HRA Approval process from an applicant’s perspective

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1. **What is HRA Approval?**
   a. HRA Approval is for research conducted in the NHS in England. It combines NHS Research Ethics Committee review with the legal and governance checks that individual NHS R&D offices or NIHR CSP previously performed.

   b. The HRA has compatible arrangements in place with national coordinating functions in Northern Ireland, Scotland and Wales. If your study is led from England, the HRA will share their assessment with the other UK nations in which there are sites and vice versa. If your study is led from Scotland, Wales or Northern Ireland and has English sites, the lead nation will share the study with the HRA so that HRA Approval can be issued for the English sites. You should not have to apply separately to the HRA.

   c. If you are seeking NHS REC review only and do not need NHS R&D permission (e.g. using NHS REC approval as a Human Tissue Authority Licence exemption) you should not use HRA Approval, [apply to the HRA for NHS REC review](#).

   d. The aim of HRA Approval is to make it easier for you to set up high quality research. It uses a combined REC and R&D Form which is submitted once to the HRA and brings more efficiency to the approvals process, ensuring that the legal and governance checks are done centrally once, and not by each NHS organisation.

   e. If you have HRA Approval, your interaction with local NHS R&D offices will focus on their capacity to deliver your study and the local arrangements that need to be put in place.

   f. There will be increased responsibility on Research Sponsors to do their checks prior to submission.
2. **Is my study eligible?**

2.1. **The studies eligible for HRA Approval are:**
   a. Clinical trial of an investigational medicinal product.
   b. Clinical investigation or other study of a medical device.
   c. Combined trial of an investigational medicinal product and an investigational medical device.
   d. Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.
   e. Basic science study involving procedures with human participants.
   f. Study administering questionnaires/interviews for quantitative analysis, or using mixed qualitative/quantitative methodology.
   g. Study involving qualitative methods only.
   h. Study limited to working with human tissue samples (or other human biological samples) and data (specific project only).
   i. Study limited to working with data (specific project only).

2.2. **The studies NOT eligible for HRA Approval are**
   a. Research Tissue Banks.
   b. Research databases do not use HRA Approval.

3. **Initial Sponsor Approval**
   a. Please inform the Research Integrity and Governance Office (RIGO) team [rigo@surrey.ac.uk](mailto:rigo@surrey.ac.uk) as early as possible of your intent to undertake research in the NHS.
   b. RIGO will need to be informed at least 4 weeks before starting the HRA application process.
   c. The HRA recommends that you have planned your project sufficiently to ensure that all sites are listed at the beginning even if you do not start work at all sites immediately.
   d. Contacts/collaborators at NHS sites will need to inform their R&D offices, at this stage, that such project is coming their way.
   e. RIGO will need an email confirmation that this has been done and contact details for both the collaborators and R&D office contact at each site.
   f. Ideally NHS sites would begin to make an assessment of their capacity and capability to deliver your study before HRA Approval has been applied for. However, the local research team and NHS R&D office will need the final version of the protocol after HRA approval.
g. The Chief Investigator and SPONSOR (RIGO) need to determine the timetable for site set up.
h. RIGO will confirm agreement to initially sponsor the study once it is satisfied that the participating NHS trusts are in principle supportive of the study.

