013.04.003>
  6. Effective writing and publishing scientific papers-Part 6: discussion.  
<http://dx.doi.org/10.1016/j.jclinepi.2013.04.017>
  7. Effective writing and publishing scientific papers-Part 7: tables and figures

<http://dx.doi.org/10.1016/j.jclinepi.2013.04.016>

8. Effective writing and publishing scientific papers-Part 8: references  
<http://dx.doi.org/10.1016/j.jclinepi.2013.06.015>
  9. Effective writing and publishing scientific papers-Part 9: authorship  
<http://dx.doi.org/10.1016/j.jclinepi.2013.08.006>
  10. Effective writing and publishing scientific papers-Part 10: choice of journal  
<http://dx.doi.org/10.1016/j.jclinepi.2013.09.014>
  11. Effective writing and publishing scientific papers-Part 11: submitting a paper  
<http://dx.doi.org/10.1016/j.jclinepi.2013.10.004>
- 
5. Responding to the editor/reviewers of your article  
Annesley TM. Top 10 tips for responding to the reviewer and editor comments. *Clinical Chemistry* 2011; 57:551-554
  6. Basic statistics:  
These are a series of primers written in the *Journal Effective Clinical Practice*. The journal no longer is published but these are one-page introductions to basic statistical concepts are useful for clinicians.
    1. Primer on interpreting surveys  
[http://ecp.acponline.org/janfeb02/primer\\_interpret\\_surveys.htm](http://ecp.acponline.org/janfeb02/primer_interpret_surveys.htm)
    2. Primer on before and after studies.  
[http://ecp.acponline.org/marapr02/primer\\_before\\_after.htm](http://ecp.acponline.org/marapr02/primer_before_after.htm)
    3. Primer on group randomised trials  
<http://ecp.acponline.org/janfeb01/primer.htm>
    4. Primer on correlation coefficients  
[http://ecp.acponline.org/mayjun01/primer\\_correlcoeff.htm](http://ecp.acponline.org/mayjun01/primer_correlcoeff.htm)
    5. Primer on statistical significance and p values.  
<http://ecp.acponline.org/julaug01/primer.htm>
    6. Primer on 95% confidence intervals.  
<http://ecp.acponline.org/sepoct01/primerci.htm>
    7. Primer on geographical variation in health  
<http://ecp.acponline.org/sepoct01/primergeo.htm>

8. Primer on type 1 and type 2 errors  
[http://ecp.acponline.org/novdec01/primer\\_errors.htm](http://ecp.acponline.org/novdec01/primer_errors.htm)
9. Primer on absolute vs. relative differences  
[cp.acponline.org/janfeb00/primer.htm](http://cp.acponline.org/janfeb00/primer.htm)
10. Primer on probability and interpreting their ratios  
<http://ecp.acponline.org/mayjun00/primer.htm>
11. Primer on scores: what counts?  
[http://ecp.acponline.org/julaug00/primer\\_on\\_scores.htm](http://ecp.acponline.org/julaug00/primer_on_scores.htm)
12. Primer on cost-effective analysis  
<http://ecp.acponline.org/sepoct00/primer.htm>
13. Primer on dissecting a medical imperative  
<http://ecp.acponline.org/novdec00/primer.htm>
14. Primer on lead-time, length and overdiagnosis.  
<http://ecp.acponline.org/marapr99/primer.htm>
15. Primer on the 95<sup>th</sup> confidence interval and the number needed to treat  
<http://ecp.acponline.org/mayjun99/primer.htm>



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