Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Sponsorship of UK research studies**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) describes the necessary arrangements that researchers must adhere to, to ensure that studies involving human subjects are appropriately sponsored and indemnified in accordance with the UK Policy Framework for Health and Social Care (2017).

The University does not Sponsor Clinical Trials of Investigational Medicinal Products (CTIMPs). Clinical Investigations of Medical Devices or studies that are defined as Level 4b risk level in the Regulations for Research Involving Human Participants must be submitted to the University Executive Board for consideration and a determination regarding sponsorship.

2. Scope

This SOP applies to all studies where the University is acting in the capacity of Sponsor, or Co-Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

3. Responsibilities

3.1 Chief Investigator

The Chief Investigator (CI) is responsible for ensuring that the research has been through the appropriate research governance arrangements as specified in the University's Regulations relating to Research Involving Human Participants and, if necessary, with the host Health and Social Care (HSC) Trust.

The CI must ensure that the study is logged onto the Insurance Database and that the correct level of risk is designated to the proposed research. The risk levels are detailed in the Regulations for Research Involving Human Participants

4. Procedure

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QUB SUMMARY OF PROCESS TO APPLY FOR NHS/HSC REC & HSC R&D APPROVAL

Contact QUB Research Governance and relevant HSC Trust R&D Office(s) at an early stage for advice.

- Complete IRAS application form
- Complete online Data Privacy Impact Assessment as required - Information Compliance can provide advice if needed
- Draft protocol and supporting documentation as applicable (eg consent form, participant information sheet, questionnaires, semi-structured interview questions or topic guides)
- Identify and secure involvement of Principal Investigator(s)/Local Collaborator(s) in HSC Trust(s)
- Complete Outline Organisation Information Document (OID) and Schedule of Events (SoE), if applicable (*If a PIC LIP not required*)
- Collect CVs for research team
- Seek Peer Review (as applicable – see Peer Review)
- Ensure GCP training is up to date (if required)

Submit the following to **QUB Research Governance** (researchgovernance@qub.ac.uk):

- Draft IRAS form
- Protocol
- Supporting documentation, as applicable
- Peer review comments & responses as applicable
- CVs for research team (Chief Investigator, research students & academic supervisors)
- Draft Outline OID and SoE

Contact the **HSC Trust R&D Office(s)** regarding the application to discuss feasibility, identify a lead trust for multi-centre studies, confirm requirements for honorary contracts/placement agreements & ACCESS NI checks, GCP certificates etc. See Guidance for Applicants.

QUB Research Governance Manager will review the application and liaise with the lead Trust R&D Office to determine sponsorship

Feedback/comments addressed and sponsorship arrangements confirmed

Upload all final documents to IRAS Form checklist & obtain electronic authorisations for IRAS form

Complete IRAS verification process, book in application online and electronically submit application
REC Manager/Research Gateway will confirm valid application.

NHS REC & HSC R&D APPROVAL PROCESSES RUN CONCURRENTLY

NHS/HSC REC

Application reviewed by full committee (within 60 days) or Proportionate Review (within 14 days)

Advised of REC decision (via email):

- Favourable opinion with conditions
- Favourable opinion
- Provisional opinion - respond to the REC and submit the further information requested via IRAS (clock stops whilst awaiting a response). Send copies of any updated documentation to QUB Research Governance
- Unfavourable opinion - modify application and resubmit

For QUB sponsored studies CI enters study on QUB Insurance Database

HSC R&D Local Site Documentation

Notification application is valid received from Research Gateway
(If a PIC site a LIP not required and m-NC-PICA should be used)

Email (using the template NI email) the following to each HSC participating site:

- Localised Organisation Information Document
- Copy of submitted IRAS Form
- Current Protocol
- Participant information and consent documents (without local logos/ headers) as relevant to the activities taking place at the participating NHS / HSC organisation
- Relevant model agreement, if applicable
- SoE or SoECAT
- Delegation log (mandatory for all interventional studies with PI)

Copy QUB Research Governance Manager on email

Application review by HSC Trust R&D office

Sponsor and HSC Trust R&D Office(s) agree and finalise the localised OID with PI local research team, networks/specialty groups

HSC Trust R&D Office(s) issue confirmation of capacity and capability

QUB SUMMARY OF PROCESS TO APPLY FOR NHS/HSC REC APPROVAL

Contact QUB Research Governance at an early stage for advice.

