UNIVERSITY OF LEICESTER

Appendix 1

Data Safety Monitoring Committee Charter for University of Leicester Sponsored Research

1. INTRODUCTION

1.1 Name (& Sponsor's ID) of trial

1.2 Objectives of trial, including interventions being investigated

1.3 Outline of scope of charter

2. ROLES AND RESPONSIBILITIES

2.1 A broad statement of the aims of the committee

2.2 Terms of reference

2.3 Specific roles of DSMC

3. BEFORE OR EARLY IN THE TRIAL

3.1 Whether the DSMC will have input into the protocol

3.2 Whether the DSMC will meet before the start of the trial

3.3 Any issues specific to the disease under study

3.4 Any specific regulatory issues

3.5 Any other issues specific to the treatment under study

3.6 Whether members of the DSMC will have a contract

4. COMPOSITION

4.1 Membership and size of the DSMC The Chair, how they are chosen, and the chairs role (Likewise, if relevant for the vice-Chairman)

4.2 The responsibilities of the DSMC statistician

4.3 The responsibilities of the trial statistician

4.4 The responsibilities of the trials unit team

4.5 The responsibilities of the Chief Investigator and other members of the Trial Management Group (TMG)

5. RELATIONSHIPS

5.1 Relationships with Chief Investigators, other trial committees (e.g. Trial Steering Committee)

5.2 Clarification of whether the DSMC is advisory (make recommendations) or executive (make decisions)

5.3 Payments to DSMC members

5.4 The need for DSMC members to disclose information about any competing interests

6. ORGANISATION OF MEETINGS

6.1 Expected frequency of DSMC meetings

6.2 Whether meetings will be face-to-face or by teleconference

6.3 How DSMC meetings will be organised, especially regarding open and closed sessions, including who will be present in each session

7. TRIAL DOCUMENTATION AND PROCEDURES TO ENSURE CONFIDENTIALITY AND PROPER COMMUNICATION

7.1 Intended content of material to be available in open sessions

7.2 Intended content of material to be available in closed sessions

7.3 Whether or not the DSMC will be blinded to the treatment allocation

7.4 The people who will see the accumulating data and interim analysis

7.5 Responsibility for identifying and circulating external evidence (e.g. from other trials/ systematic reviews)

7.6 To whom the DSMC will communicate the decisions/ recommendations that are reached

7.7 Whether reports to the DSMC be available before the meeting or only at/during the meeting

7.8 What will happen to the confidential papers after the meeting?

8. DECISION MAKING

8.1 What decisions/recommendations will be open to the DSMC

8.2 The role of formal statistical methods, specifically which methods will be used and whether they will be used as guidelines or rules

8.3 How decisions or recommendations will be reached within the DSMC

8.4 When the DSMC is quorate for decision-making

8.5 Can DSMC members who cannot attend the meeting input

8.6 What happens to members who do not attend meetings

8.7 Whether different weight will be given to different end points (e.g. Safety/efficacy)

8.8 Any specific issues relating to the trial design that might influence the proceedings e.g. cluster trials, equivalence trials, multi-arm trials

9. REPORTING

9.1 To whom will the DSMC report their recommendations/decisions, and in what form

9.2 Whether minutes of the meetings be made, if so by whom, and where will they be kept

9.3 What will be done if there is a disagreement between the DSMC and the body to which it reports

10. AFTER THE TRIAL - Publication of results

10.1 The information about the DSMC that will be included in published reports

10.2 Whether the DSMC will have the opportunity to approve publications especially with respect to reporting of any DSMC recommendations regarding termination of a trial

10.3 Any constraints on DSMC members divulging information about their delivery after the trial has been published.