Research Governance Standard Operating Procedure 7 – Registering a study

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V1.0	23/04/2026	Emily Avent	Terminology 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

Within the RGT, *Registration* refers to the act of the RGT reviewing a study's documentation and confirming they are happy for it to proceed, despite not acting as its Sponsor. This SOP describes the process for Registering a study.

This SOP 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. It helps to ensure that where a study potentially poses a risk to the University (whether reputational, legal, financial, or otherwise), these risks have been reviewed, and it has been established that they are mitigated by the standards and processes the study has in place. It can also give researchers some assurance that their research activity is being conducted within the bounds of relevant regulations or guidelines.

3. Scope

This SOP only advises on the process for study Registration. It does not advise on how to decide whether study Registration is appropriate; for this, see **RG SOP 3 – Deciding on Sponsorship, Registration or neither**.

4. Responsibilities

This SOP describes how an **RGT member** should complete the Registration of a study.

5. Procedure

The general principle behind the Registration of a study is that the study potentially poses some form of risk to the University, information about the study has been reviewed by a member of the RGT, and it has been established that the standards and processes the study has in place mitigate these risks (for instance, because the study has appropriate ethical coverage).

Once the decision to Register a study has been made, the responsible **RGT member** will need to review the study. This process can be broken down into three parts: determining the role of the University within the study, determining what approvals or agreements are required for that role, and establishing that these approvals and agreements are in place.

5.1 Determining the role of the University in the study

The **RGT member** Registering the study should first seek to understand what role the University is taking within the study; what activity is happening involving University premises, or University staff (under their University contract, and not, for instance, a separate clinical contract); in what ways these things will be interacting with human participants, their tissue, or their data.

This information can be taken from the research Registration checklist (see SOP 2), the study protocol or the grant application; equally the **RGT member** Registering the study can solicit it from the researcher directly.

5.2 Determining what approvals and agreements are required

Once the **RGT member** has this information, they should assess what approvals and agreements are likely to be required of the study, and in particular for the University's involvement in it.

The specific approvals, agreements, and other information required for Registration is determined by the Registration template needed for that study, though the **RGT member** should always use their judgement about whether the template has captured the appropriate information. Which template is needed depends on the specifics of the study, and **RGT**

members should use the Registration template matrix to decide this. As above, the **RGT member** should use their judgement about the suitability of a template for a given study.

5.3 Establishing these approvals and agreements are in place

The **RGT member** reviewing the study should now request evidence of whichever approvals and agreements need to be in place, per the template, applying those evidentiary standards described in the parentheses below, and as applicable to the study and template.

The **RGT member** should ensure that the activity being carried out with the involvement of the University (whether that be University researchers, premises, resources) is specifically covered under the relevant approvals or agreements. Besides this, however, the **RGT member** need not review the documentation with the same depth or level of scrutiny that would be applied to a study the University was Sponsoring; ultimately, that assessment is the responsibility of the study Sponsor, or other relevant committee or body.

The RGT member should look for confirmation of all of the following that apply, given the nature of the study:

- Sponsorship (typically evidenced by inclusion of the Sponsor on the HRA letter following an IRAS submission)
- REC approval (a letter from the REC, or the HRA for NHS REC)
- HRA approval (HRA letter)
- MHRA approval for CTIMP/CIMD (MHRA letter)
- Ethical coverage for storage of relevant material (NHS REC letter in combination with wording in protocol/IRAS submission, the consent forms and participant information sheet which specifies or, at the least does not, preclude the University's involvement)
- Contracts (copy of contract, or Research Contracts F2 reference to access this)

Where all the relevant approvals and agreements are in place, the **RGT member** can proceed to the next step of the procedure below. Where relevant approvals or agreements are not in place, or are in place but not evidenced, the **RGT member** should request these and repeat above process as required.

5.4 Finalising of Registration and issue of Registration email

Registration emails should be issued for CTIMPs, CIMDs, Human Tissue studies, or other high risk activity, only once all approvals are in place. For lower risk studies, it may be appropriate to issue the Registration email pending ethics approval; in this case the RGT member should amend the template to request evidence of this approval once obtained.

Once the **RGT member** has completed the appropriate Registration template, and is satisfied, per the above, all approvals and processes are or will be in place, they should send this to the researcher, and file the record within the case on F2.

5.5 Modifications

The Registration templates state that:

If the study protocol or other documentation changes in future, and those changes are substantial enough to require further review by the ethics committee overseeing this research, your study must be re-Registered by the Research Governance Team. Please contact us in this eventuality.

If re-Registration is proportionate, given the nature of the changes, the RGT member should repeat the process described in sections 5.1-5.4.

6. Related documents

Internal documents

Registration template

Registration template matrix

RG SOP 3 – Deciding on Sponsorship, Registration or neither

External documents

N/A