

Assessing, Arranging, and Confirming: clarifications on HRA terminology



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| Title:: | Assess, Arrange and Confirm: clarifications on HRA terminology |
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1. Purpose

The purpose of this paper is to provide clarity about some of the activities that the HRA expects to be undertaken at the local level to support research delivery in the NHS in England for HRA Approval studies. It aims to explain some of the terminology being used and the intended process flows. It describes sponsor activities only in the context of how they interact with organisations participating in the study.

Feedback or queries can be sent to hra.approvalprogramme@nhs.net.

Throughout the document we refer to local activities. These activities have been mapped to the description of [Research Support Functions](#) published on the HRA website. For those studies supported by the NIHR Clinical Research Network some activities will be part of the NIHR CRN Study Support Service which is currently in development. Others activities remain the responsibility of the organisation hosting the research.

2. Context

- 2.1 HRA Approval is the new process for the NHS in England that comprises a review by a NHS Research Ethics Committee (REC) (where required) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA staff. In England, it replaces the need for local checks of legal compliance and related matters by each participating NHS organisation. This allows these participating NHS organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.
- 2.2 HRA Approval applies only to the NHS in England. The HRA has compatibility arrangements in place with the [national NHS permissions coordinating functions](#) in Northern Ireland, Scotland and Wales that mean that the HRA will share information with those national coordinating functions to benefit study set up in participating NHS/HSC organisations across the UK where applicable.

- 2.3 The following published documents describe the activities to support research delivery at the local level:
- [Draft UK policy framework for health and social care research](#). See especially paragraphs 8.17 and 8.19
 - The [Research Support Functions](#) document, which HRA published in autumn 2014.
 - The NHS R&D Forum Primary Care Working Group has published a [companion document](#) which focuses on the local support functions which primary care research offices can provide.
- 2.4 The vision of the HRA Approval Programme is to make it easier to undertake responsible health research in the NHS in England as part of a UK-wide system.
- 2.5 The aim of the HRA Approval Programme is to **simplify the process** in England for approval of health research for researchers, thus reducing the time and cost of setting up studies.
- 2.6 HRA Approval will provide assurance that the study complies with required legislation and guidance and, where applicable for the study type, that a favourable opinion from an independent ethical review is in place. This assurance will include, where applicable to the study type, pharmacy and medical exposure assurance that sites can use in putting the practical arrangements in place for the study to begin.
- 2.7 HRA takes an iterative and collaborative approach to developing new processes. It should be noted that:
- Standards and guidance will refine over time
 - Processes will develop and become more efficient over time
 - IRAS will develop over time to include the requirements for HRA Approval as it evolves.

3. Applications for HRA Approval

- 3.1 Sponsors play a key role in the set up and delivery of studies – even when sometimes this is devolved to a Chief Investigator, a Clinical Trials Unit, a Contract Research Organisation, or study coordinator.
- 3.2 HRA expects applications for HRA Approval to be complete and of a high quality, and that the sponsor will work with participating organisations in a planned way to deliver the study.
- 3.3 For studies applying for support from the NIHR Clinical Research Network (CRN) the HRA will ensure that the NIHR CRN Coordinating Centre has access to information to allow it to make decisions on eligibility of the study for the NIHR CRN Portfolio.
- 3.4 Lead NHS R&D offices and Lead NIHR Local Clinical Research Networks (LCRNs), through the early engagement elements of the NIHR CRN Study Support Service, are strongly encouraged to work together to support Chief Investigators and sponsors to:
- a. plan their study well, taking into account the requirements for delivery in the NHS
 - b. make high quality applications which are compliant with legislation and guidance
- 3.5 The HRA publishes [applicant guidance](#) on the content of the application package for HRA Approval on the HRA website and within IRAS. The application package will consist of
- a. A combined IRAS Application Form (ie not separate ethics and R&D application forms)
 - b. A set of supporting documents as set out in a checklist.

The IRAS checklist is based on the existing REC and R&D form checklists and will develop over time.

3.6 Within the application to the HRA there should be clarity on the resource implications for participating organisations

- a. For commercial contract studies an NIHR Industry Costing template is included in the application checklist.

