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.

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)

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*

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).

Gie, R., & Beyers, N. (2014). Getting started in clinical research: Guidance for junior researchers. Cape Town: Department of Paediatrics and Child Health, Faculty of Medicine and Health Sciences, Stellenbosch University.