Confirmation of Capacity and Capability

Process Guidance – Submissions of Hosted Studies

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Introduction

This guidance document is intended to be used by investigators/individuals planning to undertake a research study at NuTH which will require a confirmation of capacity and capability review (CofC&C). This guidance covers hosted studies (i.e. studies that are not sponsored by NuTH).

This document provides a comprehensive overview of the research setup process for studies where NuTH is not acting as sponsor and should be used in conjunction with the following –

- NJRO-GOV-SOP-004 Gaining Confirmation of Capacity and Capability
- Host Site Capability Form Guidance

Pre-Site Selection/Feasibility

The means by which NuTH are selected as a research site may differ depending on the study type or research sponsor. Preliminary discussions with sponsors will help to identify whether it is possible for NuTH to deliver a study. This is known as study feasibility and although this can be useful, not all sponsors will conduct this. Most commercial companies will go through the feasibility process. Feasibility discussions should include:

- A robust assessment of the patient populations from which the study will recruit
- Logistical requirements for study delivery
- Support department implications –Agreement of a realistic and achievable site recruitment target
- Competing studies and team capacity to conduct the study
- Proposed set-up timelines
- Sponsors may visit or hold a teleconference (site selection visit) to discuss the study with the team (coordinator/industry/PI/research nurse/pharmacy as applicable) – this is an opportunity for detailed, two way discussion to assess whether a study is deliverable at this site.
- A site selection visit should only be arranged if the team has capacity to undertake the study.
- Sponsor should notify the PI/Coordinator as to whether the site is selected to participate – for commercial studies this is usually by way of an email following the site selection visit or teleconference. There is a separate guide to feasibility for commercial studies, however the above points should be followed for all studies and discussed as a minimum prior to setup.

Site Selection and Study Setup

When NuTH is selected as a site, there is an expectation that setup work will begin promptly. In the event that a sponsor would like to select NuTH as a site but there is an issue with capacity, please give realistic timeframes to sponsor regarding site selection/setup. If any issues are identified post/during site selection that impact on our ability to deliver the study, sponsor should be informed as soon as possible and expectations managed appropriately.

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

- A Local Information Pack will be sent out by sponsor which will include:
    - A localised Organisation Information Document
    - IRAS (Integrated Research Application System) form – this will be provided by sponsor and is a system for applying for the above approvals, normally filled in by the CI/PI of the study.
    - Protocol – A document provided by sponsor which details the entirety of the proposed research study and how it should be conducted

  - Patient Documents – All studies will have a Patient Information Sheet (PIS) which will detail the research study in lay terms for the participant. If consent is being taken, this should also be provided by sponsor.
  - Relevant Model Agreement/Contract – If a contract is required between the trust and a third party, this should be provided by sponsor in an editable version. We strongly recommend the use of an unmodified model agreement. Using a modified or bespoke agreement may result in significant delays in approving the study or may risk the study not going ahead if certain terms cannot be agreed between participating organisations.
  - Commercial studies only – NIHR Costing template or confirmation that the online interactive Costing Tool has been completed
  - Non-commercial studies only – IRAS Schedule of Events or SoECAT
  - HRA (Health Research Authority) approval – The HRA'protects and promotes the interests of patients and the public health in research. HRA is an executive non-departmental public body, sponsored by the Department of Health (HRA, 2017).
  - REC (Research Ethics Committee) approval – Nearly all studies will need a review by an Ethics committee. A REC favourable opinion will be provided when the committee are happy with their review and all relevant updates are made.
- Once confirmation that the site has been selected is received, this begins the clock for HRA metrics for performance and delivery.
- If the study involves other departments e.g. pharmacy, labs etc., then they should be notified at this point of their potential involvement in the trial and their support should be formally requested and confirmed via email.

Register your Study with R&D

As part of study set up, you need to register the study with R&D.

