Research Governance Standard Operating Procedure 3 – Deciding on Sponsorship, Registration or neither

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V1.0	23/04/2026	Emily Avent	Reference to regulations updated	V1.1	Rachel Davies	28/04/2026

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1. Glossary

Terminology is explained in the Research Governance Glossary, the most recent version of which can be found **on the Research Governance webpages.**

2. Background

This SOP describes how to decide whether a new study requires Sponsorship, Registration, or neither.

Sponsorship refers to the act of the University taking on "overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project", where that research falls within scope of the **UK Policy Framework for Health and Social Care Research**. Other guidance and regulations define additional responsibilities for Sponsors for specific types of research, but these projects would also fall within the scope of the Policy Framework.

Registration refers to the act of the RGT reviewing a study's documentation and confirming the University's involvement, where another organisation is acting as its Sponsor, or a Sponsor is not required.

Both Sponsorship and Registration involve detailed review of study documents, and therefore should only take place if needed.

This SOP therefore helps to ensure that the University is acting as Sponsor when appropriate, in line with the **UK Policy Framework for Health and Social Care Research**.

This SOP also helps to ensure that the University has some oversight over certain classes of study for which it is not Sponsor, namely those which are Registered.

Lastly, this SOP helps to ensure that we are not acting in either capacity where it is not necessary, and that the reasons for this choice are clearly documented.

3. Scope

This SOP only advises on how to decide whether to Sponsor or Register a study. It typically represents, therefore, one of the next steps in the process after initial triage of new studies as described in **RGT SOP 2 – Triaging new studies**, along with **RG SOP 4 – Approvals** and **RG SOP 5 – Agreements**. In practice, all three SOPs may be used together. The SOPs do not aim to impose a specific order of operations, and allow for fluidity in the actual execution of the initial assessments of whether the study requires Sponsorship or Registration, what approvals or agreements may be required, and so forth.

Similarly, the SOP assumes that the study has been triaged to a member of the RGT in line with **RG SOP 2 – Triaging new studies**. However further assessment of whether the study requires Sponsorship, Registration or neither, or assessment of what approvals or agreements the study requires, may reveal that the study should be managed by another member of the team, contrary to the initial assessment made at triage.

This SOP does not advise on the processes for Sponsorship and Registration; these can be found in Sponsorship and Registration SOPs, respectively. Nor does it advise on the processes

for non-study research-related activity, in the form of Research Databases and Research Tissue Banks; again, see the relevant SOPs for information on these.

All references in this SOP to Sponsorship (and its derivations) are specifically in relation to the role of Sponsor as defined in the **UK Policy Framework for Health and Social Care Research**. Funders or collaborating organisations may use the term sponsorship to refer to other forms of oversight or responsibility – such uses are outside the scope of this SOP and RGT processes. Where organisational expectations around Sponsorship/sponsorship appear to differ, establishing exactly what each party means by the term may aid resolution.

4. Responsibilities

This SOP describes how the RGT member assessing the study should make their decision. Individuals using this SOP should be familiar with the **UK Policy Framework for Health and Social Care Research**. If the responsible RGT member is unsure of how to proceed, they should raise the study either directly with the HoRG or at the fortnightly RGT NHS catch-up.

5. Procedure

5.1 Is the project 'research'?

The first point of assessment is whether the study meets the NHS definition of research (this definition does not map directly onto the more common usage of the term, nor the Frascati definition). This can be done using the **MRC/HRA Is My Study Research?** tool, and the **Defining Research Table**.

If a study is not research, then neither Sponsorship nor Registration is appropriate. Proceed to section 5.5, below.

5.2 Does the project require Sponsorship?

As above, Sponsorship, in this context, is defined in the **UK Policy Framework for Health and Social Care Research.** As such it is required for those studies which are governed by the Framework:

- Studies involving NHS patients, service users, staff, facilities, services, premises, healthcare records, etc. Typically any study that would require an IRAS application.
- Studies requiring NHS REC review for the purposes of HTA exemption.
- Studies involving UK social care organisations.*

Where historically this was, in practice, a more complicated question; differing between different types of social care provision: the Framework itself does not distinguish, and regional Integrated Care Boards now typically oversee all social care research to a uniform standard. Therefore, all social care research requires Sponsorship. This does not affect the required approvals for the study, which is still an independent assessment as per **SOP 4.*

If none of the above apply, the study does not require Sponsorship, proceed to section 5.4, below.

5.3 Will UoB act as Sponsor for the project?

An organisation agreeing to act as Sponsor for a study is not automatic and should not be assumed. It is a choice on behalf of the organisation. This decision typically rests with RGT, as

Sponsor Representatives. Disputed cases should be referred to the **HoRG**, if they still cannot be resolved, they will be escalated to the Dean of Health and Life Sciences.

In keeping with the definition in the Framework, UoB will typically act as Sponsor for a study if:

- The study requires Sponsorship ***and***
- The study CI is an academic substantively employed* by the University ***or***
- The study is led by a student at the University (for educational projects the student's academic supervisor should act as CI.)

**In exceptional circumstances an individual might lead a UoB Sponsored study whilst only having an honorary contract with the University. This is not a routine nor a desired arrangement, it will typically only occur due to a change of circumstances during the conduct of a study and will always require approval by the HoRG.*

The question of who should act as Sponsor is not always clear-cut. In some circumstances the decision will require a degree of judgement and of negotiation with other organisations involved. In such cases the responsible **RGT member** should raise the study either directly with the **HoRG** or at the fortnightly RGT NHS catch-up. Such circumstances include, but are not limited to:

- The study falls primarily within the clinical role of a University academic's joint University/NHS appointment, the study activity solely or significantly relates to standard clinical activity, or the study will involve intensive treatment or monitoring in an NHS Secondary Care setting.
- The study is commercially funded or commercially led, particularly if the commercial organisation are seeking to exercise the oversight or responsibilities of the Sponsor.
- The study is led by an academic employed by the University but relates to their role in a commercial organisation (in the case of a University spin-out, a discussion with Commercialisation is recommended).
- The study is particularly high risk and of a type not previously Sponsored by UoB – such as Advanced Therapy Medicinal Product or Phase 1 clinical trials.