4. How to apply for HRA Approval
   a. On IRAS it is critical to select the correct study category on the project filter, as this means that the appropriate questions and forms will appear for completion. Please use the Question Specific Guidance (green ‘i’ buttons) on IRAS to help you understand the categories.
   b. On filter question 4 select IRAS From.
   c. Complete the IRAS project dataset and prepare your supporting documentation as normal. This includes uploading supporting study documents to the checklist in IRAS.
   d. The SPONSOR (RIGO) will need to be approached at the very early development stages of the IRAS form, as outlined in section 3 above.
   e. If this is a non-commercial study, complete the Statement of Activities and Schedule of Events. Please ensure that this is approved and finalised with the SPONSOR (RIGO). Please be advised that Section A doesn’t need to be completed if you are doing a Site Specific Information form (for Non-NHS sites).
   f. The Schedule of Events doesn’t require you to identify costs in pounds and pence, but does need you to attribute costs to NHS definitions (Attributing the costs of health & social care Research & Development (AcoRD)).
   g. Further guidance is included at the end of each template (Statement of Activities and Schedule of Events).
   h. Check the IRAS Form before submission to make sure it is complete.
      Note. Once you have obtained electronic authorisations from all relevant parties do not amend any part of the IRAS Form, this will invalidate all electronic authorisations. This is a common reason for rejection.
   i. Contact the Central Booking Service (CBS) (you will need to do this whether you require NHS REC or not). You should receive an email confirming that your application has been booked for HRA Approval. You will be able to enter the booking information on the first page of the IRAS Form, but remember do not amend any other part of the IRAS Form as this will invalidate your electronic authorisations.
   j. On the same day as you have booked your application via CBS, you will need to submit your application for HRA Approval via the E-submission tab at the top of the IRAS Form. Supporting documentation is electronically submitted along with your IRAS Form.
   k. Confirmation of receipt of your application for HRA Approval will be via an update to the Submission History entry on the E-submission tab of your IRAS Form.
5. Approvals

5.1. Going through HRA Approval

The HRA will first validate whether your application is complete for REC review (for those studies that require REC review), you will be notified if it is valid for REC review in around 5 working days after submission.

The HRA has published their assessment criteria and standards. This includes information on what should be included in participant information sheets and the protocol, and is largely aimed at sponsors who will want to assure themselves that applications will meet the assessment criteria and standards. The HRA will assess the following (includes the relevant page number in version 3.2 of the HRA Standards document):

a. For staff who do not hold a substantive contract with the NHS organisation where the research will take place, the HRA will confirm what is needed e.g. an honorary contract, a letter of access, the necessary pre-engagement checks, etc. (page 3)

b. Principal investigator suitability (page 3)

c. The level of capacity and capability assessment needed by sites (page 4)

d. Intellectual property arrangements (page 5)

e. Assurances to NHS sites that the study is accurately described (including any treatment and participant care during and after the study) and is compliant with legislation (page 6)

f. The consent process and participant information correctly informs potential participants, meets legal requirements and is consistent with other study documents (page 9).

g. In studies where REC review is not required e.g. those involving NHS staff as participants, the HRA will consider the ethical issues and may decide REC review is required (page 10)

h. Assess the protocol content and consistency with other study documents, and the use of templates where available (see CTIMP protocol template and qualitative protocol template) (page 14)

i. Allocation of responsibilities and rights and clarity to the NHS on the agreements intended for use by the sponsor (page 15)

j. Template agreements are used without modification or justification given for modification (page 16)

k. Insurance and indemnity arrangements (page 18)

l. Financial arrangements (page 23)
m. The use of patient data and legal compliance (page 26)

n. Compliance with CTIMPs (page 33)

o. Compliance with other relevant legislation (37)

p. All relevant approvals and authorisations have been received (application is in parallel to all relevant approvals bodies, e.g. CAG, MHRA; but HRA Approval won't be given until these have been received) (Page 45)

During HRA assessment the HRA may contact you for more information, usually by telephone then by a follow-up email, so please ensure that you are available after you have submitted your application (at least for the two weeks after submission).

Following any requests for further information, you should expect to receive an Initial Assessment Letter from the HRA. When you have this you can send documents to NHS sites.

When the assessment is complete, you should expect to receive an HRA Approval letter to share with individual NHS sites. If you have any queries about the assessment of your application, email the HRA Approval team hra.approval@nhs.net

5.2. Working with individual NHS sites

a. You can identify sites at any time: before you apply for HRA Approval, after you have applied but before Approval is obtained, or sites can be added after HRA Approval as amendments. The HRA recommend that you have planned your project sufficiently to ensure that all sites are listed at the beginning even if you do not start work at all sites immediately.

b. Sites can begin to make an assessment of their capacity and capability to deliver your study before HRA Approval has been applied for or awarded, but the local research team and NHS R&D office will need the final version of the protocol. The Chief Investigator and SPONSOR need to determine the timetable for site set up.