- Complete IRAS application form
- Complete Privacy Impact Assessment pre-screening questionnaire and Data Privacy Impact Assessment as required - Information Compliance can provide advice if needed
- Draft protocol and supporting documentation as applicable (eg consent form, participant information sheet, questionnaires, semi-structured interview questions or topic guides)
- Collect CVs for research team (Chief Investigator, research students & academic supervisors)
- Seek Peer Review (as applicable – see Peer Review)

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Submit the following to **QUB Research Governance** (researchgovernance@qub.ac.uk):

- Draft IRAS form
- Protocol
- Supporting documentation, as applicable
- Peer review comments & responses as applicable
- CVs for research team (Chief Investigator, research students & academic supervisors)

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QUB Research Governance Manager will review the application to determine sponsorship

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Feedback/comments addressed and sponsorship arrangements confirmed

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Upload all final documents to IRAS Form checklist & obtain electronic authorisations for IRAS form

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Complete IRAS verification process, book in application via Central Booking Service and electronically submit application
REC Manager will confirm valid application

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NHS/HSC REC

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Application reviewed by full committee (within 60 days) or Proportionate Review (within 14 days)

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Advised of REC decision (via email):

- Favourable opinion with conditions
- Favourable opinion
- Provisional opinion - respond to the REC and submit the further information requested via IRAS (clock stops whilst awaiting a response). Send copies of any updated documentation to QUB Research Governance
- Unfavourable opinion - modify application and resubmit

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CI enters study on QUB Insurance Database on QOL

QUB SUMMARY OF PROCESS TO APPLY FOR NHS/HSC R&D APPROVAL

NHS/HSC REC APPROVAL PROCESSES RUN CONCURRENTLY

Application submitted on IRAS with outline OID

NHS/HSC R&D Local Site Documentation
***PICs** - LIP not required and the model Non-Commercial PIC agreement (m-NC-PICA) should be used*

Northern Ireland

Notification application is valid received from Research Gateway

Localise OID and compile LIPs for each HSC Trust

Email (using the NI template email) the following to each participating HSC Trust:

- Localised Organisation Information Document
- Copy of submitted IRAS Form
- Protocol and any amendments
- PIS and ICF (without local logos/ headers)
- Model agreement, if applicable
- SoE or SoECAT
- Delegation log (mandatory for all interventional studies with PI and if not supplied indicate when it will be made available)

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Sponsor and HSC Trust R&D Office(s) agree and finalise the localised OID with PI local research team, networks/specialty groups

HSC Trust R&D Office(s) issue confirmation of capacity and capability

Scotland

Notification application is valid received from NRS Permissions Coordinating Centre

Localise OIDs for each NHS Trust and compile LIP

Email (using the Scotland template email) the following to NRS Permissions Coordinating Centre (nhsg.NRSPCC@nhs.net):

- Localised Organisation Information Document(s) for all participating NHS sites in Scotland
- Model agreement, if applicable
- SoE or SoECAT
- Delegation log mandatory for all interventional studies with PI and if not supplied indicate when it will be made available)

Note: there is no requirement to resend documents submitted with the IRAS Form

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Sponsor and NHS Trust R&D Office(s) agree and finalise the localised OID with PI local research team, networks/specialty groups

NHS Trust R&D Office(s) issue confirmation of capacity and capability

England and Wales

Initial Assessment or HRA and HCRW Approval Letter received (HRA)

Localise OID and compile LIPs for each NHS Trust

Email (using the England/Wales template email) the following to each participating NHS Trust:

- Localised Organisation Information Document
- HRA and HRCW Initial Assessment Letter (or HRA and HCRW Approval letter if available)
- Copy of submitted IRAS Form
- Protocol and any amendments
- PIS and ICF (without local logos/ headers)
- Model agreement, if applicable
- SoE or SoECAT
- Delegation log (mandatory for all interventional studies with PI and if not supplied indicate when it will be made available)

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Sponsor and NHS Trust R&D Office(s) agree and finalise the localised OID with PI local research team, networks/specialty groups

NHS Trust R&D Office(s) issue confirmation of capacity and capability

Version 2.0

QUB SUMMARY OF PROCESS TO APPLY FOR FACULTY REC & HSC R&D APPROVALS

Contact QUB Research Governance and relevant HSC Trust R&D Office(s) at an early stage for advice.

