University Hospitals Bristol NHS
NHS Foundation Trust

Research Guidance Sheet No.1[c]
Guide to writing a Qualitative Study Protocol

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The aim of this guide is to help researchers with the content and structure of protocols for qualitative studies. It indicates the information that should generally be included in a protocol and has been constructed to cover important methodological considerations and requirements specified under Good Clinical Practice.

Advice of the methodological aspects of designing a research study and writing a protocol can be obtained from the Research Design Service 0117 342 0233.

Where University Hospitals Bristol (UH Bristol) is the sponsor of the research study suggested standard wording is available for the sections of the protocol marked with a *, please refer to Research Guidance Sheet No. 3b available from the Research website.

General Information

Title

- It is useful to specify both a full title and short title.
- The titles specified must be consistent across all documents relevant to the study.

Names (titles), roles and contact details of:

- Name and address of sponsor(s)*.
- Name, title, address and telephone number of the Chief Investigator.
- Name, address, title and telephone number of all other Investigator(s) (if applicable).
- Address and telephone number of study site(s).

Protocol details

- Version number and date, e.g. v2 12.09.2004.
- Final/draft.

List of abbreviations and definitions

Background

The detail given in this section should be backed up by a full literature review and should make reference to relevant papers.
This section should include:

- A clear explanation/description of the main research topic/area.
- Detailed justification for the study including:
  - A statement indicating why the study methodology is appropriate.
  - Potential benefits to patients and the NHS, relevance to current policies and priorities.
  - Description (as applicable) of the indication, its diagnosis, incidence, current treatments and their limitations.
  - An explanation of what your study will add to the body of evidence already available.
  - A discussion of the feasibility of the study.

Aims

- State the purpose of performing the study

Study Design – the scientific integrity of a study and the credibility of results obtained are largely dependant upon the study design. A description of the study design should include the following:

- The type/design of the study e.g. interview (semi-structured, structured, in depth), focus groups
- The sampling method for recruiting participants
- The expected length of time each subject will participate in the study for and the sequence and duration of all study periods
- The source of subjects (where they come from and why this group is appropriate)
- The number of centres involved
- Expected number of eligible participants available per year and proportion of these expected to agree to the trial
- The inclusion and exclusion criteria defining who is or is not eligible for the study
- Sampling strategy e.g. purposive, systematic, convenience

Subject recruitment

- Details of recruitment process and enrolment procedure including:
  - Method of recruitment (e.g. via adverts, clinics) and details of enrolment procedure.
  - Any payments, gifts, tokens or expenses available to participants.
  - Details of procedures, tests, and screenings carried out to assess study suitability.
  - Provision of patient information sheet.
  - Gaining patient consent (how consent will be obtained, who will gain consent, whether a witness will be present, how long the subject will have to decide, the arrangements for non-English speakers and special groups (e.g. mentally ill, children, those suffering from dementia).

Subject compliance

- Recording of patient compliance information (what will be recorded, when and where).
- Detail of follow-up of non-compliant subjects.

Sample size calculation & statistical analysis

- An estimate of the recruitment period for the study (calculated based on the expected number of eligible and recruited participants available per year) with justification that the required sample size will be attainable in practice.
- Include a short statement on the types of analysis that it is proposed will be used e.g. grounded theory.

Data collection, handling and record keeping

- Detail how data will be collected, e.g. flipchart, tape recording.
- Indicate who will be transcribing the data once it has been collected.
- Describe what other types of data will be recorded as part of the study e.g. patient demographics
- Specify the point at which patient data will be anonymised.
- Location where original tape recordings will be stored and/or procedures for blanking tapes (if applicable)
- Describe methods used to maximise completeness of data
- Include data collection forms as appendices (if any)
- State who is responsible and describe procedures for data collection, recording and quality
- Detail whether there will be any respondent validation.
- Describe procedures for security / storage of data.
- Describe procedures for retention of source data including the duration and location*.
- Include statement on adherence to Data Protection Act 1998*.
- Plans for archiving at the end of the study and details of where documentation will be archived.

Research Governance, Monitoring and Ethics & R&D approval

- A statement that the study will be conducted in compliance with the Research Governance Framework for Health and Social Care and Good Clinical Practice (GCP)*.
- Arrangements for monitoring / auditing conduct of the research* & the use and role of data monitoring groups and steering groups etc.
- Detail of any other steps taken to ensure quality of research.
- Description of ethical issues related to the study.
- A statement that the study will be conducted in accordance with approvals from relevant groups (e.g. MREC, MHRA, Trust(s) and other specialist approvals e.g. NIGB)*.

Finance

- Provide any details of the financial arrangements for the study if not assessed in a different document.

Indemnity

- Describe arrangements for providing cover for non-negligent and negligent harm*.

Reporting and dissemination

- Detail of plans for publicising the results of the study.

Tables, figures and references

Appendices

For example:

- Patient information sheet.
- Patient consent form.
- GP letter.
- Data collection forms/Case Report Forms
- Questionnaires/interview schedule template