Writing a research Proposal/ Protocol

Before writing your proposal there are some key points to consider:

- What do you want to do?
- What will be the value of doing it?
- How much will it cost (in terms of hard cash, resources, personnel, equipment etc)?
- How long will it take?
- What difference will the project make to the NHD/patient care?
- What has already been done in this project area?
- How will you plan to do it?
- How will you evaluate the results?
- How will you disseminate the results?

The Research Proposal

Title
The title of the study needs to strike a balance between being explicit but to the point, whilst being comprehensive enough to explain the nature of the study and its objectives.

Research Question
This section should be a concise question of what the project wants to address. It could be in the form of a Null Hypothesis.

Abstract
This gives the reader an outline of the study highlighting the main points and should be a concise summary of the project. It should be no more than 200 words. The main objectives and procedure should be mentioned including the study design, method and an outline of the expected findings. It is advisable to write this section last.

Introduction
The introduction should familiarise the reader with the subject matter and give a general idea of the proposed project. It should show how the results of the study would benefit in terms of clinical practice, policy or the NHS as a whole.

Background
This section should include a review of the current literature and should identify the extent and quality of the existing research carried out in your project area. It should identify why further research is required and how the findings may be used in clinical practice.

Aims and objectives
The general aim of the project should be clearly stated and the objectives listed.

Ethical Considerations
All research, which involves patients or their records, requires approval from the Local Research Ethics Committee. This approval is primarily concerned with the welfare and dignity of the participants of any research project together with the validity of the study. It is important that in the design of your project you consider the welfare and dignity of the participants. The three main ethical issues are confidentiality, anonymity and informed consent. Other ethical issues may arise due to the design of your study or because of your sample population. Your research protocol should identify the ethical issues and describe how you are going to safeguard the welfare and dignity of the participants. There are some
tools to help you. The multi centre ethics committees have produced guidance and examples of writing consent forms and information sheets, use these as they are tried and tested.

Method
This section deals with the study design and should include:
- Number of subjects to be studied (a power calculation is necessary for this)
- Sampling methods – how the participants will be selected
- Inclusion and exclusion and reasons for
- Recruitment strategy
- Study design – quantitative e.g. randomised controlled trial or qualitative e.g. case study.
- Intervention type
- Method of data collection, tools and measurement to be used – It is always better to use a validated tool if possible
- Method of data analysis

It may be useful to seek statistical advise in regard to sample size/power calculation and data analysis.

End-points/Outcome events
Measurement outcomes confirm/reject or generate the hypothesis. They are either primary or secondary. They may be based on safety, efficacy or another trial objective (such as radiation exposure).

The endpoint may be reached in two situations:
1. When the patient reaches the end point of the study without any adverse outcome
2. The patient has reached the end point for the study when the patient has a pre-specified protocol outcome such as heart attack or death (this of course depends on the study)

Supervision
The proposal should name the individual(s) who will supervise the research project and the intended arrangements for the supervision, if appropriate.

Dissemination and Outcome
The intended route for internal and external publication should be specified. Any implications for future practice and patient care should also be suggested.

Benefits of the study
The benefits of the study need to be identified especially in terms of clinical impact and the benefits to the patients and the NHS. Benefits can also be determined in terms of cost, knowledge or the identification of areas for further research.

Resources and Costs
All potential research costs, even if the project is unfounded, should be included-
- Infrastructure costs
- R&D Costs
- Service support costs e.g. addition patient care costs.
- Excess treatment costs.

Project plan / milestones
A time table for the project and project milestones should be included listing all activities that need to be carried out. It is a good idea to work backwards, staring at the completion date.
References
A list of references used should be included. The method of referencing system depends on which one you are used to using. (Harvard etc.) If you require assistance please contact the R&D Office

When you have finished you should make sure that your proposal answers the following questions

- Have you explained the research question and defined the aim and objectives.
- Is the research design clear
- Have you defined the sample clearly (participants)
- Have you defined the sample size clearly
- Have you clearly defined what information you will be collecting
- Have you considered how the data will be analysed.

If you require further help please contact the R&D Office

For local projects the proposal should be no longer than 4-5 pages

A work Plan

Revised November 2003
Sample Work Plan

Project Lead - Penny Smith  
Project Manager – To be allocated  
Supporting Researcher - Sue Jones and Gay Morris

<table>
<thead>
<tr>
<th>Task</th>
<th>Details</th>
<th>Time scales</th>
<th>Responsible Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocate Project Manager / lead</td>
<td></td>
<td>May 99</td>
<td>Penny</td>
</tr>
<tr>
<td>Involve interested parties</td>
<td></td>
<td>May 01</td>
<td>Project Manager</td>
</tr>
<tr>
<td>Design Methodology and data collection tools</td>
<td>To include literature search Questionnaires Letters etc.</td>
<td>June 01</td>
<td>Penny and Sue</td>
</tr>
<tr>
<td>Discuss project with R&amp;D Facilitator and Manager</td>
<td></td>
<td></td>
<td>Penny</td>
</tr>
<tr>
<td>Pilot data collection tool</td>
<td></td>
<td>June 01</td>
<td>Sue</td>
</tr>
<tr>
<td>Review data collection tool following pilot</td>
<td></td>
<td>July 01</td>
<td>Penny and Sue</td>
</tr>
<tr>
<td>Refine Proposal</td>
<td></td>
<td>July 01</td>
<td>Penny and Gay</td>
</tr>
<tr>
<td>Agree variables for analysis</td>
<td></td>
<td>July 01</td>
<td>Penny and Gay</td>
</tr>
<tr>
<td>Re-revised data collection tool following above</td>
<td></td>
<td>August 01</td>
<td>Penny and Sue</td>
</tr>
<tr>
<td>Submit to R&amp;D Department</td>
<td></td>
<td>August 01</td>
<td>Project Manager</td>
</tr>
<tr>
<td>Submit for multi centre ethics approval</td>
<td>Form on website <a href="http://www.corec.org.uk">www.corec.org.uk</a></td>
<td>September 01</td>
<td></td>
</tr>
<tr>
<td>Submit for local ethics approval</td>
<td>Following multi centre approval Submit 2 weeks before 16 copies.</td>
<td>November 01</td>
<td>Project Manager</td>
</tr>
<tr>
<td>Collect data</td>
<td></td>
<td>January 20 02</td>
<td>Penny Sue and Gay</td>
</tr>
<tr>
<td>Data entry</td>
<td></td>
<td>February 2002</td>
<td>Sue and Gay</td>
</tr>
<tr>
<td>Data analysis</td>
<td></td>
<td>March 2002</td>
<td>Penny Sue and Gay</td>
</tr>
<tr>
<td>Write up project</td>
<td></td>
<td>April 2002</td>
<td>Penny Sue and Gay</td>
</tr>
<tr>
<td>Proof Read</td>
<td></td>
<td>May 2002</td>
<td>Project Manager</td>
</tr>
<tr>
<td>Disseminate finding</td>
<td></td>
<td>June 2002</td>
<td>Penny Sue and Gay</td>
</tr>
<tr>
<td>Publish</td>
<td></td>
<td>July 2002</td>
<td>Penny Sue and Gay</td>
</tr>
</tbody>
</table>

It’s helpful when setting time scale and dates to start at the end and work backwards.