- Complete IRAS application form
- Draft protocol and supporting documentation as applicable (eg consent form, participant information sheet, questionnaires, semi-structured interview questions or topic guides)
- Identify and secure involvement of Principal Investigator(s)/Local Collaborator(s) in HSC Trust(s)
- Complete Outline Organisation Information Document (OID) and Schedule of Events (SoE), if applicable (*If a PIC LIP not required*)
- Collect CVs for research team
- Seek Peer Review (as applicable – see Peer Review)
- Ensure GCP training is up to date (if required)

Submit the following to the appropriate Faculty REC - EPS (facultyreceps@qub.ac.uk) or MHLS (facultyrecmhls@qub.ac.uk):

- Draft IRAS form
- Protocol
- Supporting documentation, as applicable
- Peer review comments & responses as applicable
- CVs for research team (Chief Investigator, research students & academic supervisors)
- Draft Outline OID and SoE (*if a PIC not required*)

Contact the **HSC Trust R&D Office(s)** regarding the application to discuss feasibility, identify a lead trust for multi-centre studies, confirm requirements for honorary contracts/placement agreements & ACCESS NI checks, GCP certificates etc. See Guidance for Applicants.

Faculty REC and QUB Research Governance Manager will review the application

Feedback/comments addressed and sponsorship arrangements confirmed

Upload all final documents to IRAS Form checklist & obtain electronic authorisations for IRAS form

Book in application via Central Booking Service and electronically submit application
Research Gateway will confirm valid application.

HSC R&D Approval

Notification application is valid received from Research Gateway
(If a PIC site a LIP not required and m-NC-PICA should be used)

Email (using the template NI email) the following to each HSC participating site:

- Localised Organisation Information Document
- Copy of submitted IRAS Form
- Current Protocol
- Participant information and consent documents (without local logos/ headers) as relevant to the activities taking place at the participating NHS / HSC organisation
- Relevant model agreement, if applicable
- SoE or SoECAT
- Delegation log (mandatory for all interventional studies with PI)

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Application review by HSC Trust R&D office

Sponsor and HSC Trust R&D Office(s) agree and finalise the localised OID with PI local research team, networks/specialty groups

HSC Trust R&D Office(s) issue confirmation of capacity and capability

QUB SUMMARY OF PROCESS TO APPLY FOR SCHOOL REC & HSC R&D APPROVALS

Contact QUB Research Governance and relevant HSC Trust R&D Office(s) at an early stage for advice.

- Complete IRAS application form
- Draft protocol and supporting documentation as applicable (eg consent form, participant information sheet, questionnaires, semi-structured interview questions or topic guides)
- Identify and secure involvement of Principal Investigator(s)/Local Collaborator(s) in HSC Trust(s)
- Complete Outline Organisation Information Document (OID) and Schedule of Events (SoE), if applicable (*If a PIC LIP not required*)
- Collect CVs for research team
- Seek Peer Review (as applicable – see Peer Review)
- Ensure GCP training is up to date (if required)
- Complete School REC application if required (see Policy on the Ethical Approval of Research)

When the application has been reviewed by School REC and ethical approval obtained, submit the following to researchgovernance@qub.ac.uk:

- Draft IRAS form
- Protocol
- Supporting documentation, as applicable
- Confirmation of Ethical Approval from the School
- Peer review comments & responses, as applicable
- CVs for research team (Chief Investigator, research students & academic supervisors)
- Draft Outline OID and SoE (*if a PIC not required*)

Contact the **HSC Trust R&D Office(s)** regarding the application to discuss feasibility, identify a lead trust for multi-centre studies, confirm requirements for honorary contracts/placement agreements & ACCESS NI checks, GCP certificates etc. See Guidance for Applicants.

