Guidelines on writing a Research Protocol

**Table of Contents**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>3</td>
</tr>
<tr>
<td><em>The Structure of a Research Protocol</em></td>
<td></td>
</tr>
<tr>
<td>Title of Project</td>
<td>4</td>
</tr>
<tr>
<td>Investigators and Researchers</td>
<td></td>
</tr>
<tr>
<td>Main Investigator</td>
<td></td>
</tr>
<tr>
<td>Co-Investigator/s/Supervisor</td>
<td></td>
</tr>
<tr>
<td>Date Protocol written</td>
<td></td>
</tr>
<tr>
<td>Research Question.</td>
<td></td>
</tr>
<tr>
<td>Abstract/Summary</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td>5</td>
</tr>
<tr>
<td>Background</td>
<td></td>
</tr>
<tr>
<td>Aims and Objectives</td>
<td></td>
</tr>
<tr>
<td>Study Design</td>
<td></td>
</tr>
<tr>
<td>Randomisation Methods</td>
<td></td>
</tr>
<tr>
<td>Study Setting</td>
<td></td>
</tr>
<tr>
<td>Details of Sample Group</td>
<td></td>
</tr>
<tr>
<td>Methods of Assessment or Measurement</td>
<td></td>
</tr>
<tr>
<td>Outcome Measures/Objectives</td>
<td></td>
</tr>
<tr>
<td>Interventions (if applicable)</td>
<td>6</td>
</tr>
<tr>
<td>Proposed Timetable</td>
<td></td>
</tr>
<tr>
<td>Data Collection, Management and Analysis</td>
<td></td>
</tr>
<tr>
<td>Risk Assessment</td>
<td></td>
</tr>
</tbody>
</table>

R&D Protocol Guidelines Updated 1st October 2009
Safety Information

Resource Requirement/Cost Factors

Ethical Considerations

Supervision

Informed Consent

Indemnity

Outcomes and Dissemination
Guidelines on writing a Research Protocol

Introduction

All research projects undertaken in Aneurin Bevan Local Health Board must have a written protocol.

The research protocol forms an essential part of a research project. As your research ideas develop into a workable study, a written protocol will help to formalise your ideas and gain feedback from others through peer review. This may seem pedantic but long term it will be worthwhile. A research project without a research protocol is like building a house without a plan. However experienced you are in building a house it would be foolhardy to attempt such a project without a very detailed plan of action, a written plan that could be shown to others, particularly for expert comment and approval. Without a plan you could find yourself buried under a pile of rubble.

The Research Protocol is a short but detailed statement of:

- **What** you are going to do
- **How** you are going to do it
- **Who** will be your participants and how you will recruit them
- **When** and
- **Where** the research will be done
- **What** the expected benefits of the project will be

A well written protocol is also necessary for your applications to funding bodies, ethics and research governance committees. The research protocol can also act as a manual for members of the research team to ensure they adhere to the methods outlined. As your study gets underway, the protocol can be used to monitor the study’s progress and evaluate its outcomes. The protocol encourages the reader to think about the study rigorously and provides communication between all of the people involved.

Before beginning your research protocol you may want to consider the following points.

- What is your research question?
- Why does it matter?
- How will you address this question? (i.e. what methods will you use?)
- How important is this activity to the NHS and to service users?
• Is your *research* question clear?
• Are your *research* methods appropriate?

There is a diverse range of types of research and your research may not fit neatly into the suggested headings given below. However they give an indication of the information that should be included in your protocol, even if you use different headings.

**The Structure of a Research Protocol**

**Title of project**
The title clearly identifies the study and may contain a brief description of the study design and objectives.

**Investigators and Researchers**
Everyone who has made a valuable contribution to the study should be named and their contact details given.

**Main Investigator**
This section must be completed in full

**Co-investigators/Supervisor**
If the researcher is a student or carrying out a study for a degree, details of the person supervising the research project on behalf of Aneurin Bevan Local Health Board must be inserted in this section.

**Date Protocol written**
Insert month & year

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

**Abstract/Summary**
To give the reader an outline of the study, summarise the main objectives and procedure including the study design, method and an outline of the expected findings. It is advisable to write this section last and should be no more than 200 words.

**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 findings may be used in clinical practice.
Aims and Objectives
Describe what knowledge the study is trying to uncover and how the study hopes to reach these objectives.

Study Design
What study design is most appropriate to answer your particular research question? Is it a quantitative design e.g. randomised controlled trial or a qualitative design e.g. case study.

Randomisation Methods
Some research strategies such as case control studies or randomised control studies, require a random allocation of patients to the different experimental groups or interventions. You will need to explain what randomisation methods you will use.

