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| **Guidance for NIHR Manchester Biomedical Research Centre (BRC) researchers** |
| **Arrangements for Hosting Grants and Sponsoring Research Projects Across the University of Manchester and Greater Manchester NHS Trusts** |
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| Elizabeth Mainwaring  | Research Operations Manager | Manchester University NHS Foundation Trust |
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| **Version** | 1.0, 18th February 2025 |

**Context**

The NIHR Manchester BRC (£64.1million awarded from 1 December 2022 – 31 March 2028) is an NIHR-funded infrastructure and partnership between:

* Manchester University NHS Foundation Trust (host organisation)
* The University of Manchester (HEI partner organisation)
* The Christie NHS Foundation Trust
* Northern Care Alliance NHS Foundation Trust
* Greater Manchester Mental Health NHS Foundation Trust
* Blackpool Teaching Hospitals NHS Foundation Trust
* Lancashire Teaching Hospitals NHS Foundation Trust

Researchers and research teams within the NIHR Manchester BRC hold substantive contracts with BRC partners as listed above and may hold honorary contracts with other BRC partners. BRC research projects are established and delivered through the BRC partners.

At the BRC International Scientific Advisory Board meeting (February 2024) a series of recommendations were produced, and this included the requirement to create some guidance with signposting for BRC researchers related to the arrangements for hosting grants and sponsoring research projects.

It is important to note that this guidance is applicable for the University of Manchester and Greater Manchester NHS Trusts. It does not extend to Blackpool Teaching Hospitals NHS Foundation Trust and Lancashire Teaching Hospitals NHS Foundation Trust

The following guidance should be considered alongside formal policies and procedures within organisations and researchers are advised to contact their employing organisation at the earliest opportunity when planning grant applications and research projects (see Table 3 later in this document).

**1.0: Greater Manchester (GM): Collaboration and Harmonisation**

Greater Manchester (GM) has several universities and major research-active NHS Trusts, necessitating efficient communication and shared processes between them and their respective, independent Research Offices.

This is different to the Joint Research Offices which exist in other places across the country, where a Research Office set in a university also performs that function for that university’s main partner NHS Trust.

That difference comes from the concentration of several major and specialist Trusts in the region across which the University of Manchester conducts much of its health research, and the intensive research activity of those Trusts in their own rights.

Multiple Research Offices and Sponsors:

* Allows organisations to pursue their own strategic responsibilities
* Ensures sponsorship can sit with the organisation that has responsibility for the trial
* Widens the talent pool of staff supporting sponsorship and governance of regulated trials
* Supports specialisations within the region including by subject or trial type.

**2.0: Sponsorship and Regulatory Processes**

The substantive employer of the chief investigator (CI) should sponsor the project.

* Non-Commercial studies which are led by an NHS employee should be sponsored by the employing Trust.
* Non-Commercial studies which are led by the University of Manchester employee or where the lead researcher is a postgraduate student should usually be sponsored by the University of Manchester.

Exceptions are where funding is administered by the Trust (e.g., NIHR funding streams) in line with the Manchester Academic Health Science Centre (MAHSC) agreement (see section 4.0). Ideally in this scenario funding administration and sponsorship are responsibilities of the **same** organisation.

It is also important to check which organisation is best to sponsor e.g. when a researcher has a choice of their University employer or hospital Trust where they hold an honorary contract (or vice versa) and where the participants are based.

If the substantive employer is not able to sponsor, or the above applies, sponsorship will be considered on a case-by-case basis.

Factors like grant hosting, intellectual property, patient involvement, and indemnity influence the decision to be agreed between the two organisations. This includes sponsorship of regulated trials, where capability and capacity to do so is also a factor in considering which organisation will sponsor. National changes in the regulatory processes may also impact decisions.

Decisions on sponsorship should be discussed early, as the sponsor will need to discuss protocol details around many factors including (but not limited to) vendors, data and practicalities.  It is an active decision, not a passive one, so discussion is key.

Table 1 below summarises the sponsorship capabilities across GM organisations. Researchers should contact the sponsorship office of the CI’s substantive employer in the first instance to agree appropriate sponsorship and refer to sponsor SOPs as required.

**Table 1: Sponsorship capabilities across GM**

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| **Study Type** | **University of Manchester** | **Manchester University NHS Foundation Trust** | **The Christie NHS Foundation Trust** | **Northern Care Alliance NHS Foundation Trust** | **Greater Manchester Mental Health NHS Foundation Trust** |
| **Clinical Trial of Investigational Medicinal Product (CTIMP)** | Yes | Yes(exc. Phase I) | Yes (with management via a CTU/CRO unless Type A single-site) | No  | No |
| **Device Trial** | Yes | Yes(exc. Class III) | Yes (with management via a CTU/CRO) | Some but not all  | No |
| **Qualitative Study** | Yes | Yes | Yes | Yes | Yes |
| **Observational Study** | Yes | Yes | Yes | Yes | Yes |
| **Randomised Controlled Trials (RCTs) - non-CTIMPs** | Yes | Yes | Yes | Yes  | Yes |
| **Other (specify)** | Yes (currently no restrictions on other research) |  | Yes (with few restrictions, principally that trials are expected to have an oncology component and the Christie would be a site) |  | Yes (other interventional trials (e.g. feasibility studies)  |
| **Specialism** | First In Human (FIH)ATIMPsClass III Devices |  | RadiotherapyCTIMPsAll IRAS categories | Any – patient facing activity is prioritised | Psychological treatments/therapies and mental health interventions. |
| **Cannot sponsor** |  | Phase I CTIMPsGene Therapy CTsClass III Devices | ATIMPs | Cannot always sponsor non-patient facing activities, especially if most protocol activity takes place at a HEI | Radiotherapy or imaging intervention trials |
| **Contact details** | Clinicaltrials@manchester.ac.uk  | research.sponsor@mft.nhs.uk  | The-christie.sponsoredresearch@nhs.net  | steve.woby@nca.nhs.uk | Researchoffice@gmmh.nhs.uk |

**3.0: MAHSC brokered documents**

Shared or consistent processes support the different Research Offices and sponsors across GM, articulated through swift and robust communication between appropriate colleagues and escalation where required. Continual harmonisation of policies and frequently refreshed personal contacts are essential to maintain this.

All GM contracts offices have access to the following:

* MAHSC Funding policy for which organisations should host NIHR, charity and Research Council grants to maximise Research Capability Funding (RCF) to Trusts and Quality Related (QR) funding to universities (see table 2 below).
* Process for deciding which organisation should sponsor a project
* Agreed model sub-contracts and other agreements between partners, including material transfer agreements (MTA)
* Costing tool and guidance for budgets of (non-commercial) grants

**4.0: Funding Policy**

The MAHSC Funding Policy maximises Research Capability Funding (RCF) to Trusts and Quality Related (QR) funding to The University of Manchester through allocating grant hosting by individual NIHR and other funding programmes.

The current version of the policy is embedded below:



Researchers are encouraged to review the full details of this policy in advance of developing a grant submission.

