Research Governance Standard Operating Procedure 5 – Agreements

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V1.0	24/04/2026	Emily Avent	Updated references to regulation	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 explains how various collaboration agreements relating to studies should be assessed by the **RGT member** reviewing the study for Sponsorship.

This SOP therefore ensures the University meets its obligations as Sponsor to comply with the **UK Policy Framework for Health and Social Care Research**, and other legislation such as the The **Medicines for Human Use (Clinical Trials) Regulations 2004**, as amended by the **Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025** .

N.B for CTIMPs only, trial sites are now referred to as 'trial locations' following the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

3. Scope

This SOP primarily applies to those studies being reviewed by an RGT member for *Sponsorship*. Studies being reviewed for registration, in line with RG SOP 7, do not typically require detailed assessment of their associated agreements – the primary exception to this being studies with incoming human tissue, on which see section 5.3 below.

Although Research Governance often has a role in the preparation and sign-off of study agreements, some responsibilities fall firmly within the remit of Research Contracts. A working document is currently being developed to set out the ways in which Research Governance works with Research Contracts.

4. Responsibilities

This SOP is for the use of RGT members in assessing whether appropriate study agreements are in place, the process for preparing these agreements and for ensuring they have been completed correctly.

5. Procedure

This procedure explains how various types of agreement document should be assessed by the **RGT member** responsible for reviewing a study for Sponsorship; relatedly, this information can be provided by the **RGT member** to a researcher ahead of their preparing these agreements.

5.1 Collaboration agreements

The term *collaboration agreement* refers to any agreement between the University, in its role as Sponsor, and another organisation involved in the research (whether a research site or a participant identification centre). These agreements can take various more specific kinds.

OID

The Organisation Information Document explains what research activities a site is expected to carry out. The OID provides key information to facilitate the regulatory review of the submission and the localised OID should be included in the Local Information Pack for the site as it contains information about the practical arrangements for delivering a study. They are required

for studies involving NHS research sites (not for PICs, see below) and will form the contractual agreement between UoB and the site unless a model Non-Commercial Agreement (mNCA) is also required (see below). Though not mandatory for non-NHS research sites, a collaboration agreement of some form will always be required and the OID is a familiar, standard format, so is recommended (unless an mNCA is required, see below).

The **RGT member** should direct the study team to complete the template OID, referring them to the HRA and **RGT OID guidance.** The RGT member should ensure there is an OID covering each non-UoB site type within the study (i.e. separate OIDs are required *if* sites will be performing different roles within the study), and that the OID makes sense on its own terms, and when assessed in combination with other study documents (they should also refer to the Study Sponsorship checklist for prompts on this). Once satisfied with the completion of the template, the **RGT member** can sign the OID following internal RGT guidance on Authorised Signatories and advise the study team to upload this alongside their IRAS application. It has been confirmed with the University of Bristol Research Contracts Team that RGT members can sign off on OIDs following the internal RGT guidance. In the event that a new OID template is rolled out at a national level, this must be sent to the Research Contracts Team for review. Confirmation will be sought from the Research Contracts Team that the RGT can implement the updated version and continue to act as signatory on the agreement. Internal OID RGT guidance will be updated as required.

After HRA initial assessment, and when site setup is required, the OID template must be localised and authorised by each site study team. This will include completing some or all of sections 6, 7, 8, 9, 10, and 11, if they were not completed in the site-type template – and must include completion of sections 16 & 17 and authorisation on the final page.

When sites return signed OIDs (possibly with a separate formal C&C email) the RGT member should check that it has been completed correctly before adding the site to the Sponsorship letter, in line with **RG SOP 6 – Sponsoring a study**. In particular, the RGT member should check:

- The OID has been signed by someone from R&D or someone who is otherwise the appropriate person to be signing the OID.
- The OID matches the template OID that was signed off and approved as part of IRAS submission – except the localised sections.
- That the appendices are the same as those in the template OID.

