

Sponsor's responsibilities under the UK policy framework for health and social care research

This checklist summarises the responsibilities of MRC units / institutes as sponsor (defined below, as stated in the UK policy framework for health and social care research). 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 MRC units / institutes that conduct research involving people as participants, their tissues or data. The UK policy framework for health and social care research applies to studies involving NHS patients or resources. However, the sponsorship responsibilities defined within the framework reflect good practice in all studies involving human participants. Therefore this checklist is relevant to all units / institutes whose research involves people as participants.

We have tried to make these sponsor's responsibilities more accessible and relevant for MRC units / institutes, so the wording differs from the framework although the principles are consistent. We have provided links to other documents which better illustrate how some of these requirements can be met.

What is a sponsor?

The UK policy framework for health and social care research states that a sponsor is an "individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report on a research project".

MRC's policy on sponsorship has been defined on the MRC website. For MRC units / institutes 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 / institute.

It is the responsibility of MRC units / institutes as a sponsor and an employing organisation to ensure that arrangements are in place for the following. (Many of these responsibilities are likely to be delegated to the Chief Investigator and Research Team and are listed at the end of this document. However, it is worth noting that it's ultimately the sponsor's responsibility to ensure that all requirements are met):

PLANNING A STUDY

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. 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.
- c. Intellectual Property
Agreements are in place for the identification, protection and exploitation of Intellectual Property.
TIP: For MRC units / institutes, further information on exploiting commercial applications can be obtained from [lifeArc](#).

Division of Responsibilities

The division of responsibilities within a project are 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, where there is more than one sponsor, that division of responsibilities are agreed and documented.

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 / institute'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. The research proposal or protocol takes into account any relevant systematic reviews, other research evidence and research in progress, to ensure the quality and relevance of the research.
- d. Potential participants should be provided with information in a suitable format which clearly explains what participation in the research would involve. Where consent will be obtained, this information should support any decision-making about taking part.
- e. Study participants, their representative groups and/or the public 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.

BEFORE THE STUDY BEGINS

- a. The sponsor should ensure that the investigators, research team and research sites are suitable.
- b. Indemnity arrangements are in place in the event of harm to a research participant.
For MRC sponsored studies, please visit the [Sponsorship & indemnity](#) page on the MRC website for more information.

- c. Each study should be appropriately managed and monitored according to the risks inherent within the study, and this should be documented. The initial risk assessment should be completed 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](#).

- d. The sponsor should ensure that arrangements are in place to make information about the study publicly available before the research begins.
- e. The study is managed and conducted according to all relevant local, national and international law and good practice guidance. Regulations and law governing research in the UK, include but are not limited to the following:

- Common law duty of confidentiality
e.g. Participant privacy is protected and any disclosure of a participant's confidential information is managed appropriately.
Members of the study team working with identifiable participant information should be aware of their responsibility to maintain confidentiality.
- [Data Protection Act, 1998](#)
- [Human Tissue Act, 2004](#)
- [Human Tissue \(Scotland\) Act, 2006](#)
- [Mental Capacity Act, 2005](#)
- [Adults with Incapacity \(Scotland\) Act, 2000](#)
- Other applicable guidance from [MRC Policies and guidance for researchers](#) (e.g. [MRC good research practice: principles and practice](#), [MRC Ethics Series](#) for guidance on research involving children, adults who cannot consent for themselves, Using information about people in health research, etc.).

Approvals

Sponsors should ensure that the appropriate approvals are in place before the research begins:

- a. Favourable opinion from a Research Ethics Committee (REC), this may be from a University REC or NHS REC. In some cases it must be from an NHS REC (see b and c below).
- b. If using NHS patients or resources
- In England, HRA Approval and individual NHS site agreement is in place.
 - In Wales, Scotland and Northern Ireland, NHS REC and NHS R&D permission is in place.
- c. Other necessary regulatory approvals are in place.
e.g. (For England, Wales and Northern Ireland only). A licence is required from the Human Tissue Authority if storing human tissues samples for research. Unless the research is covered by NHS REC approval (or where NHS REC approval is pending).

It is recommended that units / institutes 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

Conducting the study

- a. The study is conducted in accordance with the approved protocol and the terms and conditions of the relevant approvals.
- b. All projects are subject to internal and external monitoring. Units / institutes should allow access to study team, documents, devices and equipment for monitoring purposes. This should be made clear in participant information sheets.
- c. Key research records or documents are maintained in a legible condition and can be retrieved promptly. As a minimum these would 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.

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 the relevant bodies are informed.

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 approvals, and implement necessary changes.

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 clear 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

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 REC and any other relevant approval bodies that the study has finished;*
- *Ensuring the collected data will be retained for the appropriate period:*
 - For *basic research* – The MRC expects research data and related material to be retained for a minimum of 10 years after the study has been completed.
 - For *population health and clinical studies* – A minimum of 20 years.
- For further guidance on Archiving see [Using information about people in health research](#).

Dissemination

There are appropriate plans for the dissemination of study findings.

e.g. In addition to publication in a peer reviewed journal, participants and members of the public may wish to see a summary of results in another form, perhaps on a website.

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

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:

- Responsibility for the design, management, co-ordination and reporting of the research; and coordinating investigators at other centres if a multi-centre study. The CI can lead or manage others with delegated responsibility for some of these aspects.
- Ensure priority is given to the dignity, rights, safety and well-being of participants in the study.
- Ensure each member of the research team is qualified by education, training and experience for their role within the study, and their qualifications are documented.
- Students and new researchers have adequate supervision.
- Potential participants, carers and/or the public are involved in the design of the study where possible.
- 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.:

- Management of all necessary resources.
- Meeting all legal and ethical requirements.
- Favourable opinion from a Research Ethics Committee and any other relevant approvals.
- Making information about the study publicly available before the research begins.
- Submitting for approval and implementing protocol amendments.
- Reporting progress and findings.
- Dissemination of findings.
- Accessible archiving.

Research Team

- Ensure that the correct version of the protocol is followed.
- Ensure potential participants are provided with information which clearly explains what participation in the research would involve. Where consent will be obtained, this information should support any decision-making about taking part.
- Protect the integrity and confidentiality of records and data; and report any failures in these respects or suspected misconduct.
- Report adverse incidents, events or drug reactions.