National Institute for Health Research

Clinical Research Network

CRN Principles for assessing, arranging and confirming local capacity and capability

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A- Introduction

Purpose

This Guidance Document outlines the CRN principles for activities relating to assessing, arranging and confirming local capacity and capability by organisations in receipt of CRN funding.

These principles are intended to be supportive but not prescriptive. They provide the mechanism through which a consistent approach to assessment, arrangement and confirmation of local capacity and capability at individual participating organisations can be achieved across the NHS to improve the researcher and life-science company experience. This guidance builds upon the work on consistency introduced through the Coordinated System for NHS Permission local review process and reflects the main purpose of HRA Approval: to make it easier for researchers to undertake good quality research.

The organisations in receipt of CRN funding are expected to work with their Local CRN to establish a consistent approach across their local region for assessing, arranging and confirming local capacity and capability in line with national principles. This should include scenarios where Local CRNs provide resource for activities on behalf of organisations e.g. for General Practices.

CRN funding for activities related to establishing and delivering the principles in this document to ensure consistency for researchers will be determined as part of the annual review of the LCRN funding allocation model.

Suitable studies

The principles are applicable to all CRN Portfolio studies submitted for HRA Approval.

At the discretion of and supported by the organisation involved, the principles of this guidance could also be applied to:

- non-portfolio studies to avoid the creation of two different approaches for portfolio and non-portfolio studies
- research taking place other NIHR funded infrastructure such as a Biomedical Research Centre (BRC), Biomedical Research Unit (BRU) or Collaborations for Leadership in Applied Health Research and Care (CLAHRC) to further support consistency for the researcher.

Continuous Improvement

The CRN will apply the continuous improvement process of Plan-Do-Study-Act to maintain the effectiveness of this guidance. Please provide any feedback on this guidance to the Study Support Service Help Centre at supportmystudy@nihr.ac.uk.

B – HRA Research support functions aligned to local participating organisations to assess, arrange and confirm capacity and capability to take part in a study

The HRA have outlined the local activities expected when organisations are participating in studies, which are distinct from the role of the Sponsor or Lead CRN. Organisational activities are defined in the HRA document: assessment, arrangement and confirmation of local capacity and capability and are aligned with research support functions and the specific primary care R&D office local support functions developed by the R&D forum Primary Care Working Group. The key concepts from these documents relative to assessment, arrangement and confirmation of local capacity and capability are summarised in Table one below.

The HRA is working with the three Devolved Administrations to develop and maintain a UK-wide policy framework for the management and conduct of health and social care research. This CRN guidance elaborates the detailed expectations of NHS organisations in accordance with the framework.

Table One: Research support functions for participating organisations

ASSESSING	ARRANGING	CONFIRMING
Assessment of the capacity and capability of the participating organisation to deliver the study.	Sponsor and participating organisation actively puts in place all the practical arrangements to ensure it has the capacity and capability to deliver the study. A study delivery timetable is agreed.	Participating organisation confirms that it has the capacity and capability to deliver the study by email or execution of the Agreement where one is required.
Endpoint: Joint decision by the Sponsor and Participating Organisation that the Organisation is selected to take part in the study AND listed on the IRAS form.	**Endpoint:** All arrangements are in place. Sponsor confirms site participation by finalising contents of the Statement of Activities or relevant Agreement is ready to be executed AND HRA approval has been granted.	**Endpoint:** Participating organisation is ready to recruit to the study to the timetable agreed with the Sponsor.