Changes may be required to an OID after the **RGT member** has signed. 1) If changes to the study-specific content of an OID are needed prior to Sponsorship, the changes should be reviewed and agreed with the site. If previously signed, the RGT should re-sign and re-date the OID. The site will then sign as part of their confirmation of capacity and capability.

2) If changes to the study specific content of the OID are required after a Sponsorship letter has been issued for that site, the changes should be reviewed and agreed with the site. Only once all content has been agreed, the OID can be re-signed and re-dated by both parties. An updated Sponsorship letter will be prepared which details the changes made for that site. The site does not need to wait for the updated letter to commence the new activity because the changes have been agreed by the parties.

For information on when a modification is required for changes to the OID, refer to RG SOP 20 – Modifications.

mNCA

The model Non-Commercial Agreement is the template agreement for interventional research: any study to which one of the top four categories in question 2 of the IRAS form applies. mNCAs may also be needed for studies involving major grants, and in other cases where conditions in the mNCA, but not covered in the OID (for instance, anti-bribery clauses) are required. One advantage of the mNCA is that, in limited circumstances, amendment of the template can be justified; accordingly, it is more flexible than the OID.

mNCAs are managed by Research Contracts, and authorised by Research Finance, and can take time to develop; studies requiring an mNCA should be flagged to Research Contracts by the **RGT member** as soon as possible during early stages of study review. When the template mNCA is finalised, it must be confirmed by Research Contracts that the template can be submitted as part of the IRAS application.

Once the documentation has been approved by the HRA, subject to discussion with Research Contracts the study team may manage sending of the mNCA to sites, but signature is again managed by Research Contracts.

Where an mNCA is the formal collaboration agreement, NHS sites will generally also require that an OID also be submitted as part of the IRAS application (with all appendices marked as not forming the agreement). The OID should be prepared and authorised as above, by an **RGT member**. Its purpose is not contractual but rather to provide clear guidance to NHS sites regarding their role in the study, in a familiar format.

RGT member responsibilities are:

- To ensure that any delegation of responsibilities in the mNCA are in accordance with RGT expectations;
- to check that the mNCA and OID are consistent and raise any discrepancies with the study team and Research Contracts;
- To check that all signatures in the OID and mNCA have been provided by the correct parties. Where an mNCA forms the agreement, a signed version from the site is sufficient for update of Sponsor letter; a signed OID is not necessary.

PIC agreement

Participant Identification Centres, or PICs, are places where potential participants for a study are processed and identified. They do not carry out any other research activity and are not classed as research sites. PIC agreements fall into two categories: where the Sponsor (i.e. the University) is contracting with a PIC directly, or where the PIC is contracting with a research site that is itself contracting with the University as part of the study.

Where the agreement is between the University and the NHS, the **RGT member** should ensure the appropriate standard national template (mNC-PICA Sponsor to PIC) is used. The research team should be directed to complete the template, which will then be reviewed by the RGT, prior to confirmation of Sponsorship.

In the latter case, the **RGT member** should check that the appropriate standard national template is used (mNC-PICA site to PIC). Because this is a contract between two separate

organisations, the University, as Sponsor, cannot *require* any particular stipulations in the contract – though they may guide the research team to ensure they are completed. The **RGT member** should make sure that fully signed subcontracted PIC agreements in this category are filed on the case in F2 before adding the PIC to the Sponsorship letter. The PICA does not need to be submitted to IRAS, and can be reviewed after, or in parallel to, IRAS submission.

In both cases, the RGT member can sign the PIC agreement on behalf of the University. They should also ensure that the PIC agreement has been signed by an authorised signatory for the other party; typically through the R&D office.

Other
Where none of the above options are suitable, for example where the study involves a non-NHS collaborator not willing to use standard NHS templates, this should be referred to the **HoRG** and Research Contracts.

5.2 Confirmation of capacity and capability
In addition to formal agreements, confirmation of capacity and capability is typically issued by NHS organisations in England and Wales that are participating in a research study, as part of the HRA and HCRW Approval process. For sites in Northern Ireland and Scotland, the R&D Permissions process is the equivalent of this.

