STH RESEARCH DEPARTMENT

PROTOCOL OUTLINE Template[1]

	Content
1	**Project details** 1. Investigator details 2. Sponsor details 3. Project title 4. STH Project Reference number 5. Protocol version number and date 6. Signatures of Chief Investigator and Sponsor* 7. EUDRACT & CTA Number* 8. Phase of Trial* 9. STH Directorate affiliation
2	**Research question**: 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. Intervention: flow chart indicating participant's involvement throughout the course of the study 10. Safety assessment: safety parameters and adverse event reporting for interventional studies 11. Subject withdrawal (withdrawal criteria and procedures), breaking the blind (circumstances and procedures) and trial stopping/discontinuation rules* 12. Justification of use of screening tools/questionnaires, etc: include data collection tools, eg screening tools, questionnaires and Case Report Forms 13. Quality control: Monitoring and audit procedures* 14. 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 Subject Information Sheet(s) and Consent Form(s) where applicable
11	**Service users:** involvement during study design
12	**Dissemination:** methods for dissemination of the research
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
15	**Costing schedule:** specify the costs associated with the project
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 CV
19	**Other:** Contact details*

[1] For additional guidance, see 'Guidance for writing protocols for the independent scientific review process': http://www.sheffieldclinicalresearch.org/clientfiles/File/Protocol%20guidance%20notes_v1%205%2020nov12.pdf

* Sections marked with an asterisk are required for CTIMPs only