Relevant references in HRA Research Support Functions – Study Specific:	Relevant references in Supporting HRA Research Support Functions – Study Specific:	Relevant references in Supporting HRA Research Support Functions – Study Specific:
1. Providing internal and external investigators wishing to undertake a specific study at the site with: i. Practical support around agreeing arrangements for study set-up. ii. Advice on study set-up and legislative requirements. 2. Providing advice and support on research related to higher degrees to both students and supervisors. 4. Undertaking an early assessment of operational requirements for the conduct of the study and ensuring there are proportionate systems in place to mitigate and manage any identified study risks, in order to effectively deliver the study through its life cycle. 5. Ensuring that the NHS organisation has both the capacity and capability to undertake the study – that is, bearing in mind the inclusion and exclusion criteria and the resources required, will it be possible to recruit the required number of participants within the timescale of the study delivery period and conduct the study in accordance with the protocol? This can include discussions with the local study team, NIHR Clinical Research Network (if a portfolio study) and sponsor leading to a proposed start date. ..... **NOTE, where CRN feasibility services are used prior to the assess stage, this aligns with:** 3. Supporting investigators to prepare and submit expressions of interest to commercial and where required non-commercial sponsors.	6. Supporting investigators in putting in place the necessary practical arrangements to conduct the study protocol in line with the responsibilities agreed with the sponsor, including all required safety arrangements. 7. Ensuring that the appropriate management/supervision and oversight arrangements are in place for all aspects of the study. 9. Ensuring that the ethically approved arrangements are in place for identifying and approaching potential participants, including managing any transfers or referrals of patients. 12. Having delegated responsibility for, or working with, their Human Resources Department to operate the Research Passport Scheme to issue (in line with HRA Approval conditions) Honorary Research Contracts and Letters of Access for research staff not employed by that NHS organisation.	8. Executing contracts/agreements and agreeing a budget for the delivery of the study in line with HRA Approval conditions. 13. On the basis of HRA Approval, confirming that the site will participate and finalising with the sponsor a timetable for study start/study initiation and study delivery. ..... **NOTE, organisations are expected to supportively manage studies throughout their life cycle including:** 10. Managing the resources required to deliver the study both at study set up and throughout the study life cycle in line with HRA Approval conditions, HSG(97)32 and AcoRD guidance. 11. Ensuring the site recruits the number of participants stated in the original application (or a revised target) within the time line agreed with the sponsor. 14. Following an updated HRA Approval make the necessary arrangements to implement amendments or, very occasionally and in discussion with the sponsor, withdraw from participation in the study if the amendment adversely affects the capacity and capability of the organisation to deliver the research to the new information.

C – PRINCIPLES FOR ORGANISATIONS IN RECEIPT OF CRN FUNDING WHEN SETTING UP STUDIES UNDER HRA APPROVAL

What is expected of participating organisations

The activities below should be undertaken by participating organisation staff or LCRN funded staff in accordance with the approach agreed with the LCRN. It is expected that the allocation of the individual activities is clearly defined and documented. This is intended to avoid duplication by providing a clear and simple process for the sponsor and local study delivery team.

1. Engage with the Lead CRN via the participating organisation's LCRN as early as possible to:
    a. mitigate issues upfront (e.g. cost attribution)
    b. support early decision for Portfolio eligibility

2. Be aware of HRA Approval: assessment criteria and standards against which the HRA will assess studies in order not to repeat the assessment. Any areas of concern should be raised with the HRA.

3. Adhere to HRA Guidance.

4. Research management staff and research delivery staff should work together to use the information provided by the Sponsor to put in place all necessary arrangements for the site to support study delivery to time and target.

5. Take a pragmatic and tailored approach to set-up the specific study rather than a tick box exercise.

6. Ensure clear arrangements are in place to work with the LCRN to support study delivery:

    a. For studies requiring service support resources, this includes following locally agreed arrangements appropriate for the LCRN model (e.g. centralised or devolved funding) to confirm the LCRN has agreed the level of support resource required to deliver the study
    b. For studies involving independent contractors, this includes arrangements to confirm the LCRN has agreed the level of support costs as described in the 'Payments for Independent Contractor' pro-forma completed by the Lead CRN [link to form to be included once available]
    c. For studies involving participating organisations based in Primary Care, locally agreed arrangements to enable participating organisations to deliver principles outlined in this guidance

7. Copy LCRN generic email address on initial study correspondence response to Sponsor to ensure Local CRN are aware of the study to provide any necessary CRN support. This should be the same email address used during any previous interactions with CRN study support service.

8. Where relevant, participating organisations will also be notified by their LCRN where they have been listed on any new HRA Approval applications as part of the CRN study support service to ensure the participating organisations are aware of the study. Participating organisations are responsible for confirming set-up time requirements with the Sponsor e.g. if part of staggered set-up.

