The aim of this guide is to help researchers write a research study protocol for an observational study.
The guide will take you through each section of the protocol giving advice and examples oe ando-2(l giv)7(in)-3(gref:*78(ak)-5(

- Brief description of methods

The background should include a along with a full literature review, a detailed justification for the study and discussion of its feasibility.

6.1 Literature Search and Review

Precise details of the literature search completed should be given here.

- The nature of any unpublished work should also be documented here.
- Help with this aspect your intended research can often be sought form a clinical librarian. A good literature search at the beginning of the research process is invaluable and will steer the researcher in the most appropriate direction.
- Your review should make reference to relevant papers, unpublished works as well as clinical experience.

6.2 Justification

- A statement indicating the size of the problem (and effect on the health service) and why the study is appropriate
- Explain what the potential benefits are – to patients and the health service
- Explain what your study will add to the body of evidence already available.
- Discuss the feasibility of the study in terms of subject and data availability as well as length.

- Describe the primary research question
- Clearly defined objectives in terms of measurable endpoints
- Distinguish primary and secondary objectives

The two most commonly used designs for observational studies are (A) case-control studies (including nested case-control studies) and (B) cohort studies. In the former, the study groups are chosen on the basis of their disease or outcome of interest. In a cohort study the comparison groups are identified according to an exposure of interest. A description of the design should be given, along with details of any matching and blinding used. Cross-sectional studies are also discussed in (C).

- Describe an objective definition for the disease or outcome of interest and use this to define the
  .
- Describe the appropriate control group for the particular group of cases. In general the controls should be sources from a similar population as the cases, the only difference being that they do not have the outcome of interest.

- Describe the matching factor(s) and how the matching will be done. The main purpose of matching is to control for confounding. By matching on age, for example, we are attempting to ensure the cases and controls have the same (or similar) age distribution.

Other types of observational studies may involve only one group of subjects. For example, in a method comparison study, measurements will be taken on a group of subjects using two (or more) methods. The guidelines set out in this document still apply, the main difference being that a second group of subjects is not used.

Include details of:

- Source of subjects (where they come from and why this group is appropriate). For example, are they a random sample from a larger population or are they obtained from a disease register? They may be patients attending a clinic over a particular period.
- Number of centres involved or regional / national limits on possible recruitment
- Subject inclusion and exclusion criteria (with justification if necessary)
- Expected no of eligible participants available per year and proportion of these expected to agree to take part.

- useful to include table / diagram describing schedule for data collection.
- describe methods used to maximise completeness of data (e.g. telephoning patients who have not returned postal questionnaires)
- include data collection forms and questionnaires as appendices

11.2 Data handling and record keeping

- describe procedures for data collection and recording (software to be used, location of the data etc)
- detail methods implemented to ensure validity and quality of data (e.g. double entry, cross validation etc)
- Security / storage of data
- Records retention – duration and location
- Adherence to Data Protection Act 1998 and Caldicott

12.1 Sample size calculation

Details of the precision or power calculation used to estimate the required sample size based on primary outcome

- Assumptions made (statistical assumptions regarding distribution)
- Estimates of difference to be detected along with appropriate justification Deta g(r)-4(o)-25(ta)4(-2(t 4(e)4(a[De)8(Act)-

13.1 Subject compliance

- procedures for monitoring (e.g. exercise diary for subjects on a rehabilitation programme)
- recording of patient compliance information (what will be recorded and where)
- detail of follow-up of non compliant subjects

13.2 Withdrawal of subjects

- describe under what circumstances and how subjects will be withdrawn from the study
- give details of documentation to be completed on subject withdrawal (including recording reasons for withdrawal and any follow-up information collected)

Description of ethical issues related to the study. For example consider:

- Approvals from relevant groups (e.g. MREC, LREC, MHRA, Trust(s))
- Informed consent (subject information and informed consent form appended)
- Allowances for special groups (e.g. non English speakers, children, mentally ill)
- Patient withdrawal / discontinuation

- Finance and insurance details (if not addressed in separate agreement)
- Cover for non negligent and negligent harm

Details of how, where and when the results of the study will be reported / presented.

- Altman, DG. (1991) . London: Chapman and Hall, Chapter