Research Governance Standard Operating Procedure 4 – Approvals

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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 RGT members should determine which study approvals are required as part of the Study Sponsorship process. In doing so, it ensures the University is compliant with its obligations within the UK Policy Framework for Health and Social Care Research, the Medicines for Human Use (Clinical Trials) Regulations (2004), Medical Devices Regulations (2002), Human Tissue Act 2004 and Good Clinical Practice more broadly.

3. Scope

This SOP is primarily for the purposes of studies that are undergoing Sponsorship; however, decisions as to whether a study should be Registered may also require the assessment in section 5.1. It should be used in conjunction with **RG SOP 3 – Deciding on Sponsorship, Registration or neither**.

4. Responsibilities

This SOP is for the **RHTMs** and **RGOs** in assessing studies for Sponsorship. It assumes familiarity with relevant guidelines, regulations and policies.

5. Procedure

The RGT member should use the criteria below to determine which study permissions are needed. All human participant research requires ethical review; a study may need one or more additional approvals, depending on what it involves – see below:

5.1 Ethics review

All research involving human participants, their tissue or their data requires ethical review, though the exact nature of review depends on the research. The **RGT member** should use the below decision procedure:

1) If the study involves the use of relevant material, it will almost always require ethical review by an NHS REC to comply with the Human Tissue Act (except where the **RHTM** has confirmed in writing that submission of an OREMS application for University REC review is appropriate).

2) If the joint HRA/MRC **"Do I need NHS REC review?"** tool determines that NHS REC review is required, the **RGT member** should advise the applicant that an IRAS application will be required.

3) If not, but the study will involve human participants or their data, the **RGT member** should advise the applicant to **submit an OREMS application for University REC review**.

4) If it is determined that the study will not involve human participants or their data, the applicant should be advised that routine ethical review is not required. In certain circumstances University REC review may be required for other reasons (e.g. environmental impact) but that is beyond the scope of this procedure.

5.2 HRA review

Broadly, if the study will involve NHS staff as participants, *recruited as a result of their NHS role*, or otherwise use NHS resources such as facilities, equipment or staff time; it will require approval from the Health Research Authority and/or Health and Care Research Wales

(henceforth *HRA review*), to ensure appropriate legal and governance arrangements are in place.

More specifically, the **RGT member** should assess whether the study involves:

- NHS organisations acting as sites/PICs
- Research procedures/visits happening at NHS sites
- Research procedures using NHS equipment, premises or facilities (see 5.7 below on CRFs)
- Research procedures requiring the time of NHS staff, in their NHS capacity (as research delivery staff, as participants, or both)

If yes, HRA review is required.

If no, does the study involve:

- Social care organisations acting as sites / PICs
- Research procedures / visits at social care sites
- Research procedures using social care equipment or facilities
- Research procedures requiring the time of social care staff, in their social care capacity (as research delivery staff, as participants, or both)

If yes, and the organisation is NHS funded, HRA review is required and should be applied for through IRAS. If yes, but the organisation is not NHS funded, HRA review may still be required and the **RGT member** should review in further detail, conferring with RGT and ICB colleagues as needed.

Otherwise, HRA review is not required.

5.3 MHRA review

The Medicines and Healthcare Products Regulatory Agency is a national oversight body which oversees the safe and appropriate use of medicinal products and medical devices in the UK. This includes responsibility for overseeing research conducted in accordance with the Medicines for Human Use (Clinical Trials) Regulations and the Medical Device Regulations. In determining whether MHRA approval is required, the **RGT member** should apply the below decision procedure:

- Is the study a Clinical Trial of an Investigational Medicinal Product (CTIMP), **as defined in the MHRA algorithm** (broadly speaking, a study which will generate new information about the safety and/or efficacy of a medicinal product)?
    - If so, it will require review by the MHRA, via Combined Review. In this case, Combined Review will take the place of IRAS in seeking all other relevant approvals described in this procedure.
    - This study will be overseen by the **RHTM (CTIMPs)**

- Does the study involve:
    - A non-CE/UKCA marked medical device?
    - A CE/UKCA marked medical device which has been modified or is being used outside of its current intended purpose?