- Email R&D (nuth.genericqueries@nhs.net) to register the study. You should include the following information –
  - Investigator: *Must hold a clinical contract with NuTH*
  - Project title:
  - Project Acronym: (*projects often have a 'short' title*)
  - Protocol number: **Include these if you have them from sponsor**
  - EudraCT Number: **Include these if you have them from sponsor**
  - IRAS REF: This is really important to include so we don't have any duplicate studies on ReDA
  - Name of Sponsor:
  - Name of Funder:
  - Site i.e. The Freeman Hosp, RVI etc:
  - Commercial/Non Commercial: (delete as appropriate)
- Once the study has been registered, you will receive an email back from R&D which will notify you of the unique five digit identifier. This should be quoted in all correspondence related to the study.

In the event that NuTH are selected as a site but no longer wish to participate in the study or no longer have the capacity to undertake the research, the sponsor and NuTH R&D department should be notified as soon as possible.

Preparing your Submission to R&D

When a study team have completed all necessary capacity checks and sought the assurance of any support departments, the study can progress to R&D for review of Confirmation of Capacity. Please note that the delivery team and any other support departments that are involved, should be in a position to begin study activity at the point at which Confirmation of Capacity or sponsor green light (if required) is issued. In the event that the team or support departments are unable to conduct study activity due to the unavailability of equipment, facilities, staff or other factors, the submission to R&D should be delayed and sponsor should be informed. . Points to note regarding submitting your study to R&D -

- Capability Form
  - This should be the most up to date version and must be completed in line with the Host Site Capability Form Guidance
  - Please send the form as one PDF document, fully completed and signed by the relevant team members as required.
  - R&D will accept email confirmation, alongside a PDF of the finance section of the capability form, in lieu of team lead signature of the capability form, to confirm capacity and study costings. This is only if obtaining team lead signature of the form would cause significant delay.

- Documents
  - The R&D submission checklist will stipulate exactly what documents are required.
  - Prior to submission, documents must be renamed in accordance with the standard Naming Convention. For ease of reference, a user friendly version is attached at appendix 1. If there are more than 10 Patient Documents, you are not required to rename each document but you should ensure that the file name starts with the R&D Reference.
  - Please do not send additional documents that are not on the checklist.
  - Do not include any Tracked Change documents or any documents that are not on the checklist unless there is an addition Regulatory Approval for this study e.g. MHRA Approval, CAG Approval etc.
  - Documents should be sent in one zipped file (we cannot accept submissions made via drop box). If files are too large to send directly please contact R&D for further guidance.
  - Do not send EML documents – the email system automatically diverts them into our junk email box which is not checked on a regular basis.

- Costings
  - For commercial studies please note that the costs agreed between the study team and sponsor/CRO in the costing template should match exactly what is transcribed in the financial appendix of the contract with no discrepancies between the two sets of figures – it's important to communicate this to sponsors/CROs to avoid delays.
  - You should review sponsor budget and compare against what the team agree the costs should be – please refer to costing guidance for commercial and non-commercial studies.

- Contract/Site Agreement
  - Study Teams should not edit or update any of the contract/site agreement prior to submitting the study. Once the study has been allocated to an R&D Officer the contract should not be amended from the Study Team.
  - Contracts should be submitted to R&D in a Word Version. PDF or protected versions should not be submitted.
  - Trial coordinators should not edit/update or be asked to edit/update the contract in a trial. This is the job of the R&D officers; however we ask that these documents are sense checked before coming into to R&D.
  - Do not send partially executed contracts to R&D. If the delivery team receives a partially executed contract from a sponsor, they should make them aware that the contract still requires review by R&D.
  - Check that the recruitment target in the contract/site agreement matches what has been previously agreed.

- Amendments
  - Any amendments to the study prior to review of CofC&C need to be submitted in a separate zip folder. All regulatory approvals for the amendment need to be submitted.

Studies that are submitted to R&D for review of CofC&C that don't follow the process set out in the SOP or where the forms and the submission do not meet the requirements set out in the Confirmation of Capability Form guidance notes will receive an automatic rejection email.

