Health Research Authority Approval for Research Studies

SOP Reference: JRCO/SOP/039

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<th>Author: Cheuk Fung Wong, Research Governance Manager and QA Manager</th>
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<th>Approved by: Ruth Nicholson Head of Research Governance and Integrity</th>
<th>Date: 11 Jun 2019</th>
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<tr>
<th>Version</th>
<th>Date</th>
<th>Reason for Change</th>
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<tbody>
<tr>
<td>Version 1.0</td>
<td>26 May 2015</td>
<td>New SOP</td>
</tr>
<tr>
<td>Version 1.1</td>
<td>25 Nov 2015</td>
<td>Addition of cohorts</td>
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<td>Version 3.0</td>
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<td>Updates to the use of Organisation information document</td>
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1. **PURPOSE**

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Please Note: At present HRA approval only applies to research sites in England.

2. INTRODUCTION

HRA Approval is the new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments’ Research Ethics Service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

The HRA centralises the ethics and regulatory review process so that NHS Trusts are no longer required to conduct a full document review prior to providing R&D Approval. The HRA will review study documents in relation to law and ethics considerations so that research sites can focus on assessing capacity and capability in relation to supporting the research project. As such formal R&D approval will be replaced with a Organisation Information Document or research agreement depending on the research or sponsor type. HRA approval is required if your study is lead from England and involves the NHS in England. The studies can be commercial or non-commercial and be eligible for the NIHR CRN Portfolio.

Any GAfREC (Guidance Advice for Research Ethics Committees) exempt study that falls outside of this definition will be required to follow JRCO/SOP/038 ‘Obtaining ICHT Approval for Healthcare Research not requiring REC Review’ but must also obtain HRA approval.

If you are unsure whether your research meets this definition, please contact the JRCO who will advise you.

3. PROCEDURE

3.1 Sponsor Review and Approval

For projects where Imperial College London and Imperial College Healthcare NHS Trust are research sponsors, you must gain sponsor approval from the JRCO before submitting your study to the HRA.

All HRA applications for studies will be made using the on-line IRAS system which can be accessed at www.myresearchproject.org.uk.

Once you have completed the online form you will need to save a pdf copy and email it together with your study documents to the JRCO for review. Details of the sponsor review and approval process are described in JRCO/SOP/009 ‘Sponsorship and Insurance Approval’.

You will need to complete an ‘Organisation Information Document and schedule of events as part of your submission which provides details needed for HRA review and for a site to assess capacity and capability.

The Organisation Information document and schedule of events spreadsheet can be downloaded from: https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx.
3.1.1 NIHR CRN Portfolio Studies

If you wish to apply to the NIHR CRN Portfolio (external link), you are required to electronically submit a Portfolio Application Form (PAF) to the NIHR via IRAS before you submit your application for HRA Approval. Therefore, please follow the instructions below and complete all steps before submitting your application for HRA Approval:

1. In IRAS filter question 5a select the answer ‘no’ and in 5b answer ‘yes’.
2. In the Navigation Page in IRAS select the PAF and ensure that the information required is complete.
3. Electronically submit the PAF by clicking on the E-submission tab and following the instructions provided. You should save a copy of your submitted PAF for future use, as once you apply to HRA Approval the PAF and its associated submission history will not be visible.
4. The NIHR CRN will then review whether the project is potentially eligible and confirm this to the Chief Investigator. You should wait for a response from NIHR CRN before proceeding to the next step.

Once NIHR CRN have confirmed whether the project is potentially eligible return to the Filter Page in IRAS and select ‘no’ to question 5b, then follow the instructions provided in section above How to apply for HRA Approval to prepare and submit your application for HRA Approval.

The CRN for Imperial AHSC is London (NW).