**Table 2: Administrating Organisation of Funding**

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| **External Funder**  | **Submit Application via** **MAHSC Member**  | **Relevant** **Subcontract(s) to**  | **Benefit to MAHSC member** |
| NIHR Infrastructure  | NHS Trust  | UoM and/or Trust(s)  | RCF  |
| NIHR Programme Grants | NHS Trust | UoM and/or Trust(s)  | RCF |
| NIHR HTA Research Led  | The default grant host should be the associated NHS Trust, except where there is no GM NHS Trust involved or their involvement is negligible  | UoM and/or Trust(s)  | RCF (if Trust led)  |
| NIHR PGfAR  | NHS Trust  | UoM and/or Trust(s)  | RCF  |
| NIHR/MRC EME  | The default grant host should be the associated NHS Trust, except where there is no GM NHS Trust involved or their  | UoM and/or Trust(s)  | RCF (If Trust led)  |
| NIHR RfPB  | NHS Trust  | UoM and/or Trust(s)  | RCF  |
| NIHR Senior Investigator | At the discretion of the SI  | UoM and/or Trust(s)  | No RCF available  |
| NIHR i4i  | NIHR will insist on the grant being hosted by the organisation which will commercialise the invention.  | UoM and/or Trust(s)  | RCF (if Trust led)  |
| NIHR HS&DR  | The default grant host should be the associated NHS Trust, except where there is no GM NHS Trust involved or their involvement is negligible  | UoM and/or Trust(s)  | RCF (If Trust led)  |
| NIHR Public Health Research  | The default grant host should be the University  | Trust(s)  | RCF (If Trust led)  |
| NIHR Systematic Review  | The default grant host should be the substantive employer of the main applicant/chief investigator  | UoM and/or Trust(s)  | RCF (If Trust led)  |
| NIHR Global Health Research  | UoM  | Trust(s)  | No RCF due to non-NHS organisations administering the grant  |
| NIHR Research Professorships  | UoM  | Trust(s)  | No RCF due to non-NHS organisations administering the grant  |
| NIHR Fellowships including Clinician Scientists  | UoM  | Trust(s)  | No RCF due to non-NHS organisations administering the grant  |
| NIHR Policy Research Programme  | The default grant host should be the substantive employer of the main applicant/chief investigator  | UoM and/or Trust(s)  | RCF (If Trust led)  |
| AMRC Charity (CRUK, Wellcome Trust etc)  | UoM  | Trust(s)  | QR  |
| UK Research Council (eg MRC, BBSRC etc)  | UoM  | Trust(s)  | FEC  |
| Commercially Sponsored Clinical Trial i.e. recruitment site.  | NHS Trust  | UoM and / or Trust(s)  | Meets national guidance and uses model clinical trial agreement.  |
| Investigator led Clinical Trial (both commercial and grant funded excluding NIHR)  | NHS Trust or UoM - The default grant host should be the substantive employer of the main applicant/chief investigator, but may vary due to sponsor or other factors to be discussed  | UoM or Trust(s)  | International/national league tables  |
| Other  | Substantive employer or UoM if hold honorary research contract.  | UoM and / or Trust(s)  | International/national league tables  |

**5.0: Support for Researchers**

Researchers are advised to contact their Trust R&D Office or University Research Support Manager for additional guidance and support.

**Table 3: Contact Details**

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|  | **University of Manchester** | **Manchester University NHS Foundation Trust** | **The Christie NHS Foundation Trust** | **Northern Care Alliance NHS Foundation Trust** | **Greater Manchester Mental Health NHS Foundation Trust** |
| **Sponsorship** | clinicaltrials@manchester.ac.uk | research.sponsor@mft.nhs.uk  | the-christie.sponsoredresearch@nhs.net  | Hannah.howlett@nca.nhs.uk | Researchoffice@gmmh.nhs.uk |
| **Research Support** | UoM FBMH Research ServicesSBSresearchsupport@manchester.ac.ukSHSresearchsupport@manchester.ac.ukSMSresearchsupport@manchester.ac.uk  | MFT Trust research officeR&D.applications@mft.nhs.uk | the-christie.sponsoredresearch@nhs.net | Helen.moffitt@nca.nhs.uk | Researchoffice@gmmh.nhs.uk |
| **Finance** | UoM FBMH Research ServicesSBSresearchsupport@manchester.ac.ukSHSresearchsupport@manchester.ac.ukSMSresearchsupport@manchester.ac.uk | Research & Innovation Manager | The-christie.randdgrants@nhs.net  | Aishah.Abbas@nca.nhs.uk | Researchoffice@gmmh.nhs.uk |
| **Contracts** | ContractsTeam@manchester.ac.uk | research.contracts@mft.nhs.uk  | The-christie.RandDContracts@nhs.net  | Katie.doyle@nca.nhs.uk | Researchoffice@gmmh.nhs.uk |