

QUB SUMMARY OF PROCESS TO APPLY FOR NHS 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 and SSI forms (if applicable)
- 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)
- 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):

- 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)

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 and Trust specific forms (eg RAF, PIAF) etc. See [Guidance for Applicants](#).

QUB Research Governance Manager will review your application

QUB Research Governance & the lead Trust R&D Office will liaise to determine suitable [sponsorship](#) arrangements for the study

Feedback/comments addressed and sponsorship arrangements confirmed

Upload all final documents to IRAS Form checklist & obtain electronic authorisations for IRAS form
If applicable, upload documents to **non-NHS** SSI checklist(s) & obtain electronic authorisations

Complete IRAS verification process

Book in application via [Central Booking Service](#) and electronically submit application
REC Manager will confirm valid application within 5 working days & the Research Gateway will distribute the IRAS form and documents to the NHS/HSC Trust(s)

NHS REC

**NHS/HSC R&D
Local Site Documentation**

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

Complete SSI checklist(s) & obtain electronic authorisation for the SSI form(s) *(If a PIC site SSI forms are not required)*

Once signed by PI, complete 'proceed to submission' process in IRAS to lock and create final NHS/HSC SSI

Email final SSI form, associated checklist and local documentation listed to [local Trust R&D Office](#). Include any Trust specific documentation (RAF, PIAF etc)

Application undergoes validation & review (further information may be requested by HSC Trust R&D office)

HSC Trust R&D Office(s) issue governance approval letter

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

NHS REC & HSC R&D APPROVAL PROCESSES RUN CONCURRENTLY