9. Provide and utilise a consistent, generic point of contact/email address for the research management staff for the Sponsor and Researchers publicised via the contact details for NHS Organisations on the NHS R&D Forum website. The same email address should be used for all studies (portfolio and non-portfolio).

10. Use the following consistent approach and templates (where suitable) to ensure clarity:

    a. acknowledge receipt of information to Sponsors within 3 working days
    b. agree a study delivery timetable (noted under the arrange section of Table One) using the Statement of Activities or relevant Agreement as applicable
    c. document in writing using standard template correspondence [to be developed during testing of principles] when the participating organisation decides not to participate following discussion with the Sponsor. A decision not to participate due to being unable to put in place the necessary capacity and capability to deliver the study (e.g. suitable participants are unlikely to be recruited, equipment not available at participating organisation) is initially discussed with the Sponsor to explore potential resolution of any issues (e.g. protocol change)
    d. issue any objection to participation to the Sponsor within the HRA 35 day timeline for the types of studies for which the HRA has advised that confirmation of capacity and capability is not required (stated on the Ready for Review letter) [template to be developed]

11. Use of Local Portfolio Management System (LPMS) for all studies, including those not requiring local confirmation of capacity and capability, to:

    a. Record and quality check relevant workflow dates and confirm outcome status as defined in Section E
    b. Ensure Network records are visible to all LCRNs with Participating Organisations i.e. not just visible at Participating Organisation level
    c. Documents provided by the Sponsor to be logged, controlled and managed via standard process (to be developed) for updating of LPMS
    d. Collect additional data points as required locally for Continuous Improvement of processes and/or identification of barriers to rapid set-up such as understanding what departments/resources are leading to delay in issuing capacity decision. This information may be

required to support CRN audit of delivery against this guidance document and specific additional data points to support this process may be determined through the application of these principles in practice.

12. The IRAS reference number should be used as a consistent identifier in all correspondence and records to identify the study.

13. Utilise the appropriate escalation routes within the participating organisation to escalate queries as necessary to the CRN or HRA as relevant.

14. Via the relevant LCRN, participating organisation liaison with the Lead CRN regarding progress of confirming local capacity and capability to deliver the study enabling provision of relevant support and study oversight

15. Pragmatic, flexible application of competency framework (defined in Section D) for local capacity and capability activities supporting delivery of different study types and in different site types e.g. Patient Identification Centre, applying the NIHR Framework for Research Support Services tools where applicable

16. Local Standard Operating Procedures, guidance or processes in place to efficiently and effectively undertake local capacity and capability activities which:

    a. Detail the required staff skills, experience and competency to assess whether or not the participating organisation will have the capacity and capability to deliver the study and to be able to put the necessary arrangements in place.
    b. Nominate the authorised institutional representative(s) to issue confirmation through the Statement of Activities or relevant Agreement.
    c. Include arrangements for working with partner organisations (e.g. University or Clinical Trial Unit) when undertaking research involving NHS patients to clearly define roles relating to local capacity and capability
    d. Are supported by suitable local training, refresher training or use of national training modules
    e. Demonstrate consideration of the competency framework (section D) to deliver the study
    f. Provide evidence of a due diligence approach to confirmation of participation demonstrated through supporting appropriate discussions, defined local processes and involving staff empowered to make necessary arrangements to deliver the study resulting in the Agreement plus delegation log or Statement of Activity
    g. Define the specific role of the LCRN where applicable i.e. if providing support for primary care sites to confirm local capacity and capability to deliver the study

17. Work towards an initial target timeline of confirmation within 30 calendar days of site selection joint decision with defined documents to commence confirmation of local capacity and capability, noting that different study types may take different lengths of time. NOTE: Data from testing these principles in practice will provide data to refine this timeline and evidence requirement for stratification of timeline for different study types]

Placeholder for future versions:

18. For any amendments determined by the HRA to require review local, communicate any impact on CRN support requirements to relevant LCRN

19. Work towards predictable timelines for confirming local capacity and capability (potentially a range of timelines for different study types)

What is expected of Sponsors

1. Early engagement with the CRN via the Study Support Service, prior to HRA submission, to support study planning and inform site identification.

