**Guidance on content for a study protocol (maximum of 3000 words)**

Title

Protocol version number and date

Funder name (if applicable)

Research team/ key contributors: Names, contact details, roles

Background and Rationale

Research question/ aims

Study design

Study setting

Participants, recruitment and sampling

Outcome measures (if applicable)

Methods and procedures/ methodological approach

Data analysis

Data management

Monitoring and management of the project (time plan for project)

Ethical and regulatory considerations

Patient and public involvement (if applicable)

Dissemination

References

Appendix