Submitting the Study to R&D

Submissions must be made to the trust inbox – Nuth.hostedsubmissions@nhs.net using the following email subject line:

R&D Ref XXXXX – CofC&C Submission – Hosted /NuTH Sponsored – Date
e.g. *09870 – CofC&C Submission – Hosted – 2019-10-31*

R&D Validation

Submissions will be validated by the R&D admin team within 2 working days of receipt (please note if you submit on a Friday, R&D have until the following Tuesday to validate your study submission).

- Valid Submissions: Relevant contacts in the Delivery Teams will receive an email confirming that the submission is valid and will include the name of the R&D Officer responsible for reviewing their study. R&D will commence their review.
- Invalid Submissions: An email will be sent to relevant contacts in the Delivery Team (including the PI) notifying them of this. Please note it is the responsibility of the Study Team to identify what is incorrect and/or outstanding. The study will not be reviewed and needs to be re-submitted.

R&D Review

At the point a submission is validated by the R&D administrative team it will be handed over to an R&D officer for review. The R&D officer will be responsible for the review of the capability form and associated documents (contract, PI responsibility form etc.) but may involve Finance/Pharmacy. All communication or queries relating to the review should be directed to the assigned R&D officer.

- An R&D officer will assess the documents, including the capacity and capability form, checking for accuracy. In the event an R&D officer has a query, it may be necessary to escalate this to the relevant party. All studies that include pharmacy involvement will be subject to pharmacy review.
- All studies that undergo a capacity and capability review will need a finance review. An R&D officer will facilitate this.
- The allocated officer will liaise with the research delivery team regarding any queries they may have regarding finance, other departments and the contracting process.
- Once all queries are answered, the R&D officer will liaise directly with sponsor regarding the contract review/finalisation/signatures
- Partially executed contracts will be requested from the sponsor to the R&D officer who will then arrange for signature by the designated NuTH signatory.
- Once returned, the R&D officer will issue a confirmation of capacity email with the fully executed contract attached. This will be addressed to the PI with all the parties involved copied in.

Appendix 1

Naming Convention (User Friendly Guide)

Submission;

R&D number – Document Name – Date of issue or date of email using YYYY-MM-DD e.g

09127 – REC Favourable – 2019-10-21
09127 – HRA Approval – 2019-10-21
09127 – Protocol – V1.0 – 2019-10-21
09127 – IRAS Form – 2019-10-21 (last date it was signed)
09127 – Caldicott Approval – 2019-10-21 (date it was approved) – always send the email confirmation that Caldicott sent you).
09127 – NuTH Costing Tool – V7.2 (or latest version) – (date completed)
09127 – NIHR Commercial Costing Tool – V1.2 (or latest version) – date was received.
09127 – PI's Name – CV – date was signed (CV's need to be the research CV which is two pages and signed and dated)
09127 – Investigator Responsibilities Form – Date form was signed
09127 – Host Capability Form – Last date of signature
09127 – CTAg – NuTH – DRAFT – (generally names for hosted contracts) or 09127 – mCTA – NuTH – DRAFT (Commercial Contracts)
09127 – Corres – Pharmacy Approval/ Labs Approval/ TL Approval etc – date of email or date of correspondence.

Where an amendment has been made to the study prior to review of CofC&C –

(Tracked change documents aren't needed, if there are over 10 patient documents, you do not have to rename all of these documents, just make sure that the R&D number is at the front of the document.)

09127 – Amend Capability Form - Amendment REF (SA1/SA2)- – Date of Signature
09127 – IRAS Amend Notification – Amendment Ref – date of last signature
09127 – HRA CAT A/B/C - Amendment Ref – date of email (for the HRA categorisation)
09127 – REC Favourable – Amendment REF (SA1/SA2) – date of issue
09127 – HRA Approval (Amendment REF) – Date of issue/approval
09127 – Corres – Pharmacy Approval/ Labs Approval/ TL Approval etc – date of email or date of correspondence.
09127 – Patient Document - Amendment Ref – – Version – Date of approval

NB. Please remember to submit amendments in a separate zip folder. Do not include them in the Submission zipped folder.