Gaining Confirmation of Capacity & Capability to deliver research at The Newcastle upon Tyne Hospitals NHS Foundation Trust

NJRO-GOV-SOP-004

Contents

1. Background/Introduction

The Health Research Authority (HRA) approval process for NHS England comprises of a centralised risk assessment undertaken by the HRA and reviewed by an NHS Research Ethics Committee (REC) (where required). The role of individual NHS organisations in this process is assessing, arranging and confirming their capacity and capability to deliver the study. Where The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) is acting as a potential study site, a capacity and capability review will be conducted to assess the Trust's ability to deliver a study in accordance with the HRA approval and in line with the approved protocol and clinical trial agreement. The review will be initiated once the Newcastle Joint Research Office (NJRO) is in receipt of a valid submission for confirmation of capacity and capability review. Any follow-up actions and the issuing of NuTH's confirmation of capacity and capability will be dependent on the outcome of the review.

2. Purpose

The purpose of this SOP is to describe the process for confirming capacity and capability at NuTH to deliver research studies in receipt of HRA approval. Obtaining confirmation of capacity and capability is an essential precondition to the conduct and delivery of any research study regardless of study sponsor or intended study population.

3. Scope of Document

This SOP applies to all studies intending to use NuTH as a research site requiring confirmation of capacity & capability (CoC&C) Review.

4. Responsibilities

4.1 Research Sponsors are responsible for ensuring document packs are issued in line with HRA guidelines. All information provided should be sufficient in its level of detail to enable NuTH to make an accurate assessment of capacity and capability.

4.2 NuTH and NJRO are responsible for ensuring capacity and capability assessments are conducted prior to contract signature and study opening to recruitment.

4.3 Principal Investigators (PI) must oversee and sign off the site capability application form and ensure that data sent to the NJRO is complete and accurate.

5. Procedure

5.1 Feasibility

5.1.1 The way NuTH is selected as a research site may differ depending on the study type or research sponsor. HRA Guidance states that: “When considering which organisations will act as potential study sites, sponsors are strongly advised to have preliminary discussions with potential participating NHS organisations before submitting the IRAS form in order to understand if those organisations have the potential to participate.” Preliminary discussions with sponsors will help to identify whether it is possible for a speciality to deliver a study, although this feasibility work will not negate the need for a CofC&C review to take place. It is also recognised that not all research sponsors will conduct feasibility work prior to listing NuTH as a potential research site in IRAS.

5.2 Studies where the NJRO are alerted to possible NuTH involvement via the HRA

5.2.1 On receipt of any communication to the NJRO’s generic R&D inbox (nuth.genericqueries@nhs.net) regarding a proposed new research study, the following procedure will be followed:

- Recipient will review the HRA approval letter & document pack to determine the speciality group/disease area of the study.
- The relevant research delivery team will be contacted and asked if they are aware of the study and whether they wish to participate.
- The team will be asked to formally confirm their intention to participate to the sponsor.
- The team will formally confirm their intention to participate to the NJRO via the registration of the study.
- Once the team have confirmed their intention to participate, the study will be registered on the ReDA System (LPMS) and issued an R&D reference number.
- The team will be given anticipated timelines for submission to the NJRO in line with national guidelines.

5.3 Triggering of the NIHR 40 day study set-up benchmark

5.3.1 The NIHR 40 day study set-up metric will be triggered from the point that NuTH is selected as a site by the sponsor and a complete HRA document pack is submitted to nuth.genericqueries@nhs.net, the applicable research team and the Local Clinical Research Network (for Portfolio studies only). There must be a documented joint

decision between the local research team and sponsor to proceed with set up prior to the pack being submitted. Only then will the submission of the pack trigger the 40 day set-up metric. The contents of the complete pack can be found on the HRA website: http://www.hra.nhs.uk/resources/nhs-site-set-up-in-england/

5.4 Preparing an Application for NJRO Confirmation of Capacity and Capability Review.

5.4.1 Prior to submitting a study to the NJRO for CofC&C review it is the responsibility of the PI and research delivery team to assess their capacity and capability to deliver the research study. Assurance of PI/delivery team capacity and capability is achieved by completion of a capability form. The capability form must include sign off from the local Delivery Team Lead. Studies submitted without the necessary signatures will be invalidated unless there is clear justification for not obtaining Team Lead approval.

