

Identifying your project's research governance sponsor

Please note the University does not sponsor CTIMPs (Clinical Trials of Investigational Medicinal Products)

The UK policy framework for health and social care research applies to health care research.

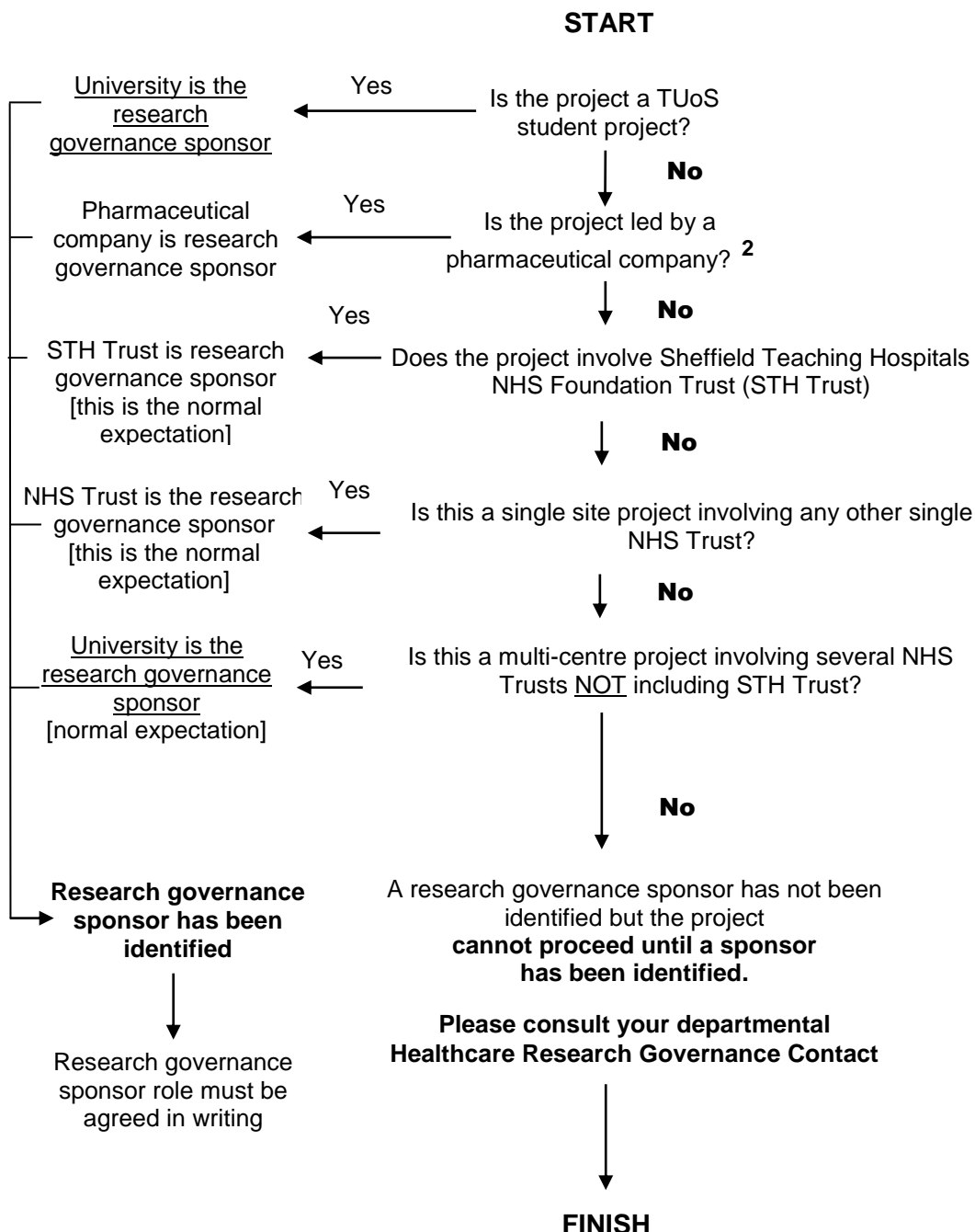
The University's position statement on research governance sponsorship is at **Annex 1**.

The following flow diagram explains how the University decides which organisation is the most appropriate research governance sponsor in respect of health care research projects whose investigator is employed by or has an honorary contract with the University. If you are unsure if your project requires a research governance sponsor please visit

Caveat: Different organisations hold different positions on how to decide sponsorship (see page 2).