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QUB Research Governance Manager will review the application

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Feedback/comments addressed and sponsorship arrangements confirmed

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Upload all final documents to IRAS Form checklist & obtain electronic authorisations for IRAS form

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Book in application via Central Booking Service and electronically submit application
Research Gateway will confirm valid application.

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HSC R&D Approval

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Notification application is valid received from Research Gateway
(If a PIC site a LIP not required and m-NC-PICA should be used)

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Email (using the template NI email) the following to each HSC participating site:

- Localised Organisation Information Document
- Copy of submitted IRAS Form
- Current Protocol
- Participant information and consent documents (without local logos/ headers) as relevant to the activities taking place at the participating NHS / HSC organisation
- Relevant model agreement, if applicable
- SoE or SoECAT
- Delegation log (mandatory for all interventional studies with PI)

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Application review by HSC Trust R&D office

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Sponsor and HSC Trust R&D Office(s) agree and finalise the localised OID with PI local research team, networks/specialty groups

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HSC Trust R&D Office(s) issue confirmation of capacity and capability

QUB SUMMARY OF PROCESS TO APPLY FOR HBS, NHS/HSC REC & HSC R&D APPROVALS

Contact Honest Broker Service and QUB Research Governance at an early stage for advice.

- Before requesting access to health data, you need to demonstrate that everyone involved in the project has appropriate information governance training (see Becoming an approved researcher through the ONS approved researcher scheme)

Application for HSC Regional Data Warehouse data

- Submit a draft of the application to HBS (hbs@hscni.net) and work with HBAS to finalise the application for submission
- Seek Peer Review (as applicable – see Peer Review Gov4 forms or provide confirmation of externally funded research)

Submit the following to **QUB Research Governance** (researchgovernance@qub.ac.uk):

- Final HBS application
- Peer review comments and responses, as applicable

QUB feedback/comments addressed and sponsorship confirmed

QUB Research Governance Manager will sign the HBS application on behalf of the Sponsor (Section A, 2)

Application for a project involving linking external datasets to HSC Regional Data Warehouse data

- Submit a draft of the application to HBS (hbs@hscni.net) and work with HBAS to finalise the application for submission
- Ensure agreements/arrangements are in place to transfer the external data
- Draft IRAS form, protocol and supporting documentation, as applicable
- Seek Peer Review (as applicable – see Peer Review Gov4 forms or provide confirmation of externally funded research)
- If the data to be linked is **held in HSC Trusts then an application for Trust governance must be made** See Guidance for Applicants) and:
  - Identify and secure involvement of PI(s)/LC(s) in HSC Trust(s)
  - Complete OID and SoE

Submit the following to **QUB Research Governance** (researchgovernance@qub.ac.uk):

- Draft IRAS form
- Final HBS application
- Protocol and supporting documentation, as applicable
- Peer review comments & responses, as applicable
- CVs for research team (CI, research students & academic supervisors)
- Draft Outline OID and SoE (if HSC Trusts involved)

QUB feedback/comments addressed and sponsorship confirmed

Upload all final documents to IRAS Form checklist & obtain authorisations for IRAS and QUB RGM will sign the HBS application on behalf of the Sponsor (Section A, 2)

Complete IRAS verification process, book in application online and electronically submit. REC Manager/Research Gateway will confirm valid application

APPROVAL PROCESSES CAN RUN CONCURRENTLY

HBS

Submit final signed application to HBS, along with peer review (and REC approval once received and if required)

Governance Board review application

Research Data Access Agreement, agreed and signed (Information Compliance Info.Compliance@qub.ac.uk are the institutional signatory for QUB)

Once all necessary approvals and agreements are in place data is extracted/linked

NHS/HSC REC

Application reviewed by Proportionate Review (within 14 days)

Advised of REC decision (via email):

- Favourable opinion with conditions
- Favourable opinion
- Provisional opinion - respond to the REC and submit the further information requested via IRAS. Send copies of any updated documentation to QUB Research Governance
- Unfavourable opinion - modify application and resubmit

For QUB sponsored studies CI enters study on QUB Insurance Database

HSC R&D

Notification application is valid received from Research Gateway

Email (using the template NI email) the following to each HSC participating site:

