Research Protocol Guideline

This guideline is intended to assist in the preparation of a research protocol. The template identifies the key elements of the protocol. Not all sections will be relevant in all instances. The research protocol requires a document identifier: version number, date (dd/mm/yyyy) and page numbers, which must be included in the footer.

Title

The title should clearly identify the study and therefore may appropriately contain a description of the study design as well as the objectives. A shortened version or unique number can be added to aid recognition of the project.

Investigators

The named investigators on the research proposal should be all those with a valuable contribution to the work. It is these same individuals who would expect to be authors on a resultant publication, although this may be a matter for negotiation. The main person/s responsible for developing the protocol, together with the supervisor, and the people asked to take responsibility for performing measurements, analyses, and report writing should be included. An individual who provides limited advice, or agrees to refer subjects/patients would not normally expect to be a named investigator on the proposal.

Introduction

The introduction to the project includes a critical background review of current knowledge, based on unpublished as well as published work, a review of gaps in the evidence, and a rationale for the investigation, in terms of the information expected from the study itself and the potential value of furthering knowledge in this field. A research hypothesis should be defined in this section, with an explanation of reasons (local, national or international) for undertaking the work.

It should be noted that reference to unpublished studies may carry less weight than published work because the data have not received a positive critical review. All evidence-based statements should reference the source of the data. Anecdote and opinion should be avoided unless relevant to the background, as they do not strengthen a scientific rationale.

Aims

These should be expressed in a small number (1 – 4) of concise and precise objectives, so that it is clear what type of answers are anticipated to the research questions. This will aid definition of the endpoints or outcome measures. The objectives should follow logically from the rationale and hypothesis for a quantitative study, and lead clearly to a cogent hypothesis for qualitative studies. Diverse aims may be better confined to separate studies.

Method

Study type/design

This section describes the important elements of the methodology. It may include all or some of the following:

- Quantitative or qualitative
- The process by which subjects will be sampled (e.g. randomised, incidental)
- The numbers of groups studied
- Whether participants and investigators will be aware, for example, of which intervention is administered (blinding)
- Whether all patients will receive all or only one intervention (e.g. cross-over, parallel group)
- Whether past or current data are collected (retrospective or prospective)
- Methods to reduce bias (e.g. control group, placebo-comparison)
- The tools used (e.g. questionnaire, interview questions/prompts, data collection tool).

Subjects / Patients

All information about the study groups should be included:

- A description of the study population, with a rationale
- The methods by which they will be found (e.g. from the electoral role, General Practitioner records) and recruited (e.g. by postal invitation, through outpatients, electronically)
- Inclusion and exclusion criteria (e.g. age range, disease)
- Sample size with rationale based on the size and type of outcome expected, drawing on previous research.

Measurements

All relevant measurements, investigations and techniques should be fully described. If there are a variety of accepted techniques that could be used, then the exact procedure should be defined. The equipment/instrument used for any procedure/aspect of the study should also be detailed. Information on the validity and reliability of the measures may be appropriate.

Interventions / Procedures

A full description of the study procedures and intervention should be provided:

- Where this involves a treatment or investigation, the dose, timing, method of providing, administering, and receiving the treatment/investigation, or the analogous features of the device should be detailed. Where this is by questionnaire or interview, as in qualitative hypothesis generating studies, the reasons for this method and possible contamination should be discussed.
- Necessary safeguards and potential risks should be highlighted, including the methods by which the intervention will be monitored at all stages from manufacture to administration to and/or by the subject
- The method of deciding the intervention given to each subject.

Endpoints

The endpoints are measurement outcomes and will be used to confirm/refute or generate the hypothesis. They should be separated into primary and secondary:

- Primary endpoints are those that are most important to the hypothesis. There should be only one or two.
- Secondary endpoints provide some support to the hypothesis, but without the expected primary outcome would not prove the theory being investigated
- The numbers of primary and secondary endpoints should be kept to a minimum because the inclusion of a number of variables will hinder the interpretation of the findings
- The expected effect on the endpoints should be described, and the size of a clinically important effect defined.

Study plan

This details the mechanisms of identification of potential participants, first contact with them, information provision and consenting procedures. It also spells out the order and timing of all study procedures, at each measurement or intervention time point. Information, equipment, treatment and documentation to be given to the subject/patient or to be collected by the investigator should be precisely detailed. What is standard care and what is different from standard should be spelt out.

Analysis

The method of data analysis should be specified within the protocol. This includes:

- Timing of unblinding of data relative to data collection, entry and statistical analysis
- Method of data entry
- Data analysis package
- Presentation of demographic and outcome data summaries
- The arithmetic, graphical and statistical manipulation of data
- Criteria for statistical and clinical significance of data.

Ethical issues

Matters relevant to and the methods by which the patient's/subject's interests will be safeguarded should be described:

- Potential for undue influence (e.g. via subject/investigator payment, relationship between subject/investigator/sponsor), and how relationships might affect the voluntariness of consent should be considered
- The purpose of new or unusual techniques/treatments, and the withholding of accepted techniques
- Risk mitigation
- Frequency of monitoring for adverse events
- Methods of checking for and dealing with potential adverse events/side effects
- Selection of patients
- Patient study information
- Method of obtaining informed consent
- Confidentiality of data

- Review by the Ethics Committee
- Amount of payment/reward for participation to subject/investigator/host organisation.

Resource requirements

The resource implications to the host organisation and any involved departments should be broadly defined. Where the study entails cooperation by individuals other than the investigators, or use of equipment or resource, then permission for use of services should be obtained from the relevant manager.

In addition, the following information is required if not explicitly stated on the Resource form:

- The timetable/schedule of the research
- The names of staff undertaking the research
- The staff involved peripherally such as outpatient and ward staff, service department personnel
- All costs (fixed or semi-fixed, such as staff employment costs for all individuals directly or peripherally involved in the work while performing measurements, analysing data, supervising; ward occupancy; lighting and heating; or non-fixed such as stationary supplies; pathology tests; equipment; and excess treatment costs).

Supervision

The proposal should name the individual/s who will supervise the research project and intended arrangements for supervision. Details of a steering group should including the role of the steering group, frequency of meetings and monitoring arrangements, and the membership of the group.

Dissemination of findings

The intended route for internal and external publication should be specified. The implications for future practice and patient care should be suggested. The method by which the change could be effected should be discussed.

References

Sources of information referred to in the research protocol should be listed.

For further information, please use the contact details below:

The Prince Charles Hospital	**Royal Brisbane and Women's Hospital**
Research, Ethics and Governance Unit Building 14 The Prince Charles Hospital Rode Road, Chermside, Qld 4032 Email: ResearchTPCH@health.qld.gov.au Phone: (07) 3139 4500	Human Research Ethics Office Level 7, Block 7 Royal Brisbane and Women's Hospital Butterfield Street, Herston, Qld 4029 Email: RBWH-Ethics@health.qld.gov.au Phone: (07) 3646 5490

Date	Version	Custodian

11/2015	1.0	HREC Coordinators, The Prince Charles Hospital and Royal Brisbane and Women's Hospital
11/2017	2.0	HREC Coordinators, The Prince Charles Hospital and Royal Brisbane and Women's Hospital