2. It is the responsibility of the Sponsor to provide the required information in a timely and reliable way to the participating organisation which enables assessment of capacity and capability to deliver the study, and the participating organisation to put the necessary practical arrangements in place to comply with the protocol. This will include either the HRA Ready for Review letter or the HRA Approval letter if HRA Approval is already in place. . This should be provided by a single email sent to the following multiple recipients:

    a. The R&D contact for that participating organisation as listed on the contact details for NHS Organisations on the NHS R&D Forum website (representing the research management staff)
    b. The local study delivery team including at a minimum the principal investigator or local collaborator and any nominated local coordinator where known. The local study delivery team are responsible for providing the information to each Multi-Disciplinary Team and Support Department involved in the delivery of the study at the participating organisation as per their participating organisation internal communication processes.
    c. For studies on the CRN Portfolio, the Local CRN generic email address [currently suggested to be] listed with each NHS organisation on the NHS R&D Forum website to enable provision of CRN support

3. The following information for the study is provided to participating organisations using the distribution list above, after submitting the HRA Approval application. Sponsors who wish to set sites up in parallel to HRA Approval are recommended to send this information no more than 10 working days from the date of the HRA Ready to Review letter.
    a. The documents submitted as part of HRA Approval submission relevant to the site, including a copy of the IRAS form, the relevant template Agreement and costing template (where applicable)
    b. A copy of the HRA Ready to Review letter

c. For commercial studies, the delegation log listing any known members of the local study delivery team. For non-commercial studies, the Statement of Activity for the participating organisation. Where the local study delivery team has not been identified or contacted previously, the Sponsor has the opportunity in the email to list the proposed team, or to request help to locate the required information.
d. A list of all above documents and their version numbers/dates

4. The following information for the study is provided to participating organisations using the same distribution list once HRA Approval has been issued:
    a. The documents approved by the HRA as part of HRA Approval relevant to the site (including a copy of the IRAS form)
    b. A copy of the HRA Approval letter
    c. A list of all above documents and their version numbers/dates

5. Where the sponsor wishes to include a new organisation after HRA Approval has been issued, the following information for the study is provided to participating organisations using the distribution list above:
    a. The current approved documents, including a copy of the IRAS form, the relevant template Agreement and costing template (where applicable)
    b. For commercial studies, the delegation log listing any known members of the local study delivery team. For non-commercial studies, the Statement of Activity for the organisation. Where the local study delivery team has not been identified or contacted previously, the Sponsor has the opportunity in the email to list the proposed team, or to request help to locate the required information.
    c. A copy of the HRA Ready to Review letter
    d. A copy of the HRA Approval letter and subsequent relevant amendment correspondence
    e. A list of all above documents and their version numbers/dates

6. The following information for the study is provided to participating organisations using the same distribution list following HRA categorisation of a study amendment requiring local review:
    a. The documents approved by the HRA as part of HRA Approval for the amendment relevant to the site (including a copy of the IRAS form)
    b. A list of all above documents and their version numbers/dates

D – COMPETENCY FRAMEWORK FOR LOCAL CAPACITY AND CAPABILITY

The HRA Ready for Review (where applicable) and HRA Approval letters will detail whether any assessment of capacity and capability will be required by host organisations (by site type), the likely extent of any arrangements, and key considerations, for confirming capacity and capability.

For non-commercial sponsored research [OUTSTANDING QUERY: definition of non-commercial sponsored research from HRA required here or link to source of information], confirmation that arrangements are in place to provide the capacity and capability to deliver the study is provided by the participating organisation to the sponsor through email agreement of the Statement of Activities, which includes a Schedule of Events for activity attribution, and, if required, the appropriate non-commercial model agreement as indicated in the HRA Ready for Review and HRA Approval letters.

