Research Governance Standard Operating Procedure 6 – Sponsoring a study

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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 the process for study Sponsorship from the point at which the decision to Sponsor has been made, through to the issue of a Sponsorship letter.

It enables members of the RGT to complete the Sponsorship process for studies in a timely, consistent matter. It also helps to ensure that the University satisfies its obligations as Sponsor, in the context of the **UK Policy Framework for Health and Social Care Research**, the MHRA's requirements for CTIMPs and CIMDs grounded in the **Medicines for Human Use (Clinical Trials) Regulations (2004)** and the **Medical Devices Regulations 2002**, and the Human Tissue Authority's requirements for research involving human tissue, based in the **Human Tissue Act 2004**.

3. Scope

This SOP explains the process for Sponsorship of studies by the University. For guidance on registration, the reader should consult **RG SOP 7 – Registering a study**.

This SOP assumes that the decision to Sponsor the study has already been made. In practice, this decision may be made in conjunction with the assessment of required study permissions and agreements described in **RG SOP 4 – Approvals and RG SOP 5 – Agreements**, and through reference to **RG SOP 3 – Deciding on Sponsorship, Registration or neither**. In deciding to Sponsor a study, and determining which permissions and agreements are needed, therefore, all three SOPs should be used together; this SOP does not aim to impose a specific order of operations, and allows for fluidity in the actual execution of the initial stages of the Sponsorship process.

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 permissions 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. For information on how to update this assessment in light of new information, see the SOPs described above.

4. Responsibilities

This SOP applies to the **RGOs** and **RHTMs** in their capacity as RGT members responsible for enacting the study Sponsorship process.

The SOP assumes familiarity with the RG SOP suite as it pertains to study Sponsorship, and the **UK Policy Framework for Health and Social Care Research**.

5. Procedure

5.1 Preliminary assessment and information gathering

Once a study has been triaged to a member of the RGT, they should make an initial assessment of what permissions and agreements will be required for the study. This can involve the output of the Research Registration Checklist, further correspondence with the researcher, and an initial information-gathering meeting. Where the Research Registration Checklist has not been completed, the RGT member should request this, and where the study is a student project (for

instance, PhD or Masters research), the RGT member should ensure that the student's supervisor has completed the CI declaration confirming the research will be carried out in line with the relevant standards, regulations and policies.

Once the RGT member has sufficient information, they can determine which permissions and agreements are needed by referring to the **RG SOP 4 – Approvals and RG SOP 5 – Agreements** respectively.

For CTIMPs and CIMDs, the respective **RHTMs** should, further to the above, attend TMG meetings to establish the nature of University involvement in the research, including the study structure (single versus multi-site), and the contractual arrangement the University has with key figures in the study, such as the CI, pharmacy, sites, PICs, and IMP supplier. This may also involve the **RHTM** arranging preliminary meetings with the trial team and relevant University functions; Procurement (the IMP, laboratory services), Research Contracts (analysis, collaboration or site agreements), HR (study personnel) or Information Governance and data.bris (data management), to name just a few examples. The **RHTM** should apprise UHBW of the planned research, and, for BTC studies, establish contact with the relevant BTC staff.

5.2 Reviewing study documents

The **RGT member** should typically review at least the study protocol (or Clinical Investigation plan for CIMDs), IRAS form .pdf output, study agreements, the consent forms, participant information and associated participant-facing material. For studies happening in more than one UK nation, the **RGT member** should refer the study team to the HRA Carrying Out Research Across Borders toolkit.

Some high-level considerations for study review are given below; more detail is available in the referenced SOPs and in the **Study Sponsorship checklist**.

- Information in the study documentation as a whole should be consistent; for instance, the protocol should align with the IRAS form.
- Protocol: At a high level, the protocol needs to be internally consistent, non-duplicative (e.g. safety reporting processes appearing in one section only), and satisfy HRA guidance. More specific information on things the protocol should contain can be found below.
    - Consent and participant information – see **RG SOP 11 – Consent processes.**
    - Quality events – see **RG SOP 8 – Quality events**.
    - Safety reporting – see **RG SOP 9 – Safety reporting**.
    - Archiving – see **RG SOP 13 – Archiving and destruction**.
    - Study closedown – see **RG SOP 14 – Study closedown**, section 5.1.
- IRAS form output
    - Ensure the IRAS project filter is completed correctly and captures the intentions of the study; the permissions identified through use of **RG SOP 4 – Approvals** should be reflected in the IRAS form output.
- Consent form, participant information, other participant-facing material (where applicable) – see **RG SOP 11 – Consent processes**.
- Agreements (where applicable) – see **RG SOP 5 – Agreements**.
- CAG application (where applicable) – see **RG SOP 15 – Confidentiality advisory group**.
- Insurance – see **RG SOP 12 – Insurance**.

