HOW TO WRITE A RESEARCH

PROTOCOL

RESEARCH PROTOCOL

A protocol for a research project is more than a research proposal. A proposal is an initial set of ideas for research which are well supported by a background literature search and perhaps a pilot study, both of which are intended to justify the study. A proposal is short and to the point; outlines the background literature supporting the study, how data might be collected and what the researcher hopes to achieve.

A protocol is the stage after this. A protocol is a **detailed** set of activities for the project you propose and these activities are supported by evidence from other research and from your preliminary investigations. It is a valuable practical timetable and guide to your activities and shows some foresight into what you are trying to achieve. It shows above all, *evidence of planning,* including anticipation of potential problems and how you intend to deal with them.

You might find it useful to read this document alongside www.sor.org/public/pdf/research_prop.ppt and http://admin.iop.kcl.ac.uk/randd/downloads/Research_Handbook_2006.pdf
Which are full of helpful tips to get you started in research.

There are several things for you to do in putting together ideas for a research protocol and these are indicated by a string of asterisks in the left-hand margin. The first instruction is:

Read through all pages in this handout before taking any action.

DUE DATES **Insert some target dates for yourself in here:**

First draft of hypothesis and aims and objectives...

First draft of protocol as described in this handout...

Final draft of protocol and all supporting documents...

WRITING A RESEARCH PROTOCOL

The aim of this exercise is to begin preparation of a protocol for a research project that could be carried out. You may not actually be carrying out the research, but we will look at the stages involved in preparing a research protocol so that when you need one you know how to make one.

The choice of the area of research is up to you. This is an opportunity for you to follow some of your own interests. I will say more later about choosing an area for research.

I. The Outline

There is no standard outline for a research protocol, but all protocols should contain:

- **TITLE** which makes clear the main area of research. If your title is 'scientific' it is also a good idea to re-state the title in layman's language.

- **BACKGROUND** to a topic to justify the need to undertake the proposed research. This is essentially your literature review and will be more detailed than the background submitted in your proposal. It is not acceptable to submit only a list of references as your background. The background should show you have a critical understanding of relevant literature and research around the area you are hoping to investigate and above all justifies you undertaking the research.

- **HYPOTHESIS** that is to be tested. This is a statement suggesting an explanation of something you've observed, or prediction of outcome e.g. *'Activation of the amygdala early in the presentation of fear-relevant stimuli will distinguish phobics from non-phobics'*. The hypothesis is always formed before you begin your research.

- **AIMS, OBJECTIVES AND RATIONALE**, These are concise statements about what you propose to do (including a brief description of the study design, sampling method and sample size calculation) and why the research should be undertaken

- **METHODS** which are to be used, justifying their choice where necessary

- **ETHICAL** considerations

- **PROJECTED OUTCOMES**. These are clear statements of what you hope to demonstrate, and include speculations on how the conclusions from your research will facilitate further research or be of benefit generally. Note this is different to your hypothesis which is a statement of predicted outcome.

COST, normally estimated for staff salaries, equipment, running costs (including chemicals, stationery, telephone, postage, travel, etc.), and any overheads (e.g. costs for office space, lighting, heating etc.). If you're applying for a grant in conjunction with an academic institution you may be asked to allow for Full Economic Costing (FEC). This does not apply if you're applying for a grant through an NHS institution however. Useful links for advice on Full Economic Costing are; www.iop.kcl.ac.uk/iopweb/blob/dowloads/locator/l_27_Full_Economic_Costing_notes_Sept_07.doc www.fec.bham.ac.uk/costing/index.shtml

II. Deciding on the topic of research.

You are free to choose any area that interests you. The range of topics is wide; from the physical sciences of image formation to the evaluation of the social context of patients' expectations of a service. Any time you ask yourself 'WHY?' in clinical practice, it is a potential research question.

It might be worth visiting the SCoR web-site where you will find the research priorities for both therapy and diagnostic radiography which are updated every year as this may also give you some ideas for undertaking research. www.sor.org/public/pdf/research_priorities.pdf

The research for which a protocol is written should involve some *practical data collection* and not be entirely computer or library based.

There will always be some limitations to your research idea:

1. Is this a graduate or part-time research project? If so there is a limited amount of time that you will be able to spend on it. Let us assume, as an approximation, that you will have the equivalent of two days per week over a year in which to collect and analyse your data and write up your report.

2. The research must also be possible with the resources that are available. For example, you may have access to equipment for physical testing, but it is unlikely to be available to you during the normal working day - if at all. Better to plan your research to cause as little conflict with clinical demand on resources as possible.