For commercial sponsored research [OUTSTANDING QUERY: definition of non-commercial sponsored research from HRA required here or link to source of information], confirmation is provided by the execution of the appropriate Model Clinical Agreement between sponsor and participating organisation supported by the appropriate NIHR CRN Industry Costing Template. Commercial Sponsored Research does not require a Statement of Activities because the NIHR CRN Industry Costing Template provides clarity on activities and resources.

Where the HRA Ready for Review letter confirms that no local assessment of local capacity and capability is required, participating organisations are expected to either be aware that the research will take place after the HRA 35 day timeline if no objection has been raised by the participating organisation or decline to take part in the study and provide the sponsor with the relevant justification(s) for this decision.

Competency Framework for Organisations in receipt of CRN funding

For participating organisations in receipt of CRN funding, the local research management staff and local research delivery staff together should have the skills, experience and competency to assess whether or not the participating organisation will have the capacity and capability to deliver the study and to be able to put the necessary arrangements in place. The work should be undertaken quickly and effectively in a way that is proportionate to the type of the study, the scale of the study and the risks involved. The NIHR Framework for Research Support Services provides tools to support such an approach.

There is no requirement to specify to the sponsor that each individual element to delivery is in place but simply to confirm that all arrangements are in place that are required for that specific study. There is no requirement for a checklist or similar to be completed. Research delivery staff and research management staff working in partnership should be clear what is needed for which specific study and have a plan in place to set the study up appropriately with all the arrangements in place on a study by study basis.

The following competency framework provides an outline of activities that should be considered during assessing, arranging and confirming of local capability and capacity as appropriate by Participating Organisation staff whom are empowered as necessary to initiate and/or undertake relevant measures for study delivery. For the purposes of this framework, the term 'Participating Organisation' includes an NHS organisation, General Practice, Tertiary Centre, Independent Provider, Any Qualified Provider or Participant Identification Centre as appropriate.

SUITABILITY OF LOCAL RESEARCH DELIVERY TEAM
• **Investigator:** The Ready for Review and HRA Approval letters will confirm if a Principal Investigator (PI), a Local Collaborator or neither is required at participating organisations. Where a PI is required, the participating organisation has identified a suitable investigator. *'Suitable' defined as a named investigator taking into account his/her professional qualification, knowledge of research field, expertise in the procedures involved, previous research experience, training in research methods (including informed consent), training in Good Clinical Practice (if applicable), PI oversight training and ability to take clinical responsibility for local research team. The Statement of Activity indicates whether a PI has been identified or identification is required.* • **Clinical Research staff:** Clinical research staff are available within all departments involved to set-up and deliver this study with appropriate specialist personnel (e.g. sub-specialist physicians/technicians/physical therapists) and/or administrative staff, who are appropriately qualified and trained to undertake their study related task(s) at the participating organisation. A sub-investigator and deputies have been identified where applicable. The PI and research team understand the requirement to document study training and competence e.g. via a Delegation of Duties Log available on the GCP Resources page. Up-to-date CVs and documented evidence of training have provided for the Site File. • **Study Management:** The management of study delivery within the Participating Organisation will be appropriately conducted by the Investigator and the research delivery team in conjunction with the research management team • **Study Follow-up**: The clinical research staff or participating organisation have the capacity to follow all procedures in the protocol which includes support study follow up as required • **Conflict of interest:** Any possible conflict of interest for Participating Organisation staff, e.g. personal involvement with the sponsor or funder, has been declared by the Investigator or Participating Organisation research team member, and the Investigator or research team member's employer is aware of this • **Supervision**: Appropriate local clinical or management supervision will be provided as required to ensure the research team and other relevant staff are suitably resourced and trained to comply with: • Good Clinical Practice acceptable to the Sponsor (e.g. NIHR GCP training) or other relevant standards are applicable to the study type. Note GCP training is not required for all types of research.