Where it is intended that the study will be included on the NIHR CRN Portfolio, prior validation of the Industry Costing Template by NIHR CRN will support swift processing through the HRA. Where the study is not intended for inclusion on the NIHR CRN Portfolio, validation will occur within the HRA following an application to the HRA.

- b. For non-commercial studies a template Statement of Activities and Schedule of events are included in the checklist for the application to the HRA. These are available on the [HRA website](#).

Work undertaken by NIHR and charity funders has identified the benefit of early completion of a schedule of events and clarity around the attribution of activities in line with the [AcoRD guidance](#). The template [Schedule](#) of Events makes this possible for all non-commercially sponsored studies. The HRA will continue to work with the AcoRD Implementation Group to ensure there is no duplication of review undertaken by NIHR funders or NIHR CRN.

3.7 All applications will require a copy of the relevant type of template to be used in confirming the local arrangements with the organisations that will participate in the study. If within the one study there are different types of activities being undertaken at different organisations, different ways of confirming capacity and capability may be required for each group of organisations. For example within any one study some organisations participating in the study may be recruiting participants as their only part in the study, another group may be delivering an intervention and another may only be involved in follow up activities.

- a. Where a model agreement is available for that study type and type of activity, the HRA expects that an unmodified agreement will be used.
- b. Where a model agreement is published for consultation in use for that study type, the HRA expects that the agreement will be used and any modifications very clearly justified. These will feed into finalising the model agreement.
- c. For non-commercial studies for which a model agreement would be disproportionate for one or more organisations, the template Statement of Activities will serve as sufficient confirmation between sponsor and participating organisation that arrangements are in place. This applies where there are limited activities or limited costs for the participating organisations. The template should be agreed by email with no requirement for wet ink signatures.

3.8 Within the application to the HRA, there should be clarity on activities to be undertaken at participating organisations. This should be contained within the protocol and, for non-commercial studies, will be made explicit in the Statement of Activities template.

It is important that all NHS organisations hosting research activities have clarity about what activities are to be undertaken and by whom.

HRA Approval will provide assurances about the compliance of proposed research activities set out in the study protocol and associated documents with relevant legislation and national standards. The HRA indemnifies NHS organisations accepting assurances from the HRA against

any claim covered by the NHS Litigation Authority (NHSLA) arising as a result of incorrect assurances. NHS organisations should have confidence in accepting such assurances without duplication of review of the proposed activities. Detailed explanations prepared with the NHS Litigation Authority are available from the HRA.

4. Local activities in the context of HRA Approval

- 4.1 The HRA wishes to encourage collaborative and common sense ways of working between NHS organisations and sponsors/research teams and, where applicable, the NIHR Clinical Research Networks.

The HRA has recognised that there is a burden to the research team in having to create applications for each participating NHS organisation and has recognised that there is variability across England in who completes the SSI application. In some places the sponsor/study team make a best guess and subsequent discussions are not captured anywhere, and in others it is a joint activity between the local research delivery team and research management team after arrangements are already in place.

The local process for HRA Approval studies will focus on collaboratively documenting what is actually going to happen. An application to each participating NHS organisation will not be made but the HRA expects that sponsors/researchers will, as many already do, discuss with the participating organisation whether or not it can put in place the arrangements necessary to deliver the study. It will be the sponsor's responsibility to ensure that the organisation receives the necessary documents to inform discussion (see section 4.5 below). Depending on the study type and nature of the activities to be undertaken locally confirmation of that discussion will be indicated within the template Statement of Activity or sign-off on an agreement. For commercial studies, this will always be by sign-off on an agreement.

The HRA asks researchers to feed back to the HRA if they are asked to complete additional local forms.

- 4.2 The HRA expects expert local research management staff to work alongside central and/or local research teams in setting up and delivering studies. Research management staff should proactively support research teams. Local research delivery teams should involve local expert research management staff in discussions with sponsors/ CIs/ study coordinators.
- 4.3 The HRA has defined the different stages that sponsors and participating organisations go through on the way to mutually agreeing that the study can open at that organisation. These stages can be used to identify time points which NHS organisations may wish to measure in order to examine where barriers to study set up and delivery occur.
- 4.4 The stages are
- a. **Assessing:** Assessing whether or not the NHS organisation has the capacity and capability to participate in the study.