3. If you plan to sample a specific section of the population (e.g. pregnant women, postmenopausal women on HRT, men who play Rugby Union) make sure that they are reasonably available to you in your data collection period.

Once you have an idea, the next stage is to do some reading around the topic. Has similar research been conducted before? Find between 6 and 10 recent articles which relate to the area of research that you are interested in. Do not be put off if someone else has already beaten you to researching your exact idea, all research will have recommendations as to what the next phase of researching in this area should be. Take these recommendations to suggest a hypothesis that needs testing or to formulate a question that needs answering.

It may be that there is no research undertaken in the area that you are interested in. For example perhaps you want to compare CT with MRI for imaging the paranasal sinus'. On reading around this topic you find that this type of study has never been previously undertaken. However, there will be other studies that have compared imaging techniques e.g. CT-v-US when looking at other pathologies/structures. Look at how these studies were undertaken; what methods were used; what were the limitations; and use this knowledge to suggest a hypothesis that needs testing or to formulate a question that needs answering.

This reading will form the backbone of the **BACKGROUND** that you will be writing, therefore keep note of the articles you read and their source. There are many programs available free on the internet which will save

your references and allow easy insertion into your text. More on these later.

III. Developing a hypothesis.

A good hypothesis addresses a new, important and interesting research question. It may break new ground, or it may help to confirm or shed light on existing research. It should not therefore simply be a repeat of someone else's hypothesis, but should address some flaw or omission in previous work, or propose a new idea which has not been tested before.

It should be specific, e.g. "^{18}FDG- PET is a sensitive screening technique for cerebral metastases" rather than general "Radionuclide scintigraphy can detect brain tumours".

What is the difference between a one-tailed/two tailed hypothesis?

If your research is testing one theory/technique against another, your hypothesis may become one or two tailed. A one tailed hypothesis predicts a direction for your outcome, whereas a two tailed hypothesis merely says there will be a difference between the two conditions being tested. E.g. "FDG- PET is a more sensitive screening technique for cerebral metastases than MRI" is one tailed as it is saying one will be better than the other. Whereas "There is a difference between the ability of FDG- PET than MRI to detect cerebral metastases" is two tailed. It's important to decide at an early stage whether to opt for a one or two tailed hypothesis as it will affect the statistical power of your results.

A good hypothesis must also be <u>testable</u>. This means that within the resources (personnel, time, equipment, and financial resources) that are available you will be able to make the necessary measurements that will

enable you to prove or disprove your hypothesis. There is no point in putting forward a hypothesis which will require an intervention, with baseline and follow-up observations made 18 weeks apart, when you have only 14 weeks in which to collect your data.

Advice: Try to develop a realistic hypothesis which you think will be testable within the resources available.

This hypothesis may need to be modified when you consider more closely the methods that you propose to use. Also, you will need to look at the question of Power (the likelihood of being able to detect a statistically significant outcome if one exists), which depends in part on the number of observations which you make.

Not every study needs to be an intervention trial. In your literature search, look for articles which assess hypotheses in a variety of ways. When you choose your own hypothesis, think about how the hypothesis can be tested using a variety of different research designs.

Not all studies have a hypothesis. A hypothesis is only used when you are trying to prove whether something does or does not happen, or a suggested explanation for what you have observed in clinical practice and which you will go on to test. Hypotheses are more commonly used in quantitative studies that collect numerical data, which are then statistically analysed. However, your interests may be more about the patient's experience of health care. In these cases you are not setting out to prove whether something is or is not the case, instead you are attempting to answer a

research question e.g.

Hypothesis

'patients prefer oral laxative to lavage when preparing for barium enema examinations'

Research Question

'How do patients feel about the bowel preparations used prior to undergoing barium enema procedures?'

IV. Developing the Aims, Objectives and Rationale.

The Aims are the main goals that you have set for yourself which include a referral to the study design e.g.

Aim: "To conduct a randomised double-blind trial to assess the performance of two laxative agents in preparing the large bowel for barium enema examinations."

Objectives:

The objectives are brief, specific descriptions of the main procedures to be followed in order that you can meet your aim e.g.

1.) To select 60 patients attending for barium enema examination, excluding those over the age of 70.
2.) Randomise patients into groups receiving preparation laxative A or B, stratifying for age, sex and disease category.
3.) Use an existing questionnaire (as identified in your background literature search) on the acceptability of the laxative (it is always better (and sometimes easier) to use existing research tools to collect

your data, even if they require some modification for your own research. If no such questionnaire exists then you may have to construct your own).

4.) Use an existing scoring system for efficacy of bowel preparation for imaging criteria. Again if one does not exist then you may have to construct your own.

5.) Assess differences between the scores for laxatives A and B used in the patient groups by a paired-t-test on the criteria scores.

6.) Report on the questionnaire responses on laxative acceptability.

The Rationale is a concise statement, not usually more than one or two paragraphs which gives a justification of both the need to test the hypothesis and the choice of methods (the choice of a particular method for measuring your main variable(s) may need to form a part of the background). It should state clearly why the research needs to be undertaken, and how the conclusions will be of benefit.

Advice: Draft the first version of your aims, objectives and rationale.

v. Choosing and describing the Methods.

For a hypothesis or question to be testable, it must be possible to obtain the necessary information. You must ensure that the variables which you measure will allow you to test your hypothesis (i.e. that they are the appropriate and relevant measurements to make), and that it is possible to make those measurements with the resources which you have available.

There are four principal areas which you need to consider:

1. The sample and its size. You need to think about the group in which the measurements are to be made and how many observations you will require. Be careful to exclude subjects whose presence may confuse the outcome (e.g. including diabetics in a survey of frequency Mars bar eating in the population).

Advice: Think of which subjects you plan to use, from where you plan to obtain them, how you will obtain them, and how long the sampling procedure is likely to take.

The size of the sample in part dictates the Power that the study will have. Very often, to have the desired power, you will need a sample size which is greater than you can manage in a small research project. It is important to try and give a realistic estimate of the number of observations that you think you will be able to make with the resources which you have available. Calculating the power that the study is likely to have will indicate whether or not it is worth undertaking the study in the first place! If it appears that you will not have enough power to test your hypothesis, it is better to abandon a research project than to commit limited resources to something that is unlikely to be able to prove what you want to prove. The one exception to this is a pilot study, or feasibility study which is undertaken to test out the robustness of your methodology, data collection and analysis. However a pilot study should not be undertaken without the commitment of moving onto the main

research study with adequate power.

It is worth noting here that studies that plan to use qualitative methods i.e. narrative observations/interviews do not need to undertake a power calculation as the aim of these studies is not to generalise to the population as a whole, but to reveal knowledge about a previously unknown phenomena. For example it is not unusual for interview based studies to use as few as four participants.

2. Variables to be measured. Before you can begin a study, you must know exactly which variables you are going to measure. They must be the ones that will give you the measurements you need to test your hypothesis. If you are measuring effluent from film processors, which chemical markers do you need to identify? If you are investigating blood cell response to contrast agents which cells do you need to target and do you need to measure plasma concentrations?

   You must also know the technique or method of analysis you are going to use to obtain each measurement. This is important both in terms of the equipment or facilities that you will need, and in terms of the errors likely to be associated with each measurement. This in turn will be reflected in the number of observations you will be able to collect. Is it better to have more, less accurate observations, or fewer more accurate observations? The answer will depend on the characteristics of the hypothesis and the resources available.

Advice: Decide on which variables you will measure, how many observations per variable per subject, and how big your sample size will be. Be prepared to justify your choices, particularly with reference to the resources available.

3. Research design and statistical analysis. Every study will have a design which will dictate how many groups are to be measured, how many observations are to be made per subject for each variable being measured, and how those observations are to be treated statistically in order to test the hypothesis. This in turn will dictate which statistical tests are to be applied to the data.

   Because you may not have covered all of the tests which you will be able to use, think at this stage simply of how many groups in which you will need to make observations, and how many observations you will make per subject per variable. Also, you should think about whether you will be looking at differences between mean or median value of groups, bearing in mind the advantages and disadvantages of each measurement; and whether you want to compare multiple variables (e.g. to see if the radiation dose to the gonads varies with the **energy** of the beam and the **quality** of the image in chest radiography).

Advice: Describe the basic design of the research (is it cross-sectional observations, group comparisons, intervention, Prospective, retrospective etc.), with some detail of the procedures that each

subject will undergo.

Qualitative research uses a particular method for analysing data as the data generated from these studies are not numerical. Instead data are narrative and so techniques such as thematic analysis, content analysis, and open coding will be used rather than statistical tests.

4. Ethical approval. All studies on humans, including data already collected from humans (i.e. from existing medical records), require approval by a committee whose main purpose is to ensure that studies are ethically sound. This includes issues such as the information which people need to be given before agreeing to take part in a study (called "informed consent"); the discomfort or pain involved in any measurements which are made, and whether the procedures to be used are safe, appropriate and necessary; whether alternative methods can be used which are safer, cause less discomfort etc; whether the risks (e.g. from blood sampling) are justified by the research; plus clarification of the right of any subject to withdraw from a study for whatever reason; etc.