- the research procedures set out in the protocol and other supporting information such as study manuals, procedures(especially those not classed as standard skills for all clinical staff)
- study specific equipment
- study specific Case Report Forms (CRFs) including eCRFs as applicable
- the requirements for reporting to the sponsor on progress and pharmacovigilance
- the monitoring arrangements expected by the sponsor
- the arrangements approved by the REC for identifying and approaching potential participants
- the arrangements approved by the REC for seeking consent – in particular where the study involves adults unable to consent for themselves, participants under the age of 16 or emergency research
- the arrangements for handling of Investigational Medicinal Product (IMP)
- the arrangements for security, storage and archiving of trial material, e.g. documents and samples
- Health and safety training requirements at the participating organisation
- Obtaining consent in accordance with the study protocol/investigational plan while considering the needs of participants who may not adequately understand verbal explanations or information written in English as necessary
- For educational studies, the academic supervisor to student ratio is determined to be acceptable by the sponsor and for students accessing data or with access to patients, co-supervisor arrangements are in place

- **Training:** The participating organisation can accommodate training format required by the Sponsor e.g. online, face to face or routine briefings within the specified time frame required by the Sponsor. Where an initiation visit has been arranged, the PI and relevant staff are able to attend.
- **Human Resources**: In line with the information provided by HRA Ready to Review letter or HRA Approval letter, any employer human resource requirements to ensure that staff only undertake study specific activities that are appropriate to the job and competencies of the individual, and that appropriate supervision will be provided as required within the specified time frame required by the Sponsor are in place. This many include arrangements to issue letters of access or an honorary contract where participants will be seen by non-NHS Organisation employees. Any Research Passport has been validated by the employing organisation for the relevant staff member as described in the HR Good Practice resource pack.

ADEQUACY OF LOCAL FACILITIES INCLUDING SUPPORT DEPARTMENTS

- **Clinical pathway:** The participating organisation offers a clinical pathway for the condition being studied or excess treatment costs will support a new pathway within the timeframe specified by the Sponsor. Any impact of the study on the local pathway is considered for staff, participants and participating organisation patients. This includes ascertaining standard of care pathway for the patient at the site.

- **Recruitment Target:** Based on the projected study timelines there are sufficient numbers of potential participants meeting the inclusion/exclusion criteria when taking into account any competing trials currently open or planned to open at the participating organisation to minimise the potential for inadequate patient recruitment or non-completion of research. The recruitment target has been assessed reliably (such as using patient databases, screening of clinic lists or previous study recruitment data) and consideration has been given to recruitment mechanisms such as advertising and increasing patient populations through use of Participant Identification Centres (PICs) as appropriate for study. The recruitment target reflects considerations for patient willingness to participate in line with the patient's standard of care treatment options.
- **Space**: Adequacy of space to recruit participants into the study along with the necessary clinical space to perform clinical trials assessments and procedures, taking into account day-case, inpatient stays, access to support services such as imaging/radiotherapy as applicable. Adequacy of secure space for storage of equipment and site files as relevant.
- **Internal arrangements**: Internal arrangements with the relevant department/directorate/practice are agreed and in place as required for that participating organisation which includes
  - suitable arrangements for peripheral clinics/access when study involves NHS patients external to the participating organisation (e.g. another NHS Organisation)
  - occupational health and safety such as those arising from the location of the research procedures (e.g. where lone worker arrangements need to be put in place in line with relevant policies and costed appropriately)
- **Suitability:** Suitability of participating organisation facilities including; adequacy of facilities for any novel procedures or for procedures not part of existing clinical activity; availability and access to resources, facilities, equipment and storage considering impact on current levels of use for non-research activities; and considering Sponsor quality expectations. This could include calibration, arranging loans of equipment from the Sponsor.
- **Impact of study on workload:** Supporting services or departments have the ability to manage additional workload such as additional processes (additional to standard of care), unfamiliar processes, intensive procedures, resource, equipment, facilities, and/or long term retention/archiving requirements (study records, worksheets) including consideration of any impact on delivery of non-research service activities
- **Support** is available for the necessary arrangements to meet the:
  - **Pharmacy requirements (where applicable)** outlined in the HRA Pharmacy Technical Review for the study taking into account drug/placebo dispensing is under the relevant blinding conditions; prescribing; drug supply; drug storage and dispensing; equipment; CRF completion; out of hours/emergency contacts.
  - **Pathology requirements (where applicable)** for the study taking into account sample processing and testing; sample storage; postage/collection; archived material (retrieval/testing); CRF completion; out of hours/emergency contacts; transfer of relevant material
  - **Imaging/radiological requirements (where applicable)** for the study taking into account that the study has been reviewed by the HRA Radiation Assurance process prior to application for HRA Approval, the ARSAC application; RECIST reporting; radioneucleotide