NB this stage will not be required, or will be minimal, for some types of studies where it is automatically expected that the NHS organisation will participate unless there is a

significant reason why not. These study types include emergency public health research, studies involving minimal local activity such as distributing questionnaires or supplying previously collected clinical data where consent is already in place, and studies where the clinical pathway has meant that a patient has been transferred for ongoing clinical care but the responsibility for the research remains with the original Principal Investigator.

NB this stage may not be required where the NHS organisation is also the sponsor of the study.

- b. **Arranging:** Putting any practical arrangements in place to provide the capacity and capability to deliver the study.

NB this stage may be very brief where the activities at the local organisation are minimal.

- c. **Confirming:** Confirming that the NHS organisation has the capacity and capability in place to deliver the study and will deliver the study.

This confirmation is given through the mutual confirmation of the contents of the statement of activities for non-commercial studies or sign-off on an agreement.

NB it is expected that a statement of activities would still be completed where the NHS organisation is also the sponsor of the study.

4.5 Assessing Capacity and Capability

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| <p>Start Point</p> | <p>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 and the LCRN for that organisation as listed in the contact details for NHS organisations and LCRNs on the NHS R&D Forum website. NHS R&D offices are strongly encouraged to keep their contact details up to date.</p> <p>The formal invitation should be made after a final protocol is ready for regulatory applications and may take place before or after the application to HRA. The purpose of this step is site selection – the site may previously have put forward an expression of interest and the sponsor may want to identify which NHS organisations have enough potential participants and the right equipment. Some sponsors may choose to undertake site selection visits as part of assessing the capacity and capability of the potential site.</p> <p>For CTIMPs in particular, sponsors should be assessing site suitability and may conduct a site selection visit in this stage. The outcome of that site selection would be a decision by both sponsor and site to set up the study. It is likely, but not necessary, that early or informal collaborative discussions may have taken place with PI/ research team/ LCRN team prior to this formal invitation, e.g. through early Expressions of Interest.</p> |
| <p>Information required</p> | <p>The Sponsor/ CI/ Study Coordinator must supply the organisation with the final protocol which will be used for regulatory applications. If an application has already been made for HRA the documentation submitted to (or approved by, depending on timing) the HRA should be supplied. This should be done by email to both the local</p> |

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| | <p>study delivery team (where known) and the R&D contact for that organisation as listed in the contact details for NHS organisations on the NHS R&D Forum website.</p> <p>Where a local Principal Investigator or Local Collaborator is required at a particular organisation they should be named if known by sponsor, or a request to identify a local research team should be made to the organisation. Where no local Principal Investigator or Local Collaborator is required, the sponsor should make this clear. HRA will confirm whether this is appropriate based upon the study type and activities proposed for that organisation.</p> |
| Activities at participating organisation | <p>Research management staff and local research delivery staff (where applicable and may include LCRN funded staff) work together to identify if the NHS organisation has the capacity and capability to deliver the study – or can put that capacity and capability in place –for example:</p> <ul style="list-style-type: none"> - The participant population required - The equipment/ space/ specialist services/ emergency processes/ safety reporting processes/ IT etc. needed to deliver the study - The staff required to deliver the study <p>For some studies a site selection visit by the sponsor may be part of the activity. Initial discussions about finance may begin.</p> |
| End Point | Joint decision by sponsor and organisation that the organisation has been selected to take part in the study. Confirmed by email. |
| Reference | <p>Reference number in Study Specific section of v 1.0 19/09/2014 Research Support Function Document: 1, 2, 4, and 5.</p> <p>NB function 3 happens prior to the formal arranging stage.</p> |
| NIHR CRN Study Support Service | The NIHR CRN has produced a summary of principles to support participating organisations to assess, arrange and confirm their capacity and capability. This will be made available to coincide with cohort 3 go-live. |

4.6 Arranging Capacity and Capability

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| Start Point | <p>Joint decision by sponsor and organisation that the organisation has been selected to participate in a study. Confirmed by email.</p> <p>This should happen after an application for HRA Approval has been made but may also occur after HRA Approval is in place. The NHS organisation should be listed in Part C of the IRAS form. If the site is added after HRA Approval has been granted then the new site should be added via an amendment.</p> |
| Information required | The Sponsor/ CI/ Study Coordinator should supply the organisation with the documentation submitted to (or approved by, depending on timing) the HRA, the HRA Initial Assessment (or HRA Approval) Letter and the locally tailored draft agreement or statement of activities based on the template submitted to HRA, and proposed payments. These documents should be supplied electronically simultaneously to the local study delivery team, the research management function, and the LCRN contact |

