

Recommended format for a Research Protocol

Project summary

Like the abstract of a research paper, the project summary, should be no more than 300 words and at the most a page long (font size 12, single spacing). Provided preferably on a separate page, it should summarize all the central elements of the protocol, for example the rationale, objectives, methods, populations, time frame, and expected outcomes. It should stand on its own, and not refer the reader to points in the project description.

General information

- Protocol title, protocol identifying number (if any), and date.
- Name and address of the sponsor/funder.
- Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each.
- Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research

Rationale & background information

The Rationale specifies the reasons for conducting the research in light of current knowledge. It should include a well documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions. It is the equivalent to the introduction in a research paper and it puts the proposal in context. It should answer the question of why and what: why the research needs to be done and what will be its relevance. The magnitude, frequency, affected geographical areas, ethnic and gender considerations, etc of the problem should be followed by a brief description of the most relevant studies published on the subject.

References (of literature cited in preceding sections)

References can also be listed at the end of Part 1.

Study goals and objectives

Goals are broad statements of what the proposal hopes to accomplish. They create a setting for the proposal. Specific objectives are statements of the research question(s). Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done). After statement of the primary objective, secondary objectives may be mentioned.

Study Design

The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The design of the study should include information on the type of study, the research population or the sampling frame, and who can take part (e.g. inclusion and exclusion criteria, withdrawal criteria etc.), and the expected duration of the study (The same study can be described in several ways, and as complete a description of the study as possible should be provided. For example, a study may be described as being a basic science research, epidemiologic or social science research, it may also be described as observational or

interventional; if observational, it may be either descriptive or analytic, if analytic it could either be cross-sectional or longitudinal etc. If experimental, it may be described as a controlled or a non controlled study.

Methodology

The methodology section is the most important part of the protocol. It should include detailed information on the interventions to be made, procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. If multiple sites are engaged in a specified protocol, methodology should be standardized and clearly defined.

Interventions should be described in detail, including a description of the drug/device/vaccine that is being tested. Interventions could also be in the realm of social sciences for example providing training or information to groups of individuals.

Procedures could be biomedical (collection of blood or sputum samples to develop a diagnostic test), or in the realm of social sciences (doing a questionnaire survey, carrying out a focus group discussion as part of formative research, observation of the participant's environment, etc.).

Standardized and/or documented procedures/techniques should be described and bibliographic references, if not provided earlier should be provided. Instruments which are to be used to collect information (questionnaires, FGD guides, observation recording form, case report forms etc.) must also be provided.

In the case of a randomized controlled trial additional information on the process of randomization and blinding, description of stopping rules for individuals, for part of the study or entire study, the procedures and conditions for breaking the codes etc. should also be described. A graphic outline of the study design and procedures using a flow diagram must be provided. This should include the timing of assessments.

Safety Considerations

The safety of research participants is foremost. Safety aspects of the research should always be kept in mind and information provided in the protocol on how the safety of research participants will be ensured. This can include procedures for recording and reporting adverse events and their follow-up, for example. It is useful to remember that even administering a research questionnaire can have adverse effects on individuals.

Follow-Up

The research protocol must give a clear indication of what follow up will be provided to the research participants and for how long. This may include a follow up, especially for adverse events, even after data collection for the research study is completed.

Data Management and Statistical Analysis

The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The statistical methods proposed to be used 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, procedures for accounting for any missing or spurious data etc. For projects involving qualitative approaches, specify in sufficient detail how the data will be analysed.

Quality Assurance

The protocol should describe the quality control and quality assurance system for the conduct of the study, including GCP, follow up by clinical monitors, DSMB, data management etc.

Expected Outcomes of the Study

The protocol should indicate how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect health care, health systems, or health policies.

Dissemination of Results and Publication Policy

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, etc.

Duration of the Project

The protocol should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken.

Problems Anticipated

This section should discuss the difficulties that the investigators anticipate in successfully completing their projects within the time frame stipulated and the funding requested. It should also offer possible solutions to deal with these difficulties.

Project Management

This section should describe the role and responsibility of each member of the team

Ethics

The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process), and data ownership.

Informed Consent Forms

The approved version of the protocol must have copies of informed consent forms (ICF), both in English and the local language in which they are going to be administered. However translations

may be carried out after the English language ICF(s) have been approved by the ERC. If the research involves more than one group of individuals, for example healthcare users and healthcare providers, a separate specifically tailored informed consent form must be included for each group. This ensures that each group of participants will get the information they need to make an informed decision. For the same reason, each new intervention also requires a separate informed consent form.

Part 2

Budget

The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item.

Other support for the Project

This section should provide information about the funding received or anticipated for this project from other funding organizations.

Collaboration with other scientists or research institutions

Links to other projects

Curriculum Vitae of investigators

The CV of the Principal investigator and each co-investigator should be provided. In general each CV should not be more than one page, unless a complete CV is specifically requested for.

Other research activities of the investigators

The Principal investigator should list all current research projects that he/she is involved in, the source of funding of those projects, the duration of those projects and the percentage of time spent on each.

Financing and Insurance

Financing and insurance if not addressed in a separate agreement and where relevant should be described.