<Study Title>

**Terms of Reference for the Trial Steering Committee (TSC)**

1. To monitor and supervise the progress of the <Short title> study (Full Title);

2. To ensure adherence to the <Short title> Protocol and to the requirements of the Department of Health’s Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice, and to the principle that the rights, safety and well-being of the trial participants are the most important considerations and should prevail over the interests of science and society;

3. To review at regular intervals new information of relevance to the research question (e.g. other

related trials);

4. To consider the recommendations of the Data Monitoring Committee;

5. To agree proposals for substantial protocol amendments (process to be developed by the Trial Management Group) and provide advice to the Trial Sponsor (Sponsor Name) and Trial Funder (Funder Name) regarding approvals of such amendments;

6. In the light of 1, 2, 3 and 4 to advise the Chief Investigator (CI Name), Trial Sponsor, Trial Funder and other relevant parties on all appropriate aspects of the trial;

7. In the light of 1, 2, 3 and 4 to inform the Trial Funder on the progress of the trial;

8. In the light of 1, 2, 3 and 4 to provide advice to the investigators on all aspects of the trial;

9. To advise the Trial Management Group and the Trial Funder on publicity and the presentation of all aspects of the trial;

10. Type and Frequency of meetings – to be agreed at the first TSC meeting;

11. Voting rights – to be agreed at the first TSC meeting.