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| | <p>for that organisation.</p> <p>The organisation must be listed in the application to the HRA, or added via a substantial or minor amendment (as appropriate)</p> |
| Activities at participating organisation | <p>Put in place arrangements to deliver the study</p> <ul style="list-style-type: none"> - Schedule staff activities - Plan and put in place any required staff training as appropriate in line with HRA guidance and sponsor requirements (NB not necessarily GCP) - If applicable put local headers on participant facing study documents once HRA Approval is in place (e.g. Participant Information Sheet if applicable) - Put in place all arrangements to deliver the study across the required patient pathway - Where applicable set up outsourced services (e.g lab tests, scans, etc.) - Put arrangements in place with support departments - Where applicable complete arrangements for honorary research contracts or letters of access - Complete negotiation and agreement of financial arrangements - If required schedule site initiation visit <p>Act on any guidance that the HRA has provided to participating organisations within the HRA Initial Assessment (or HRA Approval depending on timing) letter.</p> |
| End Point | <p>HRA Approval in place,</p> <p>And</p> <p>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.</p> |
| Reference | Reference number in Study Specific section of v 1.0 19/09/2014 Research Support Function Document: 6, 7, 9 and 12 |
| NIHR CRN Study Support Service | The NIHR CRN has produced a summary of principles to support participating organisations to assess, arrange and confirm their capacity and capability. This will be made available to coincide with cohort 3 go-live. |

