Contracting organisation and funding distribution for St George's University and St George's NHS Trust research applications/awards

Introduction

Joint Research and Enterprise Services (JRES) is responsible for facilitating and managing research grants and contracts on behalf of St George's, University of London and St George's University Hospitals NHS Foundation Trust.

Many Principal Investigators (PIs) in St George's University and St George's NHS Trust who are substantively employed by the University or the Trust have an honorary contract with the other party.

Whilst JRES works on behalf of both organisations, they are separate legal entities, and our research applications and awards need to reflect this. Research applications need to be submitted on behalf of a lead organisation, and research awards need to be contracted by a lead organisation.

This policy sets out which organisation – St George's University or St George's NHS Trust – should be the lead organisation for research applications and awards, and how the distribution of funding should be managed where both organisations are involved in the research.

Definitions

<u>"Funder"</u> means the organisation who is providing the funding the research project (for instance a company or charity).

<u>"Sponsor"</u> means the organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research should have a sponsor. This can be St George's University St George's NHS Trust or an external body (such as a company or another NHS Trust).

Lead organisation for St George's research applications and awards

- 1. The overall principle is that the substantive employer of the Principal Investigator (or Chief Investigator) should be the lead organisation for research applications/awards and the contracting party for the research contract, except where this is not allowed due to external funder or regulatory requirements.
- 2. The main instances where there are external requirements preventing the substantive employer of the Principal Investigator being the lead organisation are:

- a) Commercially sponsored clinical trials where in order to comply with research and clinical governance requirements and expectations, and to establish the correct lines of accountability for clinicians practising in the NHS, all contract clinical trials must be governed by contracts between the sponsor and the organisation responsible for the research siteⁱ. This means that all clinical trials sponsored by industry should be contracted via St George's NHS Trust, even if the Principal Investigator is substantively employed by St George's University and has a clinical honorary contract with the Trust.
- b) Some NIHR grant schemes are only open to NHS organisations to apply for. Please check the scheme rules on a case by case basis to see if they are open only to NHS organisations to apply for. In these cases, the lead party should be George's NHS Trust, even if the Principal Investigator is substantively employed by St George's University.

Distribution of funding where both St George's University and St George's NHS Trust undertake research

- 1. The overall principle is that funding should be distributed to cover the costs of the party undertaking the research. This means that:
 - a) Where the contracting party is St George's University, and the research funder pays St George's University, funding should be paid from the University to the Trust for research activity costs incurred by the Trust.
 - b) Where the contracting party is St George's NHS Trust, and the research funder pays St George's NHS Trust, funding should be paid to from the Trust to the University for research activity costs incurred by the University.
- 2. Where St George's University is the lead party/sponsor on either grant applications or investigator-led trials (i.e. investigator-led/commercially funded clinical research studies), St George's NHS Trust activity should be costed. All eligible Trust costs should be included in the costing/grant application and paid to the Trust.
- 3. Where St George's NHS Trust is the lead party/sponsor on either grant applications or investigator-led trials (i.e. investigator-led/commercially funded clinical research studies) St George's University activity should be costed. All eligible University costs should be included in the costing/grant application and paid to the University.
- 4. For commercially sponsored clinical trials where the Principal Investigator (or Chief Investigator) is substantively employed by St George's University:

- a) University costs should be included, in accordance with the requirements of the NIHR commercial clinical trial costing template.
- b) Any direct research costs which are incurred in the University should be paid to the University.
- c) Commercially sponsored clinical trials are funded with overheads at 70% of direct costs. In accordance with NIHR recommendations, Trust research income distribution policy is that 35% of the overheads are allocated to the Trust (R&D budget); and 35% are allocated to the Principal Investigator's Trust central fund. Where the Principal Investigator is substantively employed by the University, rather than 35% of overheads being allocated to the Principal Investigator's central fund, this amount shall instead be allocated to the University as University overheads, in recognition of the Principal Investigator's University employment and their University research responsibilities.
- d) In the event that the clinical trial is managed by the Clinical Research Facility (CRF), Trust research income distribution policy is that (of 70% total overheads) 24% of overheads are allocated to the Trust (R&D budget); 22% to the CRF (in recognition of the CRF costs involved); and 24% to the Principal Investigator's central fund. If the CRF is used, the University will be allocated 24% of the overheads (rather than these being allocated to the Principal Investigator's central fund).
- e) All other costs (such as capacity building and service support funding) should remain with the Trust.

Exceptions to this policy

Any exceptions to this policy should be referred to, and need to be approved by, the Trust Associate Medical Director (Research), the University Deputy Principal (Research & Enterprise) and the JRES Director.

November 2021

Next review: November 2023

¹ Model Clinical Trial Agreement (mCTA) and Clinical Research Organisation Model Clinical Trial Agreement (CROmCTA) – Guidance (January 2021)