techniques; medical physicist input; data reporting/saving; independent assessments CRF completion; out of hours/emergency contacts
    - **different research settings (e.g. a prison) or vulnerable participant populations requirements** for researchers conducting studies in these research settings
- **Agreements**: That appropriate agreements are in place before the study is initiated, which includes sub-contracts or service level agreements for services obtained in support of the study (e.g.X-rays; CT or MRI scans; echocardiograms) from another organisation, who in essence is acting as a sub-contractor, and covers relevant responsibilities for Any Qualified Provider, which may vary depending on the involvement of NHS staff (e.g. the allocation of responsibilities and rights may be described in another document such as a GP agreement or GP information sheet).
    - Any prior participating organisation contracts with the Sponsor which are related to the study e.g. Confidentiality disclosure agreements or 'Letters of Intent' are sufficiently superseded by the model agreement or do not create conflict with the study contract
- **Financial arrangements**: The financial arrangements applicable to the participating organisation are adequately described, which may include agreement of CRN provided support (including for studies involving independent contractors) or the use of NHS employees and/or NHS facilities e.g. laboratories or x-ray or post-study treatment not included in NICE guidelines or a local prescribing policy. Arrangements for excess treatment costs are agreed with appropriate commissioning bodies and documented as per local requirements.
- **Financial management:** All financial management arrangements and costs are agreed as appropriate through discussions directly between the Sponsor and participating organisation, and are documented before signing the study agreement or sub-contractor agreement, including arrangements with CRN and commissioners as applicable.
- **Equipment:** Appropriate arrangements for receiving, storing and, where applicable, servicing, maintaining and PAT testing goods including loaned or gifted equipment and where applicable segregation of trial-use only equipment. Where equipment is loaned, the contract documents the responsibilities in relation to breakages, maintenance and calibration.
- **Information Technology:** Appropriate arrangements for any study requirements such as online CRF completion, access to relevant databases, IVRS account set-up, use of encrypted USB sticks, electronic record storage (including original destruction process) as applicable.

NOTE: The RSS Planning Tool could support this assessment.

LOCAL ARRANGEMENTS TO SUPPORT RESEARCH PARTICIPANTS

- **Participant safety:** Potential impact on patient safety is minimised through implementation of suitable management plans and safeguards (e.g. the effects of additional treatments or changes in treatment; the effects of additional invasive procedures or exposures) which includes

appropriate mechanisms in place for identifying and reporting safety concerns/incidents including those reported by other healthcare professionals who are made aware of the participant's involvement in the study or during out of hours, if relevant
    - When participating organisation is **Any Qualified Provider**, the relevant responsibilities for participant safety are suitably managed in relation to the involvement of NHS staff at the participating organisation
- **Emergency procedures:** Emergency procedures that may be necessary are conducted at the participating organisation in accordance with the protocol (e.g. to protect the participant in the event of a life-threatening incident or adverse event)
- **Back-up/Support:** Backup/support arrangements necessary are conducted at the participating organisation in accordance with the HRA approved arrangements (e.g. to support a participant or research staff when discussing upsetting/embarrassing topics or news; sensitivity to a participant's confidentiality/data security; notification of other health or social care staff with an interest in the participant's care)
- **Participant comfort**: Consider requirements for participant comfort such as transfers across site, duration of visits or time of visits to site, entertainment, bed / chair availability, refreshments and their related expenses
- **Local contact information:** Where applicable to the study type that the participant is clear about the local arrangements for the study e.g. name of participating organisation (including Any Qualified Providers), address and telephone number (usually included in the letterhead of the participating organisation), contact details of the local investigator(s), and if applicable, other members of the research team, e.g. research nurses, Emergency contact information, if appropriate, contact information for complaints and, where appropriate, independent advisors.
    - Some studies are managed centrally and local contact points will not be applicable.

COMPLIANCE OF PARTICIPATING ORGANISATION

- **HRA guidance**: The HRA Approved protocol and any guidance provided in the HRA Approval letter are adhered to. This includes, but is not limited to, any patient consent, Information Governance, Human Tissue Act, and Mental Capacity Act arrangements.
- **Practicalities**: Compliance to deliver practical aspects of the protocol related to these required could include local policies/processes for:
    - accessing personal identifiable information
    - anonymisation or pseudonymisation of personal identifiable information set out in the protocol, if relevant
    - storage of data during the study and any post study archiving arrangements
    - identifying personal or professional legal representatives where the study involves adults unable to consent for themselves
    - complying with the requirements for initial and on-going assessment of capacity including arrangements for adults who may become incapacitated during the course of the research and/or research involving emergency treatment.
    - identifying personal or nominated legal consultees separate from the research team

- **Information Governance**: All research delivery staff and research management staff for the study have had the appropriate Information Governance training
- **Fraud and Misconduct**: Local systems for dealing with fraud and misconduct
- **CTIMPs (where applicable)**: CTIMPs the research is carried out in accordance with Good Clinical Practice (GCP) or equivalent as appropriate (Good Pharmacovigilance Practice – GPP) and the MHRA CTA authorisation
- **Radiation (where applicable)**: The Ionising Radiation (Medical Exposure) Regulations 2000 and the Medicines (Administration of Radioactive Substances) Regulations 1978 requirements are met
- **Transparency**: Local communication processes in place to ensure compliance with transparency requirements for research

E – ASSOCIATED WORKFLOW DATA SET FOR PARTICIPATING ORGANISATIONS

Data Point	Data Point Definition
Date site invited by the sponsor	"The Sponsor/ CI/ Study Coordinator formally invites the NHS organisation (Research Management Team) to assess their local capacity and capability to participate in a named study. This should be done by email to the R&D contact for that organisation as listed in the contact details for NHS organisations on the NHS R&D Forum website. NHS R&D offices are strongly encouraged to keep their contact details up to date. The formal invitation must happen after an application for HRA Approval has been made but can also occur after HRA Approval is in place." Source: HRA Assess, Arrange, and Confirm: clarifications on HRA terminology Paper
Date site selected	"Joint decision by sponsor and organisation that the organisation has been selected to take part in the study. Confirmed by email." Source: HRA Assess, Arrange, and Confirm: clarifications on HRA terminology Paper
Date Sponsor provides information to site to commence local review of capacity and capability	Date on which the Sponsor provides all or the last element of information as described in section C to the participating organisation to commence confirmation of local capacity and capability
Date site confirmed by the Sponsor	"Sponsor confirms site participation in writing (email) by finalising the study specific content of the unexecuted agreement ready for signature or final confirmation of content of the statement of activities." Source: HRA Assess, Arrange, and Confirm: clarifications on HRA terminology Paper
Confirmation outcome	Status either: 1. Confirmed as participating organisation 2. Not selected by Sponsor 3. Participating Organisation decision not to participate
Site ready to recruit	(i) Dates of each party contract signature (latest signature on agreement denoted ready to recruit date) OR date statement of activity accepted by both the site and sponsor. AND (ii) Agreement by Sponsor and Participating Organisation that "all other requirements" have been satisfied or a date by which these will be satisfied [OUTSTANDING QUERY: to define key elements e.g. training undertaken, site initiation, IMP shipped to site, site file in place]

ABBREVIATIONS AND GLOSSARY

Term	Definition
CI	Chief Investigator
CRF/eCRF	Case Report Form/ electronic Case Report Form
CRN	Clinical Research Network
CTIMP	Clinical Trial Investigational Medicinal Product
GCP	Good Clinical Practice
GPP	Good Pharmacovigilance Practice
HRA	Health Research Authority
LCRN	Local CRN
NIHR	National Institute for Health Research
Participating Organisation	For the purposes of this document includes an NHS organisation, General Practice, Tertiary Centre, Independent Provider, Any Qualified Provider or Patient Identification Centre as appropriate.
R&D	Research and Development
REC	Research Ethics Committee