

Guidance Notes for Completion of Research Protocol

Use these notes to help you complete the BSGDS proforma.

- The areas correspond to those on the application form.
- ALL questions must be answered.
- If a question is not applicable, **please explain why it is not applicable, do not simply enter N/A.**
- Answers should be in typescript.
- The proforma is available via the FGDP(UK) website.

1. Overview of your project.

State the title of the project and the question that needs to be answered. Outline the hypothesis the research is designed to test, aims and practical benefits. Give a brief account of any relevant research/pilot studies previously conducted in this area and explain what your study will contribute. Please ensure this section is comprehensible to non-specialist and lay members of the Committee. Please state any statistical guidance you received with the project. For example, are you sure that the numbers you intend to recruit are sufficient for statistical significance? List the results of literature searches with references. Give details of your null hypothesis or explain why you do not have one.

2. The study design.

Describe the type of study, research methodology to be employed, how the research intervention differs from usual practice, inclusion/exclusion criteria, collection and analysis of data, anticipated results. All observations and findings should be verifiable. Provide details of where the research will take place and the costs involved. Also provide a timetable for the duration of the project and how you intend to disseminate the results.

3. Participants.

Describe the type of participants, for example, patients or recruited volunteers. State any benefits or hazards this project will have for the participants. Indicate how they will be recruited, ages and numbers involved. State whether you have sought ethical approval and whether or not you intend to use a placebo. Detail how you will obtain consent and any payment/incentives that are to be used with regard to the participants. To enable participants to give informed consent, written and oral information should be presented in terms easily comprehensible to lay persons, please enclose copies. If you plan to advertise for volunteers in dental practices or approach dentists, please enclose copies of the advertisement along with any draft letters, questionnaires and the consent form.