Study Setting
Where will the research take place? Your study may take place in a number of different sites, or you may be visiting patients in their homes. You need to address any practical issues involved, such as safety procedures when doing home visits.

Details of Sample Group
Detailed information regarding your subjects should be given.

For example, describe the study population, including a rationale of why they were chosen.

Describe the methods by which subjects will be identified and recruited and what inclusion and exclusion criteria will be used.

You will need to justify your sample size and state whether sample size calculations have been used.

It may also be necessary to describe the criteria for participation or completion of the study, participation retention strategies and withdrawal criteria.

Methods of Assessment or Measurement
What data will be collected and why. For example how will you measure your participant’s quality of life?

What instruments will you use and are they the most appropriate? If you are using any equipment it should be clearly described.

Outcome Measures/Objectives
The measurement outcomes used to support or reject the hypotheses can be stated and separated into primary and secondary outcomes. For example, primary outcomes or endpoints are most important to your hypothesis, there may be only 1 or 2. Secondary
outcomes may provide some support to the hypothesis, but without the primary outcomes they could not confirm the hypothesis.

**Interventions (if applicable)**
Not all studies will involve any interventions, but if yours does a description of the study intervention should be provided. If you are giving a treatment or investigation, the dose, timing, method of providing, administering and receiving the treatment should be detailed. All necessary safeguards and potential risks should be made clear, including the methods by which intervention will be monitored.

**Proposed Timetable**
Specify the proposed start and end date of the research project. 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, starting at the completion date.

**Data Collection, Management and Analysis**
Explain how the data will be collected and managed and who will have access to it. The method of the data analysis should also be specified including any statistical tests and may include the following points:
- Method of data entry
- Plan of analysis, including assumptions of analysis
- Data analysis package
- Presentation of demographic and outcome data summaries
- Planned presentation of the data i.e. graphs, tables, figures

**Risk Assessment**
Outline the methods by which the patient/subject’s interests will be safeguarded. For example, the process of risk limitations, how you will maintain confidentiality or anonymise patient’s data and how you will monitor any adverse side effects.

State whether there has been any user involvement in the design of the study.

If applicable, state whether you have followed the Clinical Trials Directive, and you have Regulatory Authority approval.

You must state who will provide indemnity in case of harm to your participants through negligence.

The protocol should clearly state who is sponsoring the research study and what interest they have in its outcome. You must also state whether the sponsors are to provide indemnity in the case of negligent harm to participants.

**Safety Information**
If applicable describe how you will report a Serious Adverse Event(SAE) or a Suspected Unexpected Serious Adverse Reactions (SUSAR). Include details of the
person/people responsible for reporting such events as well as definitions of what to report and what not to report.

Resource Requirement/Cost Factors
All potential research costs, even if the project is unfunded, should be included. Items to be considered include:

- Personnel Costs
- Equipment costs
- Supplies/disposables
- Office/Administrative costs (phone, photocopy, postage etc)
- Travel costs
- Overheads

In addition, you must outline the timetable/schedule of the research and costs. This includes details of materials/equipment/staff required to carry out the research. Details of these costs must be included.

Financial help can be obtained from Mrs Carol Pullar, Financial Administrator, Ext 8140

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 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.

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

Informed Consent
Describe how you intend to obtain Informed Consent

For example: The Principles of the Declaration of Helsinki (if appropriate) will be adhered to and these include:

- All participants involved in the study will be required to give their written informed consent before starting the study.
- The nature of any possible side effects will be fully explained.
- Participants will receive written information concerning their participation in the study.
- The participants will be informed that they are able to withdraw from the study at any time without being required to state a reason and without prejudice to their future care.

Indemnity

R&D Protocol Guidelines Updated 1st October 2009
Research projects cannot commence unless they have been approved by the respective committees:

- Health Board Research Scrutiny Committee
- Health Board Research Risk Review Committee
- Research Ethics Committee (an external body accessed via NRES, the National Research Ethics Service).

Approval from these three committees ensures that your project will be indemnified by the Health Board.

In addition, Commercial Trials have to be indemnified by the Health Boards Associate Medical Director, Research & Development and this is only done following approval from a Research Ethics Committee and the Health Board Research Risk Review Committee. The R&D Office is responsible for organising the indemnity of Commercial trials.

**Outcomes and Dissemination**

You need to describe how the study’s findings will be made available. State whether you intend to publish or present the findings. You may decide to do both.

Any implications for future practice and patient care should also be suggested. Other implication may be a new research tool, teaching or clinical aids.