**Writing your protocol – The Basics**

**1) Introduction**

A research protocol is essentially a detailed set of activities for your proposed project, supported by evidence from other research and from your preliminary investigations. It provides valuable evidence of accurate planning, a practical timetable and guide to your research activities and illustrates what you are trying to achieve.

**2) Structure of the protocol**

1. **Title**
* Should be concise and descriptive.
* Should include the protocol identifying number and date if applicable.
1. **General Information**
* Name and contact details of the Sponsor/funder.
* Name and contact details of the Chief Investigator(s) responsible for conducting the research.
* Name and contact details of all collaborative partners involved in the research including statistician and data management.
1. **Abbreviations and Glossary**
* List of abbreviations and acronyms
1. **Contents Table**
2. **Project Summary**
* This is similar to an abstract and should summarize the central elements of the protocol, what you plan to achieve, the justification for the research and how you are going to do it.
* The summary should consist of a brief background to the project then the concise objective or aim, followed by a brief outline describing participant population, interventions, methods, time frame, outcome measures and proposed analysis.
* The summary should be a stand-alone, short synopsis (300 words) and should not refer the reader to points described later in the body of the protocol.
1. **Rationale and Background**
* Here you must formulate your research question clearly; you should have an answerable question that is clear and sufficiently well-defined/focused for you to deliver the research implied within an appropriate time frame.
* The rationale should explain the reasons for conducting the research in light of current knowledge. Here you must detail the background and context of your proposed research. It should answer the question of why and what: why the research needs to be done and what will be its relevance.
* This should be followed by a brief summary of the most relevant studies and published literature that support your research idea.
* Consider where there are gaps in existing literature - You must make a convincing case as to why your research would create valuable and useful knowledge and the potential impact of your study findings.
* The background should not be exhaustive, but should give the reader a clear idea of the research question and how it will benefit science and your target population.
1. **Study Aims and Objectives**
* The study aim is a broad statement of what the project proposes to accomplish.
* Objectives should be simple, concise and specific.
* After statement of the primary objective, secondary and exploratory objectives may be mentioned at this point.
1. **Study Design**
* Type of study - What study design is most appropriate to answer your particular research question?
* Setting and site selection– Where will the research take place? Is this a single site study or multi-centre? How will you choose sites?
* Research population – Who are your sample population? What is your sample size? Why have they been chosen? Include participant identification and recruitment procedures and justification of sample size.
* Inclusion/exclusion criteria.
* Withdrawal of patients including participant retention strategies.
* Co-enrolment guidelines (when participants are recruited to more than one study).
* Duration of the study – Define clear start and end dates. Is there any eventuality in which the data collection period might be extended?
1. **Methodology**
* This section should include detailed information on all methods of assessment or measurement, including study interventions, proposed procedures, observations and investigations.
* It should clearly state what data will be collected, how, when and why it will be collected and by whom.
* If your project is multi-centre methodology should be standardized and clearly defined
* Interventions should be described in detail including a description of the drug/device/treatment/intervention that is being tested including dose and timing and method of administration e.g. who is going to deliver them and how.
* All necessary safeguards and risks should be made clear including the methods by which the intervention will be monitored.
* Procedures in a research study could mean sample collection, vision testing, radiology or the administering of questionnaires.
* Screening procedures and randomization - Some studies require a random allocation of patients to different groups or interventions. The process for randomisation and blinding in the case of randomised controlled trials should be documented including a description of stopping rules for individuals and code breaking procedures and conditions.
* A graphic outline of the study design and procedures using a flow diagram or table should be provided. This should include the timing of assessments and all observations and study procedures.
1. **Safety Considerations**
* The safety of research participants is foremost. Safety aspects of the study should always be kept in mind and information should be provided in the protocol on how the safety of research participants will be ensured. Think carefully about safety considerations in respect of patients. ***It is useful to remember that even administering a research questionnaire can have adverse effects on individuals****.*
* Safety documentation should include procedures for monitoring, recording and reporting adverse events and their follow-up; how will adverse events be identified and acted upon?
* What are the processes for risk limitation?
* How will you maintain the confidentiality and anonymity of patient data?
* What are the investigator/institution responsibilities with regard to safety reporting?
* Consult appropriate ethical guidelines and ask yourself how/whether your project follows these. ***Ethical approval will be obtained from an NHS Research Ethics Committee.***
1. **Follow-up and Study Closure**
* Provide a detailed flowchart or assessment schedule as part of the protocol.
* The research protocol must give a clear indication of what follow up will be provided to the research participants, for how long and how often.
* What procedures are to be followed when patients are “lost to follow up”
* Define the formal start and end dates of the study, how will study closure be reported and describe the procedures in place for the archiving of study documents.
1. **Data Management and Statistical Analysis**
* The protocol should provide information on how the data will be managed, including data handling and storing, monitoring and verification.
* The statistical methods proposed for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study, level of significance to be used and procedures for accounting for any missing data etc.
* Highlight the reason, procedure and timeline for interim analysis if required.
* For projects involving qualitative approaches, specify in sufficient detail how the data will be analysed.
* Formulate a study-monitoring plan – how often will the study be monitored? This will depend on your risk assessment and if your study is classed as high or low risk
1. **Quality Assurance**
* The protocol should describe the quality control and quality assurance procedures for the conduct of the study, including regulatory authorities and Good Clinical Practice (GCP), any external committees overseeing the study such as Study Steering Groups or Data Monitoring Committees (DMC), and follow up by clinical trial monitors and data management.
1. **Dissemination of Results and Publication Policy**
* You may already have considered what sorts of things might be publishable and where you would like them to appear
* The protocol should specify not only dissemination of results in the scientific media, but also to the community and/or the participants, and consider dissemination to the policy makers where relevant.
* Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications.
1. **Finance**
* The budget section should stipulate who is funding the project and should contain a detailed breakdown of direct and indirect costs per item along with a justification for each item.
* The payment breakdown per patient is covered in detail in the HRA Organisation Information Document and Schedule of Events (SoECAT) but can also be listed in the appendices.
1. **Insurance and Indemnity**
* If not addressed in a separate agreement or covered by an overarching NHS Indemnity Policy then any additional insurance policies can be detailed here.
1. **Links to Other Projects (if applicable)**
2. **References**
* Include full references of all your cited works.
1. **Appendices**
* Include paper versions of the tests/questionnaires you are using.
* If you are using computerized versions provide a verbal description and a link.
* You should also append participant information sheets and consent forms, GP letter and consent to contact forms and any advertising materials.
* List of study roles and responsibilities if applicable.