STH CLINICAL RESEARCH & INNOVATION OFFICE

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**: Justification of research, including scientific, clinical and involvement of public in development of the research question 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. Is relevant and likely to benefit patients and the public 4. 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, involvement of the public in determining acceptability to participants 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 participants with description of how barriers to participation for under-represented groups will be addressed, and how any public involvement may have influenced approach of participants and informed consent process 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. Participant 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 including involvement of people with relevant experience as patients/members of public who have contributed to ensuring study respects rights, safety, dignity and wellbeing of participants; include Participant Information Sheet(s) and Consent Form(s) where applicable
11	**Service users/public involvement: description of** involvement during all aspects of study. If no service user involvement, you will need to justify why this is the case (the HRA expect it in all types of health research)

12	**Dissemination:** plans for sharing findings of the research with: ● Participants ● Wider public ● Researchers & health professionals
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	**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.
16	**References**
17	**Other:** Contact details*

[1] For additional guidance, see 'Guidance for writing protocols for the independent scientific review process': http://www.sheffieldclinicalresearch.org/for-researchers/useful-documents/forms-and-guidance/

* Sections marked with an asterisk are required for CTIMPs only