5.4.2 This phase of the process should include (but may not be limited to) the following actions:

- Communication with sponsor to agree local recruitment targets, study timelines, study budgets and any other arrangements or action required from sponsor.
- If the study involves the use of support departments (e.g. Radiology, Labs, Pharmacy) assurance of the departments' ability to accommodate the research must also be sought. This assurance should come via email or support department sign off within the Newcastle Research Application Submission Portal (N-RASP).
- Caldicott approval will need to be sought from the NuTH Information Governance Team.

5.5 Applying for NJRO Confirmation of Capacity and Capability Review.

5.5.1 Initial Submission

5.5.1.1 Applications for NJRO CofC&C review should be made via email if the study is NuTH sponsored or via the N-RASP if the study is not sponsored by NuTH. Submissions to the generic R&D inbox (nuth.genericqueries@nhs.net) should arrive in the following format:

- Email subject line: R&D Ref XXXX – CofC&C Submission – PI Name – Date.
- All documents required for CofC&C review should be attached in one zipped folder.
- All attached documents should include R&D reference number and document identified e.g. PIS, Consent Form, Protocol in the document title.

- All documents should be current versions and should not include track changes.

5.5.1.2 In the event that documents are too large to send or any other issues are encountered, individuals are encouraged to contact the NJRO who will agree alternative means of submission.

5.5.1.3 For the purposes of review the individual submitting the study for CoCaC will be assigned the point of contact (PoC) unless instructed otherwise.

5.5.1.4 Individuals submitting via the N-RASP will be guided through the completion and submission of the online forms via the system.

5.5.2 Submission Validation

5.5.2.1 Applications for CoCaC review can be made at any time and will be processed and validated by an R&D Administrator within 2 working days of the submission.

5.5.2.2 In the event that a submission is judged to be invalid, communication will be sent to the PoC, PI and research team lead informing them of the reason(s) for invalidating the submission and the required corrective action.

5.5.2.3 At the point which a submission is judged to be valid, an R&D Officer will be assigned to the study and the PoC, PI and research team lead will receive confirmation of submission validation and assigned R&D Officer.

5.5.3 Confirmation of Capacity and Capability Review.

5.5.3.1 During the CoCaC review process R&D Officers will review the capability form and associated documents for completeness and accuracy.

5.5.3.2 All studies submitted for CoCaC will also be required to undergo a finance review.

- This review will be undertaken by members of the R&D finance team and will be conducted in parallel to the R&D Officer review.
- Applicants will not be required to make separate submissions for finance review as this will be facilitated by the NJRO.

5.5.3.3 Any studies which are classified as a Clinical Trial of an Investigational Medical Product (CTIMP) or involve pharmacy input will be sent to pharmacy for review in parallel with the R&D and Finance reviews.

5.5.3.4 The assigned R&D Officer will be the primary reviewer and main PoC for CoCaC however it may be necessary to escalate complex queries to a member of the NuTH Expert Panel.

- The Expert Panel is made up of individuals who can offer expert guidance on areas such as medical queries, operations or resource queries, complex governance issues or industry issues.

5.6 Feedback

5.6.1 NuTH stakeholders such as the PoC, Research Team Lead and PI will receive communication detailing initial R&D Officer feedback within 5 working days of submission validation.

5.6.2 Any subsequent finance, pharmacy or expert panel feedback will be communicated as soon as it becomes available.

5.6.3 In the event that a finance issue is identified which requires sponsor confirmation or input, the assigned R&D Officer will communicate this to sponsor and work with them to resolve the matter.

5.6.4 Only when all queries have been satisfied and all requested changes have been made, can a CoCaC review be completed and arrangements made to initiate contract signature.

5.7 Issuing Confirmation of Capacity and Capability

5.7.1 Once the CoCaC review is complete and all queries have been resolved, the assigned R&D Officer will issue CoCaC via N-RASP or email using the agreed email template and with a PDF copy of the Model Clinical Trial Agreement or Organisation Information Document attached.

5.7.2 CoCaC emails will be sent to the PoC, Local PI, NuTH R&D finance, research delivery team lead, NJRO Information Manager, sponsor representative and any other departments or individuals relevant to the study e.g. Pharmacy.

5.7.3 The assigned R&D Officer will arrange for any wet ink copies of the contract to be sent back to sponsor (if required).

5.7.4 On receipt of the CoCaC email it is the responsibility of the PI or member of the study team to contact sponsor to make any final arrangements before participant recruitment begins.

6. Review and Monitoring

This SOP will be reviewed every 2 years or in the event of a change to the regulatory guidelines or NuTH Process.

7. References

HRA Site set-up Guidance:
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/

NIHR 70 Day Benchmark Guidance:
https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm