Confirmation of Capacity and Capability –

Host Site Capability Form Guidance

Introduction

This guidance is to be used by all investigators or individuals (e.g. Clinical Trial Co-ordinators) wishing to submit a hosted study to Research and Development (R&D) for a Confirmation of Capacity and Capability (CoC&C) Review.

All applications for CoC&C review should be made via email to nuth.hostedsubmissions@nhs.net.

You must submit a Host Study Capability Form (form available on request from the hosted submissions mailbox) which has been fully completed in line with the guidance set out below (together with email confirmation from support departments, team leads where indicated etc). This should be submitted with a full set of supporting documents (these are listed in the R&D Capability Checklist).

All submissions must fully satisfy the requirements set out in this guidance. Incomplete submissions will be returned to the research delivery team and will not be reviewed. These will need to be resubmitted, which may lead to delays in setting up the study.

Completing the Host Site Study Capability Form

Research Details

1. **Full Study Title**: This can be found on either your protocol or fully signed IRAS form. This can also be found within your HRA approval and REC if required for the study.
2. **Short Title**: Not all studies will have a short title; however it will either be on the study documents or your sponsor should be able to notify you of this.
3. **R&D ref**: This is the five digit number provided by R&D upon study registration e.g. 09876
4. **IRAS Ref**: This is the 6 digit number which is generated once an IRAS form is complete. It is found in the bottom right hand corner of the IRAS form and can also be found on HRA approval and REC (if required).
5. **Research Team**: Enter the team number or specify which platform will be responsible for overseeing research delivery.
6. **PI**: Please fill in full PI name with title e.g. Professor, Dr, Mr. **ORCID No**: This is a specific ID no. used by researchers. If you know what this is, please enter number.
7. **Research Nurse**: Please state lead nurse on study if applicable.
8. **Trial Coordinator**: Please state who will be the Trial Coordinator for this study.

9. **Contact for Upload to LPMS (ReDA)**: Please state the name of who will be uploading accruals to LPMS.
10. **Funding Category:** Please state if the study is commercial/non-commercial and if the study is portfolio adopted. If portfolio adopted, please give the LCRN reference number (this number will be on correspondence from the LCRN confirming portfolio adoption).
11. **Funder Details**: Please fill in the full name of the funder for your study. This can be found on question A65 on the IRAS form.
12. **Study Sponsor**: Please fill in the full name of the study sponsor. This can be found on question A64 of the IRAS form.
13. **Sponsor/CRO Contact Email**: Please state the name and email address for the main Sponsor/CRO contact who will be dealing with the site agreement. This will be the person who R&D will liaise with to agree and arrange for contract signature.
14. **CRO (if applicable)**: Please fill in name of CRO.
15. **CRO Contact Email (if applicable):** Please state the name and email address for the main Sponsor/CRO contact
16. **Has the Study been reviewed by …** Please state whether your study needs/has already had
    a. Early Phase Group
    b. New Interventions Committee
    c. Gene Therapies Committee (if studies involve genetic modification)

    Please see the separate guidance on additional committees If you have ticked 'yes' to any of these, we will require email confirmation of the review. If you require any further clarification, please direct your query to Nuth.genericqueries@nhs.net.
17. **Caldicott ID Number:** If Caldicott approval is required, you should enter the ID number and provide the email confirmation of Caldicott approval (you should not send the actual application). If Caldicott is not required, you will still need to send an email to confirm this. Any changes made by sponsor during setup or amendments to the study may impact the Caldicott approval - please contact the Caldicott guardian for further advice
18. **Collection/Storage of Tissue:** Please provide brief details of any tissue being used/taken in the study, along with how it may be used/stored/transported.
19. **PIC Sites**: Please state whether the study includes any Patient Identification Centres (PICs) e.g. where NuTH, as a participating site is using other centres to refer in or identify potential participants. Typically, this may be GP surgeries or other Trusts. If unsure, this should be indicated in Q73-1 of the IRAS form. If PICs are used, please note that the host site is now responsible for initiating the PIC agreements (this used to be Sponsor responsibility) so R&D will require further details from the Delivery Team to populate the model PIC agreement. Please complete the 'Information for PIC Agreements' form and include with your submission.
20. **Sites where the study will take place**: Please select which sites will be involved in the research.

Departmental Capacity

21. **Sufficient Nursing Support?** Team Lead should confirm this.
22. **Sufficient Study Coordination Support?** As above
23. **Sufficient Data Management Support?** As above
24. **Has the following support been confirmed (if applicable)?:** If the study involves any support departments, they should be informed of the study as early as possible in order that they can provide their costs and confirm they can meet the study requirements. An email from each relevant support department confirming their support should be provided as part of the submission to R&D. For pharmacy set up of studies please see Pharmacy Clinical Trials Guide.
25. **Are any additional support departments required?:** Please indicate whether there are any further support departments involved which are not listed in Q24 and provide details together with email confirmation of support.
26. **NuTH Recruitment Target**: Please state the total recruitment target as agreed between the sponsor, the PI and the study team. This may be an overall target or a range i.e. minimum and maximum.

Proposed Timeframes

27. **Initial Site Selection Date**: This is the date that the sponsor confirmed NuTH site selection and issued complete document pack to begin the local setup process.
28. **Proposed SIV Date** – The proposed date of the site initiation visit. It is accepted that this may change.
29. **Commercial Only**: If the sponsor is a commercial company, do they need a fully executed site agreement before the SIV can take place?
30. **Proposed Recruitment Start Date**: Self-explanatory. This should have been agreed between the sponsor, the PI and the delivery team.
31. **Recruitment End Date**: Self-explanatory but please note that there should be no patients recruited beyond this date.
32. **End of Study Date**: The actual end date of the study (when all follow ups are complete) provided be stated on the IRAS form (Q69-1) this but may change as amendments may be made by sponsor later in the study. The recruitment end date should be before the end of study date.

Pharmacy (if applicable)

33. **Does the Study contain any of the following**…. Please confirm if any drugs/devices/gene therapies are contained within the study or any other elements which may need pharmacy input e.g. food supplements.
34. **Phase of Study**: Please state phase of study

35. **Controlled Drug**: If there is a controlled drug involved, please specify the classification e.g. class 2.
36. **Home Care Nursing:** Indicate whether the study involves any home care nursing and if so, you should send a copy of the draft SLA.

    Any further information: Please enter any additional relevant information which pharmacy may require for review including drugs involved, projected timelines for the study etc.

Finance Section

This section should be completed for all studies, including those where there is no funding associated with the study.

- **File Name:** Please make sure that the most up to date costing tool is submitted with appropriate version control using the format given in the form i.e. and enter details in form.

- **Total Value of Tool:** This should include every cost included in the trial. This will be automatically calculated by the costing tool when fully populated.

Please complete either Section A (Non Commercial Studies) or Section B (Commercial Studies). Section C should be completed for all studies.

Section A – Non-Commercial

General

The costing tool should reflect all the costs of delivering the research trial, regardless of whether there is funding or not. This enables an informed decision on accepting any trials where it is necessary to fund from NuTH resources.

In practice NuTH may decide to undertake a trial where some or all of the costs are not funded fully. Some judgement is required on which elements are unfunded as the payment profile in the Trial Agreement may be different to the NuTH costing.

Unfunded Research Delivery Team costs

This relates to costs which fall under the research delivery team i.e. research nurse/data manager time, and trial coordination. Where unfunded Research Delivery Team costs are identified -

- Costs up to £1,000 - The Delivery Team Lead can authorise the acceptance of costs,

up to a maximum of £3,000. Email confirmation from the Team Lead should be included with your submission.

- Costs over £3,000 – The Clinical Director of Research needs to approve these costs. It is the responsibility of the Delivery Teams to obtain this approval and a copy of the email should be sent with the submission.

Unfunded Support Department / Research Directorate costs

The cost of scans, lab tests, pharmacies etc. are borne by the relevant support department, with income from the Clinical Trail being allocated to them. Where there is insufficient funding in a trial to cover the cost of these, approval from the relevant support department manager is required for the trail to proceed and you should include a copy of this confirmation with your submission.

Where consultant costs are unfunded, approval from the Specialty Clinical director is required and you include a copy of this confirmation with your submission.

Unfunded Set up Cost

All clinical trials include some element of setup and coordination costs, including a site file and archiving.

- Archiving Costs - The Head of the NJRO can accept the costs of archiving as unfunded. It is the responsibility of the Delivery Team to obtain this approval and you should include a copy of the approval email with your submission.

- All other unfunded setup and coordination costs – These are borne by the Delivery Team, and require approval from the Delivery Team Lead as part of the £1,000 referred to in Unfunded Research Delivery Team costs. Email confirmation from the Team Lead should be included with your submission.