Advice: Think about the ethical issues that are likely to arise in conducting the research you are proposing. If you are unsure about ethics visit the SCoR web site where you can find further information. www.nres.npsa.nhs.uk where you will find plenty of advice on how to conduct ethical research.

VI. The Title.

You probably have enough of an idea now to be able to think of a title which reflects the hypothesis or research question you wish to test and which reflects the design of the study which you are proposing.

VII. First Drafts.

*** Write the first draft of your **hypothesis**, **aims** and **objectives**. Not more than one A4 page. .

*** Write the first draft of your **research proposal**.
It should include:

The **TITLE**

Under **BACKGROUND**, simply list the references which you have used in your initial library search. You will expand this later.

The **HYPOTHESIS or RESEARCH QUESTION**

The **AIMS, OBJECTIVES AND RATIONALE**

The **METHODS**

- Sample selection
- Sample size
- Main variables to be measured
- A clear statement of the study design, and the procedures
- A brief list of what you see as the main ethical issues.

The COSTS

Omit **PROJECTED OUTCOMES** at this stage.

WRITING A RESEARCH PROTOCOL. Stage 2.

The protocols that you have started can now be developed in more detail.

With regard to your present work, you should now begin to draft the background in more detail, starting with the references. The background should provide more detail about what work has been done to date, and how your own project will take this research forward. The following points need to be clarified:

Sample: what are the inclusion and exclusion criteria?

Procedures: How you are you actually going to undertake the study. If you plan to compare two (or more) groups, make sure that you state which variables you are going to use to decide whether or not your groups are comparable, or on which variables you intend to match your subjects (if appropriate). Where appropriate, mention randomisation procedures (e.g. the order of administration of two or more alternative pharmaceuticals).

Ask yourself if the length of any proposed data record is long enough to produce the desired effects. Evidence from the literature may be important

to support your design.

At this stage, you should also prepare:

1. Study information sheet: to be given to any subjects before undertaking a study. This should state how the subjects were recruited, the procedures to be undergone, and a statement regarding confidentiality. www.**nres**.npsa.nhs.uk for further help and advice on how to put together a participant information sheet.

2. Consent form: There should be two copies and should include check boxes for the most important invasive aspects of taking part in the research e.g. I agree to have my medical records looked at; I agree to be audio taped; I agree to have blood tests taken. These should be signed and dated by both the participant and the researcher with a copy being held be each party. Visit www.**nres**.npsa.nhs.uk for further help and advice.

3. Questionnaire/interview/observation schedule: draft or proposed form of questions. You do not need to produce a "finished product", but you should specify the key questions that you propose to ask or observe.

4. Data sheet: on which you plan to record all your measurements for each subject.

WRITING A RESEARCH PROTOCOL. Stage 3.

The protocols which you prepared should now be reaching their final stages of development. There are several points which may still need to be addressed.

1. **Length and nature of intervention and any patient acceptability assessment**. Both of these need to be justified in the rationale. For example, the amount of any medication should be specified, together with the nature of any placebo.

2. The protocol should now include the following:

   -Summary of proposed project (not more than 150 words). This is similar to an abstract and should be written in layman's terms.
   -Background
   -Hypothesis
   -Rationale
   -Aims and objectives: should include a description of the study design
   -Methods
   -Costs (at least some detailed estimation)
   -Sampling: population, sampling method, Exclusion criteria, number of subjects
   -Procedures: all procedures and measurements to be undertaken
   -Powers of study (quantitative studies only)
   -Statistical assessment: Tests to be used or methods of analysis in qualitative research.

-Ethical Issues: State the risks involved and any ethical issues related to subject safety, confidentiality, and data protection. State where ethical permission would be obtained, or include a copy of the approval is already obtained.

-Projected outcomes: This is NOT a restatement in a different tense of what you have said in the aims and objectives, but a forecast of the benefits that you see accruing from the work, and any further research that is likely to be needed as a direct consequence of the work undertaken.

-Study information: This should include information about how subjects will be selected (source, permission, etc.), procedures, and confidentiality regarding names and addresses and the use of the data. **It should also include your name and telephone number/e-mail address where you can be contacted.**

-Consent form: required for all human studies.

-Data sheet: should include any potential confounding variables that will need to be measured.

-Questionnaire: If needed.

-References:

Your Protocol is now complete.