- Localised OID
- Copy of submitted IRAS Form
- Current Protocol
- SoE or SoECAT

cc QUB Research Governance Manager

Application review by HSC Trust R&D office

Sponsor and HSC Trust R&D Office(s) agree and finalise the localised OID with PI, local research team

HSC Trust R&D Office(s) issue confirmation of C&C

5. References

UK Policy Framework for Health and Social Care 2017
https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Final_Accessibility_uk-policy-framework-health-social-care-research_.pdf (last accessed September 2021)

HRA CV template: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/ (last accessed September 2021)

QUB Research Governance, Ethics and Integrity Sponsorship
https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Sponsorship/ (last accessed September 2021)

6. Work Instructions

Work Instructions 1 – Funding for Research
Work Instructions 2 – Research Governance Sponsorship Review
Work Instructions 3 – Research Sponsor
Work Instructions 4 – Indemnity Arrangements
Work Instructions 5 – Permission to Start

Work Instructions 1 – Funding for Research

1. Where external funding is sought for a research study, the CI should liaise with the relevant Research Development Manager/Officer assigned to your Faculty in R&E and Faculty Finance.
2. It is at this early opportunity that an assessment is made as to whether the research involves human participants, their data and/or the health service, and whether there are any pertinent ethical implications. Research Governance (researchgovernnnance@qub.ac.uk) must be contacted at an early stage when the funding application requires Sponsor acknowledgment/approval and the intention is for the University to Sponsor.
3. A draft of the funding application must be submitted to Research Governance in order to confirm the University can undertake the role of Sponsor if awarded.

Work Instructions 2 – Research Governance Sponsorship Review

1. The researcher must submit the documentation as listed on the relevant flowchart above to the University's Research Governance Team (researchgovernance@qub.ac.uk):
2. On receipt of the complete set of the required documentation, the Research Governance shall assign a unique identification number and inform the research team of the Research Governance Manager allocated the application review.
3. All studies with a level 4b insurance risk must be reviewed by University Executive Board (UEB). The UEB must approve all such studies before the University will assume the role of Sponsor. The research team must provide all documentation as requested and attend the meeting if required.

Work Instructions 3 - Research Sponsor

1. The Research Governance Team will liaise with the Trust and negotiate the appropriate sponsorship arrangements and the division of same, when necessary. The Memorandum of Understanding for Research Governance between the University and Trust(s) will be applied on a case by case basis.
2. The CI will receive written notification of either full sponsorship by the Trust or University, or that the two organisations have entered into a co-sponsorship arrangement. In the event of a co-sponsorship agreement the CI will be required to sign the co-sponsorship agreement. All researchers must comply with the requirements of a co-sponsorship agreement.
3. Where the University is the sole sponsor, the CI will be advised of the same through a formal letter of sponsorship. This letter will outline the University's requirements of the CI to ensure that the necessary indemnity arrangements are in place and will be accompanied by a Terms of Sponsorship memo containing the University's expectations for research integrity and legislative compliance.

Work Instructions 4 - Indemnity arrangements

1. All research must be appropriately insured prior to commencement. The current 'clinical trials' insurance policy provides for both Negligent and Non-Negligent Harm.
    - *Negligent Harm*: Any action or process that is held by a court to have caused harm as a result of lack of due diligence, lack of care, omission or duty or an act of carelessness towards a participant in a research study.
    - *Non-negligent Harm*: Circumstances where there is no specifically identified causative factor relating to the harm of a participant in a research project, but harm is likely, on the balance of probabilities, to have arisen from the participant taking part in the research.

2. Research Governance will assess the level of indemnity/insurance cover required for a sponsored research study as part of the sponsorship request process prior to confirming sponsorship.
3. There are certain exclusions within the University's Clinical Trials insurance policy. Where the University is Sponsor and exclusions apply, the Research Governance Manager reviewing the study for sponsorship will liaise with the University insurer and /or the University's Insurance Office, as appropriate to determine cover.

Work Instructions 5 - Permission to Start

1. The study must not commence until the CI, or site PI, is in receipt of the appropriate permissions documentation from the University and/or other interested parties (see Green Light SOP RGEI-).