

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 Privacy Impact Assessment [pre-screening questionnaire](#) and [Privacy Impact Assessment](#) and [Privacy Notice](#) 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
- [Privacy Notice](#), if required
- 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 via [Central Booking Service](#) and electronically submit application
REC Manager/Research Gateway will confirm valid application.

NHS/HSC REC

HSC R&D Local Site Documentation

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

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:

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

- 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

NHS REC & HSC R&D APPROVAL PROCESSES RUN CONCURRENTLY