In some circumstances, C&C may not happen at the level of individual sites. ICBs and RDNs may also provide letters of no objection, or even confirmation, on behalf of multiple sites, particularly for primary care organisations, though this may not be formalised in the same way as NHS R&D offices and local processes can vary dramatically. ICBs and RDNs should be engaged with on an organisation-by-organisation basis, as required by their procedures; it may also be useful to refer to previous cases when dealing with them.

***However**, C&C is not required for, nor relevant to sponsorship. A mutually authorised collaboration agreement is the relevant confirmation of an organisation's involvement in the study. We can confirm sponsorship on the basis of an agreement with no C&C but **not** on the basis of C&C without an agreement.*

5.3 Material transfer agreements
A Material Transfer Agreement explains how human tissue will be moved between two parties.

Sponsored studies
The collection of samples by a research site and transfer into the University should be covered by the site agreement, i.e. the OID or mNCA.

The outwards transfer of samples, from the University to an external party, should be governed by an MTA, unless a collaboration agreement with appropriate terms already exists. The preparation of an MTA for Relevant Material is managed by the **RHTM** using existing template agreements, in consultation with the Research Contracts if adjustments are required.

Other
For non-University Sponsored studies seeking to transfer Relevant Material into the University, the **RHTM** should assess whether an MTA is required; typically, it will be the agreement of choice unless a collaboration agreement with appropriate terms already exists.

An MTA is usually also needed for Relevant Material provided by an external Research Tissue Bank. It is good practice, but at the discretion of the provider, for an agreement to be proposed in other circumstances (e.g. imported tissue, commercial supplier). Any agreement should include assurances of consent and ethical approval from the provider. Though such agreements are received and managed by Research Contracts, the **RHTM** should be notified and can assist accordingly.

Incoming Relevant Material must be held under NHS REC approval, unless already covered by an NHS REC favourable opinion that the provider holds (for instance, where the material is from an external Research Tissue Bank, or for a hosted study Sponsored by another organisation).

In all cases, the SOPs **RG SOP 6 – Sponsoring a study**, **RG SOP 7 – Registering a study**, and **RG SOP 20 – Modificationss** should be referred to as needed.

5.4 Research passports

Research passports facilitate access for non-NHS research staff to multiple NHS sites. Access checks are completed by a single NHS organisation, who then issue a passport confirming the outcome of those checks. Individual sites, presented with the passport, will then issue a letter of access, in relation to a specific study. Researchers in need of a research passport should refer to their Faculty HR and to the research site.

5.5 Service Level Agreement

The University has a standing arrangement with UHBW wherein UHBW carry out safety reporting, pharmacy services and monitoring activity for studies Sponsored by the University, even when UHBW is not acting as a site for that study.

5.6 Clinical Research Facilities (CRFs)

The access process for CRFs varies from facility to facility, and in general the researcher should engage with the facility to understand their local process. The NIHR Bristol CRF, hosted at UHBW, has a detailed guide to their access process to which RGT members should refer. At a high level, though, this can be summarised as follows:

- Study team should contact the CRF operations manager for initial discussion.
- If CRF is suitable for study, documents requested from study team, and risk assessment completed by study team and CRF operations manager.
- Study team complete SMPG review with assistance of CRF operations manager, and either HRA review process or UHBW R&D no objection process, as advised by CRF operations manager.

6. Related documents

Internal documents

RG SOP 6 – Sponsoring a study

RG SOP 7 – Registering a study

RG SOP 20 – Modifications

RG SOP 25 – Authorised signatories

RGT Study Sponsorship checklist

RGT OID guidance

External documents

HRA mNCA guidance

HRA OID guidance

HRA PIC guidance

UK Policy Framework for Health and Social Care Research

Uk Clinical Trials Regulations

The Medical Devices Regulations 2002

The Human Tissue Act (2004)