Upon the decision that a study requires Sponsorship by the University, the responsible **RGT member** should change the case name in F2 using the appropriate naming conventions (see F2 User Guide section 5 on updating case name), and refer to **RG SOP 6 – Sponsoring a study**.

> *Other uses of the word 'sponsor'*
> This SOP specifically addresses Sponsorship as defined in the **UK Policy Framework for Health and Social Care Research**. **RGT** are responsible for determining when such Sponsorship is required, whether UoB will accept the responsibilities of that role, and for carrying out those responsibilities.
>
> Where a funding or collaborating organisation requires that the study have a 'sponsor' with a different definition, or no clear definition, it *may* be appropriate for **RGT** to accept or reject that role on behalf of UoB. If the role of 'sponsor' is not clearly defined, the responsible **RGT member** should seek clarification from the other organisation. If the role entails the same or similar responsibilities as the Policy Framework definition, it is appropriate for **RGT** to accept or decline this role. If the role relates instead to other responsibilities, for example; financial oversight or

contractual obligations, this decision should be referred to the appropriate UoB department (e.g. **Research Finance** or **Research Contracts**).

Administratively, a study's F2 case should only be labelled as 'Sponsored' in relation to the Policy Framework definition.

5.4 Deciding when to Register

If a study is not Sponsored, it may still need to be Registered. There are no hard and fast rules for when this should happen. The chief principle underlying the decision to Register a study is that the study potentially poses a risk to the University (whether reputational, legal, financial, or otherwise) and that review of the study as part of the Registration process can demonstrate that these potential risks have been mitigated by the standards and processes applied to the setup process.

A non-exhaustive list of examples where this applies, and where the responsible **RGT member** should typically decide to Register the study is as follows:

- The study is Sponsored by another organisation, but the University is acting as a 'site' as defined in the Research Governance Glossary (in this instance, the study *must* be Registered by the RGT), *or*
- The study is Sponsored by another organisation, the University is not acting as a 'site' but University staff will be undertaking significant study tasks, e.g. laboratory analysis, data analysis, qualitative work, etc. *or*
- The study is otherwise particularly high risk (for example, work on extremist groups, the dark web or other subject matter which requires computer logging by IT Services; work on contentious health areas (i.e. those which attract extreme responses); work involving participants who are known to be dangerous; work involving travel to dangerous places), *or*
- A researcher has requested some form of due diligence from the RGT, *or*
- The study involves collection and storage of human tissue in line with an HTA license exemption (other than NHS REC exemption), and is seeking University REC approval (with prior agreement from the RHTM), *or*
- The study is bringing Relevant Material into the University to store and use under the appropriate ethical approval of a non-University Research Tissue Bank, *or*
- The study is bringing Relevant Material into the University to store and use under the appropriate ethical approval of another Sponsor, *or*
- The University are 'Manufacturer' (in the MHRA sense) of a Medical Device being used in the study, but are not Sponsoring the study, *or*
- The study is using a Medical Device which is Sponsored by another organisation and has project-specific ethics approval in place
- The study has been approved by a University REC but involves potentially higher risk interventions assessed as requiring Registration, *or*
- The study involves educational establishments (for instance, schools or colleges), local authorities or social-care services and assurances/permissions have been provided by and /or to RGT, *or*
- The study involves other organisations, e.g. local authorities or private care services who require additional assurances.

If a study does not meet any of these criteria but has involved considerable additional support or assessment by RGT; we may choose to Register it, in order to maintain a record of the work involved.

Upon the decision that a study requires Registration by the University, the responsible RGT member should change the case name in F2 using the appropriate naming conventions. (See F2 user guide section 5 on updating case name), and refer to **RG SOP 7 – Registering a study.**

5.5 Deciding when to neither Sponsor nor Register
If the study does not meet the criteria described above, then, in general, the responsible RGT member should decide to neither Sponsor nor Register the study.

Upon the decision that a study requires neither Sponsorship nor Registration by the University, the responsible RGT member should change the case name in F2 using the appropriate naming conventions. (See F2 user guide section 5 on updating case names).

5.6 Once a decision on Sponsorship, Registration, or neither has been reached
If the relevant **RGT member** has decided Sponsorship is appropriate, they should follow the procedure in the Sponsorship SOP.

If the relevant **RGT member** has decided Registration is appropriate, they should follow the procedure in the Registration SOP.

If the relevant **RGT member** has decided neither Sponsorship nor Registration are appropriate, they should determine whether UoB REC review is required and whether it has been sought - consulting with the **REIM** or **REA**s if necessary. They should write to the researcher, with the string "Sponsorship and Registration not required" in the subject line for searchability. The relevant **RGT member** should state in the email that they have assessed the study and the University's involvement, and that they can confirm neither Sponsorship nor formal study Registration are required – and advise on seeking UoB REC approval, if relevant. The **RGT member** should file this to the case 2019 – 415 in F2.

6. Related documents

Internal documents

RG SOP 2 – Triaging new studies

RG SOP 4 – Approvals

RG SOP 5 – Agreements

RG SOP 6 – Sponsoring a study

RGT SOP 7 – Registering a study

F2 user guide v4

External documents

UK Policy Framework for Health and Social Care Research.

Uk Clinical Trials Regulations

Medical Devices Regulations 2002.