

Research & Development (R&D) Directorate	
Standard Operating Procedure: Sponsorship	
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Signature:

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Date: 24/10/07

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1.0 Background

The Department of Health's Research Governance Framework¹ requires that all health related research has a formal sponsor.

1. The sponsor is the individual or institution that takes formal responsibility for the initiation, management and financing (or arranging the financing) of the study. The sponsor satisfies itself that the study meets the relevant standards and ensures that arrangements are put and kept in place for management, monitoring and reporting.

2. Sponsors can formally delegate one or more of the elements of sponsorship, e.g. to the Chief Investigator, but the sponsor remains accountable for all aspects of sponsorship, whether delegated or not.

3. Where an investigator undertakes a study on behalf of his/her employing institution and the funding body is unwilling to act as the sponsor, the employing institution may act as a sponsor.

4. The University of Manchester will accept the role of sponsor for <Name of Study> led by <Name of CI>. However, the duty of care remains the responsibility of the host institution, irrespective of which organisation accepts the role of sponsor.

5. The activities of the sponsor can be delegated as follows:

Responsibilities of Investigators	C.I	P.I
Obtain a favourable opinion from a Research Ethics Committee (MREC)	√	
Obtain Management (R&D/ Research Governance) approval	√	√
Responsibility to maintain a Master File ¹ containing essential trial documents and to make the file available for inspection if required by the sponsor	√	
Responsibility to apply to the Research Ethics Committee (& relevant stakeholders) for any significant amendments to the approved protocol	√	
Responsibility to report all Serious Adverse Events to the Sponsor ² , ethics committee and other relevant stakeholders ³ within the agreed timeframes	√	
Responsibility to notify all stakeholders of the end of the trial (including if terminated early)	√	
Responsibility to ensure that PIs conduct the study in accordance with Good Clinical Practice, the DH Research Governance Framework and the laws and statutes, and any local requirements as may be specified by their host institution	√	
Responsibility for putting and keeping in place arrangements to conduct the study according to Good Clinical Practice, the DH Research Governance Framework and the laws and statutes that relate to the study	√	√
Responsibility to ensure that all members of the study team are able by knowledge, training and experience to undertake the roles assigned to them		√
Responsibility to maintain a Site File containing, the essential documents and to make the site file available for inspection if requested by the CI (on behalf of the Sponsor)		√
Responsibility to conduct the study in accordance with the agreed research protocol <i>except where necessary to eliminate an immediate hazard(s)</i> - These circumstances must be reported to the CI who will be responsible for reporting within the sponsor organisation and to the research ethics committee		√
Responsibility to use all reasonable efforts to ensure that the data collected and reported are accurate, complete and identifiable at source; and that record keeping and data transfer procedures adhere to the Data Protection Act 1998	√	√
Responsibility for monitoring the study in accordance with the arrangements outlined in the submission to the Sponsor	√	√
Responsibility to supply documentation and reports as deemed necessary by the Sponsor to fulfil its obligations	√	√
Responsibility to cooperate with audits undertaken by the host institution or the Sponsor as required	√	√
Responsibility to assist investigations into any alleged research misconduct undertaken by or on behalf of the Sponsor	√	√
Responsibility to make the necessary provision for archiving essential documents	√	√

2.0 Procedure

The researcher (PI) should contact the Trust R&D Lead at the early stages of project initiation to obtain confirmation of sponsorship. An individual should not be named as a sponsor. The sponsor should be identified at the point of R&D project registration (and prior to submission to the Ethics Committee), and entered on the database accordingly. In general the following summarises sponsorship allocation:

¹ All essential documents e.g. protocol, PIS & consent form templates should be version numbered/ dated, to ensure most recent is being used and pages are numbered e.g. page 2 of 3

² The PI: Reporting of Adverse Events locally within the host organisation (e.g. NHS Trust). The CI: Reporting of Adverse Events to The University of Manchester REC & MREC.

³ The CI to take responsibility for informing of AE's to all other PIs/ sites

- | | |
|-------------------------------|---|
| a) Student Research Project | - University |
| b) Led by University employee | - Non- CTIMP University |
| c) Led by University employee | -CTIMP Co-sponsorship – University/ PCT |
| d) Led by PCT employee | - PCT |
| e) Led by Commercial Company | - Company |
| f) Led by SRFT employee | - SRFT |

For externally funded commercial projects the external funder will usually act as Sponsor.

Where the study is a clinical trial of an investigational medicinal product the researcher should contact the R&D Lead at the early stages of project initiation to obtain confirmation of sponsorship. An individual should not be named as a sponsor.

3. Other related procedures, policies, legislation or guidance

- (i) DOH 2005 Research Governance Framework for Health and Social Care 2nd Edition
- (ii) European Agency for the evaluation of Medical Products Notes for Guidance on Good Practice 1997

4. Glossary

Standard Operating Procedure (SOP)

Chief Investigator (CI)

Principle Investigator (PI)

5. Appendices (File Attachments)

Sponsors Responsibilities

Sponsors Letter