

**SPONSORSHIP**

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| **Version** | **Date** | **Reason for Change** |
| 2.0 | 9th June 2020 | Links within the document have been updated, in line with new policies. |

This is a controlled document. The master document is posted on the RKE website:

http://www2.mmu.ac.uk/research/research-governance/

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1. **Background**

All research which falls within the scope of the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) requires a research sponsor. The framework defines the sponsor as “the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project’.

Some funders may also require the allocation of a research sponsor as part of the application process.

1. **Purpose**

This SOP describes the process for obtaining Manchester Metropolitan University (MMU) sponsorship for research projects led by staff from MMU.

1. **Procedure**
	1. **Who should apply for Sponsorship**

It is the responsibility of the Chief Investigator (CI) to request Sponsorship. However, it is recognised that this responsibility may be delegated to another member of the research team with sufficient knowledge of the research activity.

Where the research is being conducted as part of an undergraduate or postgraduate taught degree course, the Academic Supervisor should act as the CI when applying for Sponsorship.

* 1. **When to apply for Sponsorship**

The CI should liaise with the RKE Research Governance Manager as early as possible to discuss Sponsor responsibilities.

Normally the CI would be expected to request Sponsorship once funding for a research project has been confirmed or in the case of student research projects when the Academic Supervisor has approved the study. Sponsorship should be confirmed (‘in principle’ as a minimum) before application to any of the following:

* Host organisation (NHS Trust, Local Health Board, Primary Care Trust, etc);
* NHS REC

In circumstances where the funding body requires confirmation of Sponsorship prior to submission of the funding application, contact the RKE Ethics and Research Governance Manager.

* 1. **How to determine if MMU is the likely sponsor**

MMU should normally act as research sponsor for projects where the CI is employed by (or is a student of) the university, the university is managing the research, and no external staff have been involved in protocol development. Where external staff or organisations are involved in the development or management of the research it may be more appropriate for another organisation to act as sponsor, or to enter into a co-sponsorship arrangement. MMU will not act as research sponsor for any research which comes under the [UK Clinical trials regulations.](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/)

* 1. **Applying to MMU to accept Sponsorship**

As a minimum, the following documentation is required by the Ethics and Research Governance Manager before the sponsorship assessment may be made:

* + 1. A completed IRAS form or [EthOS Application](https://ethos-apply.mmu.ac.uk/)
		2. A completed MMU Insurance Checklist
		3. Signed CI Internal [Agreement](https://www.myresearchproject.org.uk/Help/contents/mNCA_Version_2.1_Jul18_FINAL.docx?web=1)
		4. Project protocol
		5. Participant Information Leaflet (PIL) and consent form (where applicable)
		6. Full information on third party collaborations (partner organisations, etc.)
		7. Confirmation of research funding
		8. CV of CI

Further information and/or documentation may be requested as necessary. The CI (or nominated individual) will need to be available to answer any additional questions raised.

The Ethics and Research Governance Manager will undertake a risk assessment in order to establish whether the sponsor’s responsibilities will be executed properly by the trial study team.

* 1. **Issuing a Sponsor letter**

Following satisfactory review of the requested documentation the RKE Office will issue a sponsorship letter. The letter may only be signed by authorised signatories in the RKE office.

* 1. **Co-Sponsorship**

The institution may wish to approach another organisation to act as co-sponsor for the study and assume some of the sponsorship responsibilities. The delegation of responsibilities between the two sponsors should be agreed, documented and authorised by appropriate representatives of both sponsor institutions/organisations.

* 1. **Other third party agreements**

The sponsor should issue contracts/agreements to third parties (e.g. manufacturers, non-NHS laboratories etc), monitor contract activity and ensure that the third parties comply with the study protocol. For NHS organisations it is recommended that the [Model agreement for Non-Commercial Research (mNCA)](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mNCA) is used as this has been approved for use by most NHS organisations. Any agreements must only be signed on behalf of the sponsor by the financial director.

The CI should monitor any contract activity, and at each site the PI should ensure that the research team complies with any site-specific delegated responsibilities outlined in the model agreement.

A copy of the signed contracts/agreements must be kept in the SMF and Site File where relevant (see [SOP7 Study Master File and Site File Set-up](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP7-Study-Master-File-and-Site-File-Set-up.docx)).

1. **Related Documents**

[Model agreement for Non-Commercial Research (mNCA)](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx%22%20%5Cl%20%22mNCA)

[SOP7 Study Master File and Site File Set-up](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/sop/SOP7-Study-Master-File-and-Site-File-Set-up.docx)

1. **References**

[UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

[[UK Clinical trials regulations](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/)](http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/clinical-trials-of-investigational-medicinal-products/)