Sponsor's Responsibilities

This checklist summarises the responsibilities of MRC Units as Sponsor (defined below, as stated in the Health Departments' Research Governance Frameworks (RGFs)). It should not be used for trials that test the safety or efficacy of an Investigational Medicinal Product (for these trials please see Sponsorship within the Clinical Trials Toolkit).

This checklist is for all Units that conduct research involving people as participants, their tissues or data. Although the RGF does not apply to studies which do not involve NHS patients or resources, these Sponsorship responsibilities reflect good practice in all studies involving human participants, and as such this checklist is relevant to all units that work with people as participants in their research.

We have tried to make this list of Sponsor's responsibilities more accessible and relevant for MRC units, so the wording differs from that in the Health Departments' RGFs although the principles are consistent. We have provided links to other documents which better illustrate how some of the requirements can be met.

What is a Sponsor?

The RGFs state that a Sponsor is an "individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study".

MRC's policy on sponsorship has been defined on the MRC web pages. For MRC units these sponsorship responsibilities are delegated to the Director. MRC policy states that information should be held centrally on all relevant research being undertaken within the Unit.

It is the responsibility of MRC units as a Sponsor and an employing organisation to ensure that arrangements are in place for the following (Many from this list of responsibilities are likely to be delegated to the CI and Research Team; these have been listed at the end but it is worth noting that it is ultimately the Sponsor's responsibility to ensure that these requirements are met):

PLANNING A STUDY

1. Resources

   a. The necessary resources (including finances; expertise; training and professional development; experience and qualifications of personnel) are in place to deliver high quality, value for money research which produces accurate data and allows appropriate data analysis.

   If a multi-centre study, this is normally delegated to the PI of each centre. It is worth noting that the Sponsor has ultimate responsibility to ensure that this is in place for all centres.

b. All study sites have high standards of Health and Safety and, where applicable, follow guidelines for Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Clinical Practice (GCP).

c. Systems are in place to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of research, so that it is possible to deter, detect and deal with fraud or scientific misconduct.

d. Intellectual Property
Agreements are in place for the identification, protection and exploitation of Intellectual Property (IP).

TIP: For MRC units, further information on exploiting commercial applications can be obtained from MRC Technology.

2. Division of Responsibilities

The division of responsibilities within a project is agreed, documented, understood, and duplication avoided. This is particularly important in student projects and collaborations with external organisations.
i.e. All individuals/parties understand their role within a study. It is especially important that if there is more than one Sponsor, division of responsibilities are agreed and documented.

3. Protocol Development and Peer Review

a. The research proposal respects the dignity, rights, safety and wellbeing of participants.

b. Independent scientific peer review has demonstrated the work to be worthwhile, of high scientific value and good value for money.

TIP: For studies that form part of an MRC unit's core programme of work, this process will have been carried out at Quinquennial Review (QQR). However, individual projects may require additional peer review.

c. All existing sources of evidence, especially systematic reviews, have been considered before undertaking research to ensure the quality and relevance of the research proposal.

d. Appropriate arrangements are in place for obtaining informed consent from those who cannot give consent themselves.

e. The diversity within society is valued, so where necessary, special arrangements should be made to include in research those who do not have English as a first language or have a disability. *e.g. providing an interpreter or making the information available in Braille.*

f. Study participants or their representative groups should be involved, wherever possible, in the design, conduct, analysis and reporting of research.

TIP: The group People In Research can provide information on this.

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g. Compensation
Indemnity arrangements are in place in the event of harm to a research participant.
For all MRC studies, please visit the RSC Sponsorship & indemnity page for more information.

4. Management and Monitoring

a. Each study should be appropriately managed and monitored according to the risks inherent within the study, and this should be documented at the protocol development stage.

TIP: One way to achieve this is by documenting a simple risk assessment for each study and an associated management and monitoring plan. Further information is available on the Data and Tissues Tool Kit, MRC Guidance on managing risk in public health research.

b. All projects are subject to internal and external monitoring. Units should allow access to study team, documents, devices and equipment for monitoring purposes. This should be made explicit in participant information sheets.

c. Essential documents are maintained in a legible condition and can be retrieved promptly. As a minimum these include the following:

- Protocol and amendments, including management and monitoring plan;
- Participant information sheets and consent forms;
- Submissions to ethics and regulatory authorities, and letters of approvals;
- Study-specific Standard Operating Procedures.

5. Legislation and Good Practice Guidance

The study is managed and conducted according to all relevant local, national and international guidelines, regulations and legislation governing research, including in the UK but not limited to the following:

a. Data Protection Act, 1998
e.g. Participant privacy is protected by ensuring that all research data are held securely (both physical and electronic security), in order to minimise any potential breaches in confidentiality.
Members of the study team working with identifiable participant information should be reminded of their responsibility in terms of maintaining confidentiality.

