UNIVERSITY OF LEICESTER, UNIVERSITY OF LOUGHBOROUGH
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1028 UoL

Convening a Data Safety Monitoring Committee for Research Sponsored by the University of Leicester (UoL)

Version 3, November 2016

OFFICE BASE

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1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the process to be adopted when convening a Data Safety Monitoring Committee / Board for research studies sponsored by the University of Leicester (UoL).

The outcome is that, where required, a Data Safety Monitoring Committee / Board (DSMC/B) for research sponsored by UoL are managed and convened using a consistent process.

2. SCOPE

This SOP applies to all research studies, sponsored by the University of Leicester, where a DSMC/B is required.

3. DEFINITION

A Data Safety Monitoring Committee (DSMC) is a group of people, independent of the trial team, who review accumulating data and advise the Sponsor (directly or indirectly) on the continuing and future management of a research study. A DSMC mainly review safety and efficacy data, but where appropriate may also be asked to review quality and compliance data.

The DSMC is usually 'unblinded' and therefore is privy to interim comparisons by arm. They often see data in a format that is not normally widely shared beyond the DSMC, or a statistical analysis team.

4. WHICH RESEARCH STUDIES REQUIRE DATA SAFETY MONITORING COMMITTEES?

The decision about whether or not a DSMC is required will depend on the complexity, duration and end-points of the trial. The decision will be made in collaboration with the Chief Investigator, and will be considered as part of the Sponsor risk assessment. There may also be a requirement from the funding award body as a condition of funding.

UoL as Sponsor would expect that a DSMC be established for research studies involving:

- subjects with life-threatening illnesses
- vulnerable populations and/or with significant potential risk of harm, or
- unknown or uncertain risks

DSMCs may be appropriate for all types of randomised research studies, including those not using Investigational Medicinal Products e.g. research studies of surgical interventions or radiotherapy.

Where a discussion about whether a DSMC is required occurs, the evidence of the discussion must always be recorded in the Trial Master File (TMF). Subsequent plans to establish a

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DSMC or put other formal safety monitoring arrangements in place must be described in the Protocol.

5. WHO SITS ON A DATA SAFETY MONITORING COMMITTEE?

DSMC members are generally experienced trialists and it is recommended that at least one member of a committee has served previously on a DSMC. A formal DSMC usually consists of three (3) or more people comprising clinicians and at least one statistician.

6. HOW IS THE ROLE OF THE DATA SAFETY MONITORING COMMITTEE DESCRIBED?

The role and function of the DSMC should be described in writing before the DSMC reviews any trial data. This can be described in a Charter which covers the membership, roles and remit, permissible recommendations, frequency and organisation of meetings, how decisions are reached, whether they are advisory or executive and who they report to (how and when).

A suggested template charter is provided in Appendix 1.

7. INDEPENDENCE OF THE DATA SAFETY MONITORING COMMITTEE

The DSMC members must ensure that any potential competing interests are declared at the outset and any new competing interests recorded in the record of each DSMC Meeting.

DSMC meetings to review unblinded data will be “closed” meetings at which the Sponsor and trial team will not be present. The DSMC may also hold “open” meetings with the Sponsor to discuss conclusions and recommendations.

8. REPORTING RESPONSIBILITIES

It is the role of the DSMC to make recommendations to the Sponsor on trial conduct, such as the need to amend the protocol or to terminate the trial early. This is normally done directly with the Sponsor, unless a Trial Steering Committee (TSC) has also been set up, in which case the DSMC may report to the TSC.

It is the responsibility of the Sponsor to communicate DSMC recommendations to the competent authority and REC in an appropriate manner. If such recommendations require implementation of an urgent safety measure it must be ensured that this is reported to the competent authority and REC in the required timeframe. The Sponsor should notify the REC of any recommendations made by the DSMC and provide summary reports where appropriate. It is not necessary for the REC to see minutes of DSMC meetings.

Similarly it is important that any outputs from the DSMC are clearly documented to ensure that the data used to make decisions are robust and the decisions themselves are documented and retained. It is advised that the documentation verifies who prepared and checked any reports and listings - this being particularly important if unblinded reviews are taking place to provide evidence that the trial team remained blinded.

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9. RESPONSIBILITIES

Responsibility	Undertaken by	Activity
Sponsor	Research Governance Manager or their delegate	Discuss with CI requirement for a DSMC
Chief Investigator	Chief Investigator	Coordinate with Sponsor the set-up of a DSMC
Chief Investigator and Sponsor	Chief Investigator	Ensure DSMC charter is completed and Chair appointed
DSMC	Chair	Ensure Sponsor receives copies of open DSMC Meetings
Sponsor	Clinical Trial Pharmacists	Ensure that appropriate regulatory authorities are notified of any changes required as a result of DSMC discussions or Urgent Safety Measures.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Development and approval Record for this document

Author/Lead Officer:	Joanne Thompson Wendy Gamble (Amendments)
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Approved by:	Professor Nigel Brunskill 
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