PROTOCOL OUTLINE

The following is intended as a guide to help write your protocol – the level of detail required will depend on the type of research you are doing and it may not be necessary to include all sections.

	Content
1	**Project details** 1. Project title – the title should be brief but informative. It is important that it is clear and easy to understand and describes what your proposed research is. 2. Protocol version number and date
2	**Research question**: this should be clearly defined and answerable
3	**Abstract**
4	**Aim of the study:** State the objectives and purpose of the study. Is the research **original** or is it intended to fulfil taught course requirements? Will it make a useful contribution to the field? Student projects, specify: Undergraduate/ Masters by dissertation/ Masters by thesis/ Doctoral
5	**Background**: clinical and scientific justification To include evidence of whether the research: 1. Is of clinical significance 2. Has previously been undertaken, and whether all sources of evidence, especially systematic reviews, have been fully considered 3. Fits in with the strategy of the directorate to which it belongs
6	**Plan of the investigation** 1. Methodology 2. Design: type of study design and justification 3. Setting 4. Participants 5. Sample size: Power of the study. Viability and representativeness of the sample 6. Recruitment: method used to identify, approach, recruit and consent 7. Outcome measure(s) 8. Analysis including statistical methods, where appropriate 9. Data storage and protection 10. Intervention: flow chart indicating participant's involvement throughout the course of the study 11. Safety assessment: safety parameters and adverse event reporting for interventional studies 12. Subject withdrawal (withdrawal criteria and procedures), breaking the blind (circumstances and procedures) and trial stopping/discontinuation rules* 13. Justification of use of screening tools/questionnaires etc. Include data collection tools, screening tools, questionnaires and Case Report Forms 14. Quality control: Monitoring and audit procedures* 15. Project plan with timescale and clearly delineated milestones
7	**Statistical opinion:** recommended for quantitative studies; include evidence and discuss as applicable
8	**Project management:** describe what arrangements have been made
9	**Expertise:** of the researcher and associated team
10	**Ethical issues:** description of issues and methods used to address them; include Participant Information Sheet(s) and Consent Form(s) where applicable
11	**Patient and Public Involvement:** describe any service user/carer involvement during study design; justify if none

12	**Dissemination:** methods for dissemination of the research, including plans to inform participants of the results e.g. internal report, conference/seminar presentations, peer reviewed journals
13	**Taking the work forward:** describe the strategy for development if the research project is productive
14	**Intellectual Property:** describe what arrangements have been made (if applicable)
15	**Costing schedule:** specify the costs associated with the project (if applicable)
16	**Funding arrangements:** If there is no funding associated with the project, explain the agreement with the host research team/ clinical area for the use of resources.
17	**References**
18	**Curriculum Vitae:** include brief CVs for investigators
19	**Other:** Contact details*

* Sections marked with an asterisk are required for Clinical Trials of Investigational Medicinal Products (CTIMPs) only