c. In order for sites to fully arrange capacity and capability, you will need to provide full documentation when you have received your Initial Assessment Letter from the HRA. You should send the following local document package to the study delivery team and NHS R&D office (and local CRN if relevant) at the participating NHS site:
i. Copy of IRAS Form as submitted for HRA Approval  
ii. Protocol  
iii. Any changes / amendments  
iv. Participant information and consent documents  
v. Statement of Activity relevant to the participating NHS organisation (non-commercially sponsored only)  
vi. Relevant template contract/model agreement (if needed in addition to Statement of Activity)  
vii. Costing template (commercially sponsored only) or Schedule of Events (non-commercially sponsored only)  
viii. Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study  
ix. Copy of HRA Initial Assessment letter and (when issued) HRA Approval letter and final document versions.  

d. Where site researchers are not employed by the NHS site, the applicant should work with the NHS R&D office for that site to put HR arrangements in place in accordance with the research passport guidance.  

**NHS SSI forms are not required for studies going through HRA Approval.**

6. Approval obtained  

6.1. HRA Approval  

a. You should receive an HRA Initial Assessment Letter not long after application (the timeframe will depend on whether there is more information that they need from you).  

b. Ethics review - You will be notified by the HRA Ethics Service of the outcome of the REC review within 10 working days after the meeting if the outcome is not favourable, provisional or favourable with conditions.  

c. If the outcome is favourable and HRA Approval is ready on the same working day these will be communicated together within 10 working days. **If HRA Approval is not ready,** the favourable ethics opinion will be sent to you separately. More information on REC review is available.

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d. When HRA assessment, REC review and any other approvals (e.g. section 251) are complete you will receive an HRA letter with the outcome: ‘HRA Approval’ or ‘not approved’, and guidance on what to do next. If it is approved this is the HRA Approval letter. You can’t start the study in a particular location until that site has formally confirmed to the SPONSOR that all arrangements are in place.

e. There are some study types (mainly staff questionnaire or interview studies) which do not need formal confirmation – if this is the case for your study this will be made clear in the HRA Initial Assessment and HRA Approval letters.

6.2. Site confirmation
Each site will confirm in writing that you can start site initiation. The exact form of confirmation will be specified in the HRA Approval letter, e.g. an agreement of the Statement of Activities by email, or another written contract / agreement exchange. Once the site has confirmed in the specified way, you can start any necessary site initiation procedures. Following initiation the site will be ready to start recruitment.

6.3. Non-NHS sites
If your study includes non-NHS research sites, you may need to generate and submit non-NHS Site Specific Information (SSI) forms in IRAS. Please refer to the HRA website Site Specific Assessment section for more information.

7. During the study (Amendments and reports)
Once your study has HRA Approval you will need to keep the HRA and research sites informed of any changes to your study. The following text summarises the HRA guidance on ‘During your study with HRA Approval’.

7.1. Amendments:
   a. For substantial amendments to studies that have undergone REC review you submit the appropriate notification form and any supporting documentation to the REC.
b. For all non-substantial amendments or substantial amendments to studies that did not require REC review submit the appropriate notification of amendment form and any supporting documentation by email to hra.approval@nhs.net.

c. The substantial amendment form is on IRAS, once you have approval the ‘Amendment’ tab will appear at the bottom left of the ‘Navigation’ page. At this stage it needs to be created and emailed, you can’t submit it electronically yet.

d. Adding a new site to a study is not a substantial amendment, unless it is a CTIMP and the site wasn’t listed on the original application.

e. Include the IRAS ID for your project in the subject line of the email along with the text “Notification of Amendment” and ensure that your email includes your contact details (email and phone number).

f. The HRA will review amendments and will provide information about the arrangements for handling the amendment with participating sites.

7.2. Progress reports

Studies must make regular progress reports to the HRA, and may need to make safety reports, in line with normal requirements. These requirements apply to all studies with HRA Approval.

8. End of the study

You should send this notification by email to hra.approval@nhs.net including your IRAS ID and your contact information (phone and email).