- A CE/UKCA marked medical device being used within its intended purpose, but involving a change to standard care?
  - If so, the study will require further review by the **RHTM (CIMDs)** to determine whether the study is a Clinical Investigation of a Medical Device, by asking:
    - Will the study generate information about the device which will, or may, be used to support the licencing, change of licence or marketing of the device?
      - If so, the study will require review by the MHRA, applied for via IRAS. This will require significant input about the nature of the device, typically from the manufacturer. The study will be overseen by the **RHTM (CIMDs)**.
      - If not, the study will not require review by the MHRA, but may need additional support. The **RHTM CIMDs** and the **RGO**s should determine between them who will oversee the study.

If a study is a CTIMP *and* involves a medical device, it follows the process for a CTIMP but will require input from both **RHTM**s.

5.3.1 Pharmacy Assurance

Pharmacy Assurance is a standardised process to confirm that relevant pharmacies can comply with the needs of a study and the requirements of the Clinical Trials Regulations. It is intended to streamline the site setup process. CTIMPs with multiple NHS secondary care sites can apply for pharmacy assurance prior to IRAS submission. This is generally managed by the trial team, the **RHTM** can advise if required.

5.4 CAG review

Researcher access to identifiable healthcare information requires consent from the person whose data is being accessed. However, section 251 of the NHS Act 2006 allows the Secretary of State for Health to grant access without consent, in specific circumstances. In practice, permission is sought by applying to the Confidentiality Advisory Group, via IRAS (more detailed information is in **RG SOP 15 – Confidentiality Advisory Group**).

In determining whether CAG review is needed, the **RGT member** should apply the following decision procedure:

- Does the study involve accessing any NHS data (e.g. healthcare records, demographic data, lab results, imaging, recordings or transcripts of consultations or talking therapies, etc.) of individuals without their consent?
- Is there no way to conduct the study without doing so?
  - If the answer to both questions is yes, CAG review should be applied for through IRAS; again, referring to **RG SOP 15 – Confidentiality Advisory Group**.
  - If the answer to the first is Yes, but the answer to the second is uncertain, this should be discussed further with the research team - as CAG approval will only be granted if it is absolutely necessary.

Note, this process specifically applies to NHS data. All other handling of participants' identifiable data must be managed in accordance with all applicable Data Protection legislation.

5.5 HMPPS review

His Majesty's Prison and Probation Services (HMPPS) are responsible for prisons and probation in England and Wales. Where the study may involve people under their jurisdiction, the **RGT member** should apply the following decision procedure:

- Does the study involve participants who have been identified or selected because they are currently incarcerated, on parole, or an employee of HMPPS?
    - If yes, this study will require HMPPS approval, which should be applied for through IRAS.

5.6 Non-NHS management approvals

Research in settings not specifically covered above (e.g. schools, charities, other public services, non-NHS social-care) will often still require some form of oversight and/or approval, though the approvals route may not be as formalised as in the NHS setting. The study team and RGT member should work with the organisation to understand what arrangements are required for study to be conducted.

The RGT member should also refer to **RG SOP 5 – Agreements.**

5.7 CRF

Information on the process for accessing the NIHR Bristol CRF, and CRFs more generally, can be found in **RG SOP 5 – Agreements.**

6. Related documents

Internal documents

RG SOP 3 – Deciding on Sponsorship, Registration or neither

RG SOP 5 – Agreements

RG SOP 6 – Sponsoring a study

RG SOP 15 – Confidentiality advisory group

External documents

ICH E6 (R2) GCP

UK Policy Framework for Health and Social Care Research

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

The Medical Devices Regulations 2002

The NHS Act 2006