Excess Treatment Costs

Where the costing of a trial identifies excess treatment costs, the trial Sponsor should have made arrangements via a SoECAT (Schedule of Events Cost Attribution Tool) submitted to the NIHR for the reimbursement to sites.

Where this is not included in the Local Information Pack, this should be discussed with the Sponsor to identify how these costs will be recovered.

Section B – Commercial

In most cases, Commercial Contracts include prices taken directly from a validated Industry Costing Template. The exception to this is Merck, Sharpe & Dohme who have a different standard for costing which normally exceeds the value in the Industry Costing Template.

Delivery Teams are required to prepare an Industry Costing Template from the trial protocol to confirm that the contract value equals or exceeds the cost of delivery.

Credit Vetting

Where the sponsor is a commercial company their credit rating should be checked.
The R&D Finance Pre-Award team maintain a list of credit ratings for known sponsors, which is updated and re-issued monthly. If the sponsor is not included in the list then request a credit vet early in the evaluation stage. Companies are required to be re-vetted every 3 years as part of our internal policy. If there are concerns around the commercial company's credit rating, Finance will recommend credit terms for agreement between the Industry Team and Sponsor.

Section C - Contract Related Finance Question - All Studies

The HRA strongly recommend that an unmodified model agreement is used as these have been negotiated with English law and comply with governance arrangements. Where modified/bespoke agreements are used, this may lead to delays in R&D being able to obtain Confirmation of Capacity and Capability.

- Travel and Refreshment – Please do a 'sense check' to ensure that these appear to be reasonable. If unsure, you should speak to your Team Lead.
- Screen Failures – We would not normally accept a ratio. A cap is allowed.
- Unscheduled Visits – Again, you will need to do a 'sense check' on this. If unsure, you should speak to your Team Lead.

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Where there are Pharmacy or Cellular Therapies costs involved, these will be provided in the form of a separate table from the respective departments. These should have already been negotiated and agreed with Sponsor. This table should have been inserted into the financial schedule section of the draft contract by sponsor.

Finance will also check the terms in the financial appendix to identify those that they view as unacceptable (please try to be aware of these before you submit your study to R&D). Key points to note as follows -

- The financial appendices should reflect all aspects of the study funding, including per-patient costs, additional items, other costs, setup fees, and the milestones that trigger payment.
- Payment terms should be no longer than 45 days
- Payment should be quarterly in arrears
- Setup fees should be invoiced on execution of contract

- No retention or holdback of study fees - except Boehringer where the eCRF fee will be held until the end of study
- Check for a screen fail cap
- Ensure unscheduled visits are paid for
- Commercial studies – contract needs to match the costing tool
- Check VAT treatment – Some studies need to have VAT included in costing.
- The sponsor may require a particular reference to be added to the invoice which identifies this study to the sponsor (for example, some sponsors ask for the protocol number and others ask for the study name)
- Check that arrangements for Purchase Order (PO) numbers are properly reflected (if a PO number is required)

R&D will undertake a full contract review and insert relevant standard clauses and invoicing details as part of their review of the submission.

Information to be completed by the Principal Investigator

36. **Date of GCP**: Please state date of GCP training. This should be within the last 3 years.
37. **Summary of Interventions**: PI to provide a brief summary of the research together with a summary of the interventions that are involved within the study. They should include details of any deviations from standard of care and any estimated excess treatment costs.
38. **Details of Follow Up Visits**: PI to provide key details of patient follow up visits and whether they are fully funded throughout the study
39. **Exit Strategy**: This should be completed for all ATIMPS and CTIMPs. PI should state whether the patient will continue to receive drug after the trial (if applicable) and how patients will be informed of what will happen at the end of the study. This may have been covered in the PIS or will be communicated by the person taking consent.
40. **Consent**: Please confirm who is taking consent i.e. are they medical GCP trained staff or non-medical staff appropriately trained staff. If the latter, you should provide further details. NJRO-GEN-SOP-011 'Informed Consent for Research' refers.
41. **Declaration regarding novel clinical procedures**: PI to confirm that any novel procedures have been approved by the New Procedures Committee and additional costs or other deviation from standard care has received required approvals. Please include email confirmation with the submission.

Declaration

- Names must be printed so we can clearly identify each signatory.
- If a PI, Team Lead or Research Clinical Lead is not available to sign the form we will accept email confirmation from them in lieu of signature.