RESEARCH GOVERNANCE SPONSOR ¹ FLOW DIAGRAM

(accompanying notes are on the next page)



Notes accompanying the flow diagram:

¹ The research governance sponsor is the 'organisation that takes on overall responsibility for the project from conception to final completion, including arrangements for the project's initiation, management, and financing. The sponsor satisfies itself that the project meets the relevant standards, and makes sure arrangements are put and kept in place for management, monitoring and reporting. The project's research governance sponsor remains responsible for the project but reserves the right to delegate sponsor duties in respect of the project (e.g. for the initiation, management, monitoring and reporting) to another institution'. In other words, the buck stops with the research governance sponsor.

Where the University is the co-applicant to a project the University will expect to receive confirmation, in the first instance from the lead project applicant, or in the second instance from another co-applicant, that another organisation is the project's research governance sponsor. Where appropriate the University will take on the responsibility of confirming aspects of research governance to the project's research partners.

² Pharmaceutical companies will be the research governance sponsors for commercially-led clinical trials of investigational medicinal products (IMP-trials).

Other known positions of NHS Trusts:

The Sheffield Children's NHS Trust will be the research governance sponsor of health care research projects that only involve it. However, it won't agree to be the research governance sponsor if it concludes that overseeing a particular project would be too resource intensive given the nature of the project. Where this is the case then the University of Sheffield will be the research governance sponsor.

Doncaster & Bassetlaw Hospitals NHS Foundation Trust will normally be the research governance sponsor of health care research projects that only involve it.

Gloucestershire Partnership NHS Trust will normally be the research governance sponsor of a health care research project where the idea for the project has originated from the Trust's employee(s).

Royal Liverpool & Broadgreen University Hospitals NHS Trust will normally be the research governance sponsor of health care research projects that only involve it.

University of Sheffield**FORMAL POSITION STATEMENT ON
RESEARCH GOVERNANCE SPONSORSHIP OF
UNIVERSITY-LED HEALTH CARE RESEARCH PROJECTS**

1. The 'research governance sponsor' (sponsor) is the 'organisation that takes on overall responsibility for a health care research project (project), as defined by the Department of Health's 'Research Governance Framework' (RG Framework), from conception to final completion including arrangements for the project's initiation, management and financing. The sponsor must satisfy itself that the project meets the standards prescribed by the RG Framework and makes sure arrangements are established and kept in place for project management, monitoring, reporting and audit'.
2. While the sponsor retains overall responsibility for the research governance of a project, it is recognised that a sponsor may reserve the right to 'delegate' sponsor duties to another institution. The University recognises it may agree to be the sponsor of a project or a party to a project with certain delegated research governance duties.
3. The University's expectation is that all sponsor responsibilities and recovery of associated costs (see 4.2) are explicitly and formally agreed in writing before it enters into any contractual commitments with partners or funders. Consequently, any parties with delegated sponsor duties (including the University) should also formally and explicitly agree this in writing with the sponsor before that party in turn makes any contractual commitments with the main contractor or funders.
4. The University's expectation is that, normally, the institution that employs the project's Principal Investigator (or Chief Investigator in the case of a multi-centre project) should be the project's sponsor. However, the following will apply:
 - If the project involves Sheffield Teaching Hospitals NHS Foundation Trust (STH Trust) then the expectation is that STH Trust will be the project's sponsor.
 - If the project involves any other NHS Trust (but does not involve STH Trust) then the expectation is that the 'lead' NHS Trust will be the project's sponsor. Note: If there is no clearly identifiable 'lead' NHS Trust then, normally, the University will agree to be the project's sponsor.
 - The project's sponsor, or parties with delegated duties for research governance (e.g. the University or NHS Trust), may reasonably expect to recover costs associated with these duties from either the funder(s) or any partners in the project. This should be formally and explicitly agreed in writing before any contractual commitments are made (see 2 and 3).
5. Whilst understanding that each project must have a designated sponsor, the University recognises that the University and other institutions reserve the right, on a project by project basis, to decline to be a project's sponsor.
6. The University recognises that the issues of indemnity provision and insurance cover in respect of a health care research project are not determined by which organisation is the sponsor.

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