

## Identifying your project's research governance sponsor

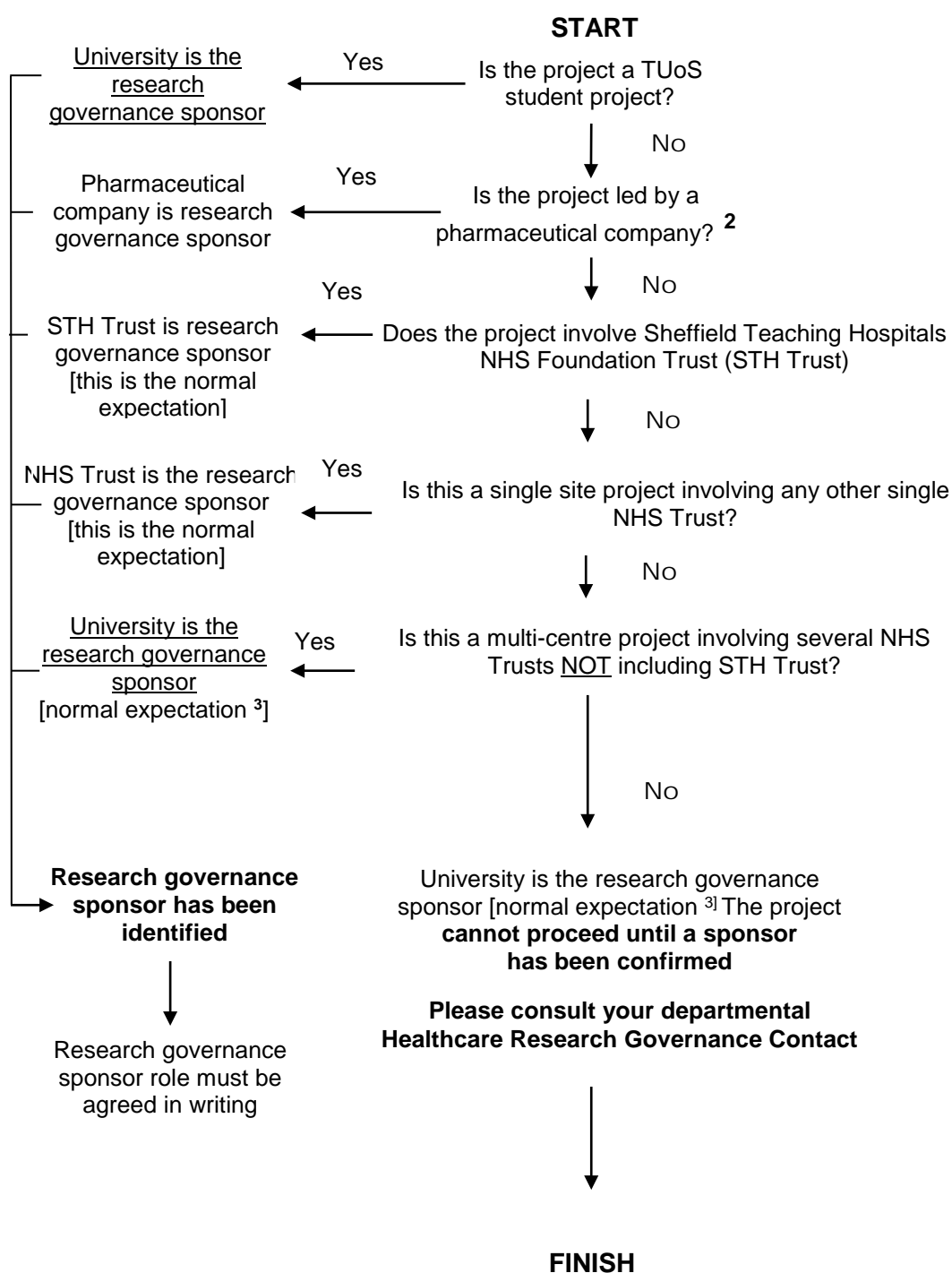
**Please note the University does not sponsor CTIMPs (Clinical Trials of Investigative Medicinal Products)**

In accordance with the *UK policy framework for health and social care research*, the following flow diagram explains how the University decides which organisation is the most appropriate research governance sponsor in respect of health and social care research projects whose investigator is a student of, employed by, or has an honorary contract with, the University. If you are unsure if your project requires a research governance sponsor please visit <https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance>.

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

### RESEARCH GOVERNANCE SPONSOR<sup>1</sup> FLOW DIAGRAM

(accompanying notes are on the next page)



## Notes accompanying the flow diagram:

<sup>1</sup> 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.

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

**<sup>3</sup> The University will not sponsor clinical trials of investigative medicinal products (CTIMPs) or clinical investigations of devices which fall under the UK Medical Devices Regulations (an alternative sponsor must be found for such studies, e.g. NHS Trust, pharmaceutical company, device manufacturer). In addition, the following types of human interventional study require additional approval before the University will agree to accept sponsorship:**

- Studies involving the administration of a substance outside the terms of its existing licence; or
- Investigating the safety/tolerability of a substance in humans; or
- Investigating a substance in order to ascertain the appropriate dose to administer in humans.

Please contact your department's research governance contact for further information:  
<https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance>.

## **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<sup>3</sup>.

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.