TIP: One way of achieving this may be through asking each member of staff to sign a confidentiality statement.

b. Human Tissue Act, 2004
c. Human Tissue (Scotland) Act, 2006
d. Mental Capacity Act, 2005
e. Adults with Incapacity (Scotland) Act, 2000
f. Principles of Good Clinical Practice or ICH GCP, if industry partnership.
g. Other applicable guidance from MRC Research Policy & Ethics.

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6. Approvals

a. A Research Ethics Committee has given favourable opinion (ethical approval).

b. NHS R&D permission is in place if using NHS patients or resources.

c. Other regulatory approvals are in place as necessary.
e.g. (For England, Wales and Northern Ireland only). If storing human tissues samples for potential research projects that are not covered by an ethical approval (or where ethical approval is not pending) then a licence is required from the Human Tissue Authority.

It is recommended that units have a system of internal monitoring/audit, to ensure that projects have all of the necessary approvals in place before they commence.

DURING A STUDY

7. Conducting the study

a. The study is conducted in accordance with the approved protocol and the terms and conditions of approval by the relevant REC(s) and R&D office(s).

b. Research is conducted to principles of Good Clinical Practice, or ICH GCP if appropriate (e.g. if industry is a partner).

8. Significant developments and adverse incidents

All individuals involved in the study know who to report significant developments or adverse incidents to, and that such new evidence is acted on. Systems are put in place to ensure that lessons are learned to prevent recurrence.

e.g. if a member of the research team becomes aware of any information which might impact on participant safety, they would know who to inform to ensure appropriate action is taken;
or
if new scientific information comes to light that impacts on the design or methodology of the study, appropriate amendments are made to the study protocol and relevant bodies are informed (see 9 also).

9. Study amendments/ modifications

The sponsor should approve any modification to the design of studies, and ensure that arrangements are in place to obtain any necessary ethics, NHS R&D or regulatory approvals, and implement necessary changes.

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10. Reporting Adverse Events

In the event of an untoward medical occurrence an adequate system for reporting, recording and reviewing must be in place and made explicit within the protocol. There are specific requirements for Clinical Trials of Investigational Medicinal Products, please see Safety Reporting within the Clinical Trials Toolkit for more information.

CONCLUDING A STUDY

11. At the end of the study

Arrangements for the conclusion of the study are in place, for example:

- *Ensuring databases are locked prior to analysis;*
- *Notifying the ethics committee and NHS R&D that the study has finished;*
- *Ensuring the collected data will be retained for the appropriate period (see 13 Archiving).*

12. Dissemination

There are appropriate plans for the dissemination of study findings.
e.g. In addition to publication in a peer reviewed journal, which is not always accessible to study participants, participants and members of the public may wish to see a summary of results in another form, perhaps on a website.

13. Archiving

a. Study data are retained for an appropriate period.
e.g. the MRC expects that research records relating to clinical or public health studies are maintained for at least 20 years.

b. Essential documents are retained/archived in suitable conditions and for sufficient periods to allow for audit and inspection by regulatory authorities.

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Many of these responsibilities are typically delegated to Investigators and members of research teams; the following list outlines typical Investigator and team roles:

Roles of Investigators and Research Team

14. Chief Investigators and Principal Investigators

A senior individual must be designated as Chief Investigator (CI) for any research involving the NHS; this person is accountable for the research to their employer and the sponsor. For multi-centre studies in addition to the CI, who takes responsibility for leading the study overall, there will be a lead investigator at each site - the Principal Investigator(s) or PI(s). The CI and/ or PI(s) are likely to be delegated the following:

a. Responsibility for the design, management, co-ordination and reporting of the research; and co-ordinating investigators at other centres if a multi-centre study. The CI can lead or manage others with delegated responsibility for some of these aspects.
b. Ensure that the research team gives priority to dignity, rights, safety and well-being of participants in the study.
c. Each member of the research team is qualified by education, training and experience for their role within the study, and their qualifications are documented.
d. Students and new researchers have adequate supervision.
e. Potential participants or carers are involved in design of the study where possible.
f. All relevant care professionals are informed that their patients are being invited to participate in the research study.

Responsibility for the on-site implementation of Sponsor responsibilities e.g.:

g. Management of all necessary resources.
h. Meeting all legal and ethical requirements.
i. Ethics submission and favourable opinion.
j. Submission to other relevant regulatory bodies and NHS R&D.
k. Registration of Randomised Controlled Trials (e.g. ISRCTN).
l. Submitting for approval and implementing protocol amendments.
m. Reporting progress and findings.
n. Dissemination of findings.
o. Accessible archiving.

Research Team

p. Ensure that research follows the current version of the protocol.
q. Is conducted in line with the principles of Good Clinical Practice.
r. Help healthcare professionals to ensure the delivery of appropriate care.
s. Report adverse incidents, events or drug reactions.
t. Protect the integrity and confidentiality of records and data; and reporting any failures in these respects or suspected misconduct.