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)

**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**

**NHS 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**

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

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

**Version 3.0**