The RGT member must also make sure appropriate peer review is in place, using the instructions in **RG SOP 10 – Peer review**.

Complex data matters (i.e. those outside the scope of the **RG SOP 13 – Archiving and destruction** and **RG SOP 15 – Confidentiality advisory group**) should be referred to the Information Governance team at data-protection@bristol.ac.uk. The RGT member can refer the study team to the University's data protection webpages, but these matters are not otherwise within the Research Governance remit.

A Schedule of Events or Schedule of Events Cost Allocation Tool explains the costs associated with different study activities being carried out by a site. The RGT member should ensure there is an SoE/SoECAT for each OID type:

- NIHR portfolio studies, and non-portfolio studies involving reimbursement to the NHS, require an SoECAT.
- Less commonly, where there is no or non-standard payment, use of an SoE or just an OID may be agreed.

However, specific review of or guidance on the SoE/SoECAT should be provided by Research Finance, or where applicable by AcoRD specialists within the RDN.

For CTIMPs, the **RHTM for CTIMPs** should, further to the above, request the Combined Review form (rather than the IRAS form), Investigator Brochure, SmPC/IMPD (as applicable), labels, emergency card and other documents as further described in **RG SOP 21 – CTIMP Management**. As study set-up progresses, operational documents such as Delegation Log, Case Report Forms, Manuals and key study SOPs will be requested for review. More detailed guidance on CTIMP review by the **RHTM** is in the **Study Sponsorship checklist**.

For CIMDs, the **RHTM for CIMDs** should, further to the above, confirm the classification and categorization of the device. They should review the application to be submitted to the MHRA. They should also request and scrutinise the Investigator Brochure and documentation establishing the testing and safety of the device.

For studies involving relevant material, as defined in the Human Tissue Act 2004, the **RHTM** should again follow the processes described in the above SOPs; moreover, they should ensure assurance as to the ethical provenance and consent arrangements of any non-UoB sourced tissues, and an exit strategy for the relevant material upon conclusion of the study.

If the **RGT member** is satisfied with the study documents they should proceed to the instructions on IRAS form submission below.

If the **RGT member** review identifies issues, they should return the documents to the study team with comments on the necessary changes. If the changes required are minor, they may permit the study team to make the changes and submit the IRAS form without further RGT review. If the changes required are substantial, they should request that the study team refer the updated documents back to the **RGT member** for further assessment, using the instructions in this section.

5.3 Submission to study review bodies

Once satisfied with the quality of the study documentation, the **RGT member** should confirm this to the study team, and ask the team to validate their IRAS form and request authorisation of

the IRAS form via the joint email address (research-governance@bristol.ac.uk). The **RGT member** should authorise the form, download it and save it to the F2 case. They should also request from the study team a copy of all documentation that has been submitted for review, and save this to the F2 case.

The **RGT member** should now sign and return the OID. If an mNCA is used in addition to the OID, the study team must have an approved version from the Research Contracts Team to be included in their submission; they are not permitted to finalise the mNCA themselves.

The RGT member can now provide the insurance letter to the study team, following the guidance in **RG SOP 12 – Insurance.**

For CTIMPs and CIMDs, once the study documents have been submitted to review bodies, the respective **RHTMs** can begin drafting a Green Light Plan document.

5.4 Receipt of approvals

Following submission of the IRAS Form and study documentation, the bodies described above and in **RG SOP 4 – Approvals** (for instance, the NHS REC, HRA, MHRA, CAG) will validate and review the study documents. Among other things, these bodies may request further information, changes to the documentation, or issue approvals conditional on particular changes or actions. The **RGT member** should offer to support the study team in replying to such matters.

In parallel to review by the bodies described above and in **RG SOP 4 – Approvals**, the **RGT member** should offer support to the study team in seeking the necessary permissions from participating organisations as outlined in **RG SOP 5 – Agreements.**

As relevant approvals and permissions are received, the **RGT member** should update the case guide, and the research team and **RGT member** should complete any outstanding requests in the approval letters. When all approvals are in place, the **RGT member** should now move to the 'signing of Sponsorship letter' process below. Where multiple permissions from participating organisations are required, it may be appropriate to provide initial Sponsorship based on one or more initial organisations, and update as more are added.

If all relevant approvals are not received, the research team should apply any feedback from the relevant committees, in collaboration with the **RGT member** as required, before resubmitting.

