KCH R&I Minimum Document sets

The following documentation is required for KCH Research & Innovation Office to start processing a new study.

The exact documentation required will depend on whether the study is to be sponsored by KCH, or whether KCH is intended to just act as a recruiting site.

The full document set as listed below, should be emailed to the R&I Office generic mailbox kch-tr.research@nhs.net and a facilitator will be allocated to process your study and will be in touch within 5 days.

For KCH Hosted studies, for confirmation of Capacity and Capability:

- Feasibility Form *(This can be a draft copy, it should be fully completed, but does not need to have PI or R&I Lead signatures at this point)*

Local Document Pack containing:

- IRAS Form – confirm KCH has been added as site
- Protocol
- Regulatory approval for amendment already processed
- Regulatory approval confirming that KCH has been added as a research site
- Approved Participant information and consent documents
- Statement of Activity relevant to the participating NHS organisation
- Relevant template contract/model agreement (if needed in addition to Statement of Activity)
- Schedule of Events
- Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
- Substantial Amendments with latest approved documents (if applicable)
- Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions
- Principal Investigator CV

For KCH Sponsored studies, for sponsorship confirmation:

- Feasibility Form *(This can be a draft copy, it should be fully completed, but does not need to have PI or R&I Lead signatures at this point)*

Sponsorship Document set:

- IRAS Form – confirm KCH has been added as site
- Draft Protocol
- Participant information and consent documents
- Statement of Activity relevant to the participating NHS organisation (only required if multi-centre study)
- Schedule of Events (only required if multi-centre study)
- Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
- Evidence of Funding

- Chief Investigator CV

For Database studies, for confirmation of Capacity and Capability:

Local Document Pack containing:

- Feasibility Form *(This can be a draft copy, it should be fully completed, but does not need to have PI or R&I Lead signatures at this point)*
- Copy of IRAS form – confirm KCH has been added as site
- Approved Protocol
- Copy of REC application and approval letter including signature of (R&D lead as) Data Controller
- Local documents as applicable (PI sheet(s), consent form(s), GP letter, advertisement)
- CV of CI/PI

Other documents as required for trust approval:

- REC approval letter including signature of (R&D lead as) Data Controller
- REC approval letters of amendments to the initial application
- CAG authorisation if consent not being sought
- Confirmation of funding
- Template contract if required
- Signed and dated PI CV and PI GCP certificate
- Copy of HRA Initial Assessment letter (if applicable) and (when issued) HRA Approval letter
- Substantial Amendments with latest approved documents (if applicable)

Sponsorship Document Pack containing:

- Feasibility Form *(This can be a draft copy, it should be fully completed, but does not need to have PI or R&I Lead signatures at this point)*
- Draft IRAS form– confirm KCH has been added as site
- Draft Protocol
- Local documents as applicable (PI sheet(s), consent form(s), GP letter, advertisement)
- CV of CI/PI

Other documents as required for trust approval:

- Confirmation of funding
- Template contract if required
- Signed and dated PI CV and PI GCP certificate