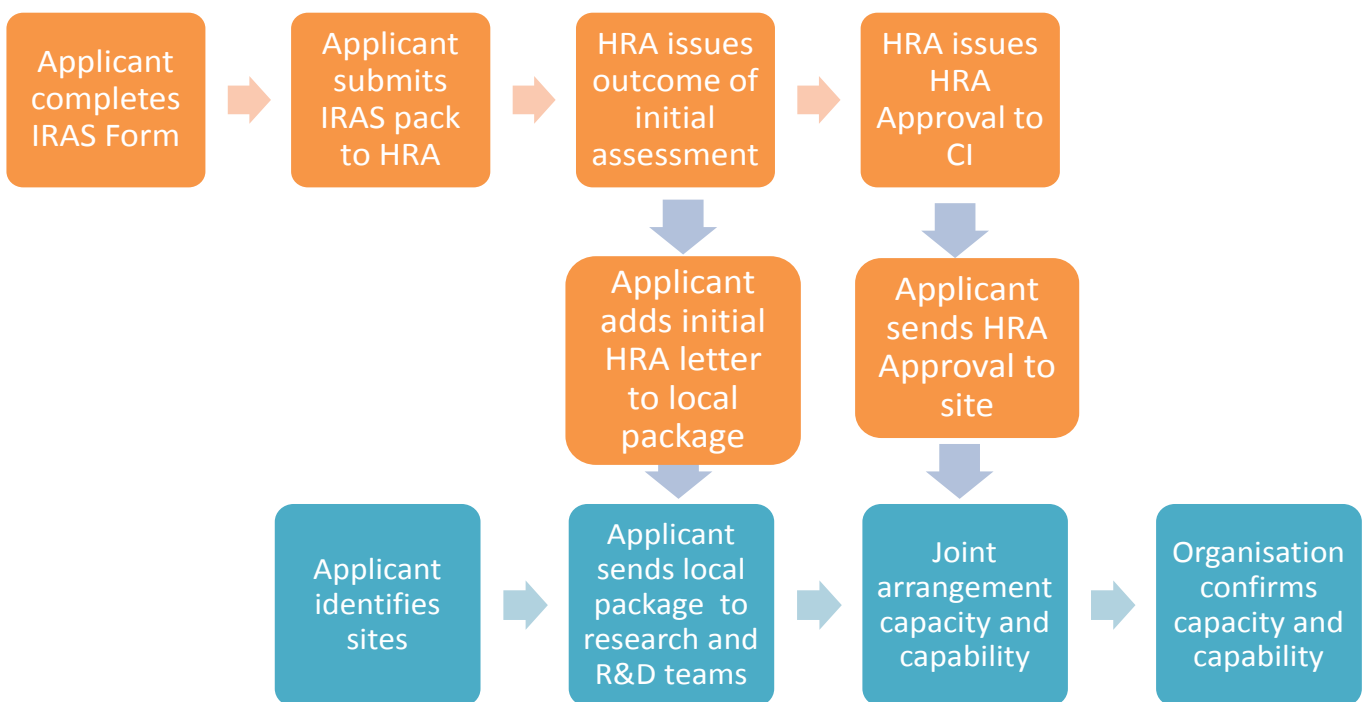
4.7 Confirming Capacity and Capability

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| Start Point | <p>HRA Approval in place,</p> <p>And</p> <p>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.</p> |
| Information required | Final unexecuted agreement ready for signature or finalised local statement of activities, based on the template submitted to the HRA |

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| Activities at participating organisation | Confirmation of capacity and capability using local statement of activities by email or by signature of the agreement by a person at the NHS organisation authorised to do so. Ensuring that the research team, including the Principal Investigator where applicable, are suitable in terms of training and experience, have appropriate management or supervision arrangements in place, and that there are no conflicts of interest remain a responsibility of the participating organisation. |
| End Point | Research activity may commence at participating organisation. |
| Reference | Reference number in Study Specific section of v 1.0 19/09/2014 Research Support Function Document: 8, 13 |
| NIHR CRN Study Support Service | The NIHR CRN has produced a summary of principles to support participating organisations to assess, arrange and confirm their capacity and capability. This will be made available to coincide with cohort 3 go-live. |

4.8 NHS organisations are expected to supportively manage studies throughout their life cycle. (Research Support Functions study specific references 10, 11, 14). A key aim of HRA Approval is to free up capacity in the NHS to support high quality delivery of studies. Once HRA Approval is fully implemented, expert research management staff will be better able to support the ongoing oversight of projects, ensuring that recruitment is completed on target, that data is collected and submitted on time, and sponsor queries are addressed promptly.

4.9 The following diagram represents the information flow between the sponsor/Chief Investigator/study coordinator and the participating NHS organisation when HRA Approval is fully implemented.



5. Metrics

- 5.1 The HRA are working with sponsors to look at end to end improvements in the efficiency of study set up. Not just time lines, but predictability and simplicity that will bring cost benefits.
- 5.2 Because neither HRA Approval nor confirmation of local capacity and capability directly equate to existing review processes, the current methods of measuring efficiency of study set up at the NHS organisational level will evolve. This relates particularly to the Department of Health Performance in Initiating and Delivering Clinical Research data and the NIHR CRN High Level Objective 4 as the data points currently used will not be meaningful or available for HRA Approval studies.
- 5.3 HRA Approval is premised on the notion that NHS organisations support sponsors to set up and deliver research to a planned and predicable timetable for that specific study rather than on an absolute number of days. However there will be a continued interest in set up times which need to be as efficient as possible in order to continue to attract commercial research to England, and to provide value for money for non-commercial research. From the outset discussions with sponsors should include expected start and end dates for the study.
- 5.4 The HRA are encouraging organisations, working alongside NIHR CRN staff supporting study set up of NIHR CRN Portfolio studies, to record and observe a series of local data points and metrics associated with the stages of assessing, arranging and confirming as outlined above in order to understand and improve upon their own efficiency.
- 5.5 The observation of local metrics will allow sites to be able to predict for sponsors how long it will take to set the study up at their site. Measuring performance to agreed targets for an individual study should be as important as measuring the actual timeline
- 5.6 The HRA has no remit to mandate the collection of these local metrics. The Department of Health and NIHR CRN will be reviewing the metrics that they collect.

6. Document Change History

| Version | Status | Date | Changes |
|---------|----------|------------|--|
| 1.0 | Approved | 13 04 2015 | Initial document |
| 1.1 | Approved | 27 04 2015 | Typo correction |
| 2.0 | DRAFT | 23 11 2015 | Minor revisions to language to reflect developing nature of the programme and clarifications to section 4.5 – 4.9. CRN input included. |