5.5 Initial signing of Sponsorship letter

Once all the required Study approvals and agreements are in place, the RGT member can prepare a Sponsorship letter for signature, using the templates in the 'Templates – full Sponsorship' folder within the Research Governance on the University filestore.

The relevant **RGT member** can now send the following documents (using the F2 'Gather docs for review' task if preferred) to the **HoRG (**or their delegate, in accordance with **RG SOP 25 – Authorised Signatories**) to request review of the documents, and review and signature of the Sponsorship letter:

- Draft Sponsorship letter
- Authorised IRAS form

- Letters of approval (if applicable)
    - REC favourable opinion letter
    - HRA approval letter
    - MHRA CTA (CTIMP) or Clinical Investigation approval (CIMD)
    - Confirmation of capacity and capability (NHS organisations) or equivalent organisational approvals (non-NHS organisations). The minimum required for confirmation of C&C is the return of a signed agreement (OID, PICa or equivalent), but a Trust's R&D department or an ICB may prefer to issue a more formal C&C in addition, and may prefer for that to be the time point at which C&C is considered confirmed – non-NHS organisations may have other processes. We can accommodate these preferences so long as they are clearly communicated (either on a case-by- case basis or as the general preference of a regular collaborator). Sites / PICs can be added to the Sponsorship letter as C&C is provided; see section 5.7 for details.
    - CAG approval letter
    - Green Light Process document (CTIMPs and CIMDs only)
    - Insurance confirmation (if not PL/CT standard, but CT confirmed)
- Evidence of peer review (where this has been solicited as distinct to funder peer review, in line with **RG SOP 10 – Peer review**)

When the **HoRG** is satisfied that the study is ready to proceed, they should sign the Sponsorship letter using DocuSign and return the letter to the relevant **RGT member**.

5.6 Issue of Sponsorship letter

Sites are greenlit upon issue of the Sponsorship letter with that site named upon it; the RGT provide no greenlight authorisation over and above this. If the RGT member receives queries to this effect, they may refer the study team to the bolded paragraph explaining this in the Sponsorship letter.

Once the letter has been issued, a copy of the record should be filed on F2 and the case guide updated.

Issue of the Sponsorship letter is also a useful opportunity for the RGT member overseeing this study to remind the study team of their responsibility to register the study, in line with **RG SOP 16 – Registries and transparency**, and broader HRA/MHRA and open research/transparency standards.

The date of issue of the Sponsorship letter is the agreed point at which study conduct can begin. The sponsorship letter should not, under any circumstances, be backdated.

5.7 Issue and signing of further Sponsorship letters

In the following three cases, the Sponsorship letter must be issued anew with an updated signature.

- Organisations named on the original IRAS form, but not on the initial Sponsorship letter, that have now provided C&C and associated OID/mNCA and are ready to begin activity.
- Organisations not named on the original IRAS form, but which have been added via amendment and now provided C&C and associated OID/mNCA and are ready to begin activity.

- An amendment has been applied to the study which involves a significant change in the nature or management of the study. This only applies in exceptional circumstances; most amendments will be confirmed by email (see **RG SOP 20 – Amendments**).

In these three scenarios, the **RGT member** responsible for the study is permitted to sign, using DocuSign, the updated Sponsorship letter in line with the following process:

- Organisation and organisation type (site; PIC; other) is listed on the IRAS form or the subject of an amendment.
- Agreements appropriate to the organisation type are in place, in with **RG SOP 5 – Agreements.**
- The organisation has been added to the Sponsorship letter in line with the template formatting.

The letter must be issued to the study team, those sites on the letter, and filed on the F2 case.

6. Related documents

Internal documents

Sponsorship letter template

Study sponsorship checklist

RG SOP 2 – Triaging new study

RG SOP 3 – Deciding on Sponsorship, Registration or neither

RG SOP 4 – Approvals

RG SOP 5 – Agreements

RG SOP 8 – Quality events

RG SOP 9 – Safety reporting

RG SOP 10 – Peer review

RG SOP 11 – Consent processes

RG SOP 12 – Insurance

RG SOP 13 – Archiving and destruction

RG SOP 14 – Study closedown

RG SOP 15 – Confidentiality advisory group

RG SOP 16 – Registries and transparency

RG SOP 20 – Amendments

RG SOP 21 – CTIMP Management

RG SOP 25 – Authorised Signatories

External documents

UK Policy Framework for Health and Social Care Research

The Medicines for Human Use (Clinical Trials) Regulations (2004)

The Medical Devices Regulations 2002