3.2 Submission to the HRA

For studies where your lead NHS R&D office is in England, you are expected to prepare your application for HRA Approval in IRAS and electronically submit it to the HRA. This is a straightforward process, if you follow the steps below:

1. Ensure that the IRAS project filter has been accurately completed for your project. Please refer to the question specific guidance (QSG), which may be accessed by clicking the green “i” buttons, for further information about filter questions and options.
2. At question 4 in the project filter select the option for ‘IRAS form’.
3. When the project filter is completed, click on Navigate. You will notice that on the Navigation Page for your project in IRAS, under the Project Forms list, there is a form labelled ‘IRAS Form’. This is the application form that you will need to electronically submit to apply for HRA Approval. There will be no separate REC and R&D application forms.
4. Complete your dataset and prepare your supporting documentation as usual.
5. When you are ready to submit, select your IRAS Form and carefully review it to ensure that it is complete.
6. Supporting documentation for your application is electronically submitted alongside your application form by uploading all the files to the relevant rows on the Checklist tab of your IRAS Form.

**IMPORTANT NOTE ABOUT SUPPORTING DOCUMENTATION:** Your application to the HRA may need to include the Organisation Information Document and Schedule of Events, for each type of site in your study. Where this is required, please include each document in a new row in the ‘other’ section of the Checklist by using the ‘add new row’ button.

7. Obtain the required electronic authorisations for the IRAS Form, by selecting the Authorisations tab for the form and following the instructions provided.

8. Before electronically submitting your application for HRA Approval you need to contact the Central Booking Service (CBS). You need to complete this step for all studies applying for HRA Approval. You will receive an email confirming that your application has been booked for REC and/or HRA Approval. You should enter the booking information on the first page of the IRAS Form.

**IMPORTANT NOTE:** Do not amend any other part of the IRAS Form as this will invalidate your electronic authorisations.

9. On the E-submission tab for the IRAS Form you should click the button to electronically submit your application for HRA Approval. You are expected to do this the same day that you book your application via CBS. This will submit your IRAS Form and the supporting documentation you uploaded to the Checklist. Confirmation of your submission will appear in the Submission History area at the bottom of the E-submission tab.

The HRA will confirm receipt of your submission and commence their review. At this stage sponsor can forward site specific Organisation Information Document to the applicable research sites so review can occur in parallel.

Once the HRA has completed its review The Chief Investigator and JRCO will be informed. The HRA may issue an initial assessment letter where changes are required; if this is undertaken after REC approval is in place then an amendment may need to be made to REC depending on if the amendment is minor or substantial.

### 3.3 HRA Review

Once an application for HRA Approval has been received it will be reviewed to ensure that the form has been completed correctly and all required supporting information and documents are available (known as ‘ready for review’).

As part of HRA assessment studies will be assessed against the following areas:

#### 3.3.1 Compliance and delivery

- The HRA will assess the protocol to ensure it is consistent with the application and any participant information.
• The HRA will ensure that information provided in the application complies with the Data Protection Act.
• The HRA will assess the studies compliance with any other laws and regulations, including Clinical Trials regulations
• The HRA will advise on whether any assessment of capacity and capability to undertake the research will be required by NHS organisations, and give any key considerations for confirming capacity and capability of the organisation.
• Insurance and indemnity arrangements will be confirmed.

3.3.2 Contract assurance

• The suitability of any agreement provided by the sponsor will be reviewed, including whether an agreement is required. A new ‘Organisation Information Document’ will be used for studies where there is no agreement.
• Financial arrangements to the participating organisations will be confirmed; however the HRA will not look at cost attribution.

3.3.3 Investigator suitability

• The HRA will advise whether a local investigator or other form of local contact is required.

3.3.4 Human resource arrangements

• The HRA will advise whether a Letter of Access or Honorary Research Contract is required and the necessary pre-engagement checks (if needed).

3.4 Trust Approvals

For projects sponsored by organisations other than Imperial, the sponsor will contact the divisional research team to inform them of the study and its status of approval. For non-commercial projects a Organisation Information document must be provided by the sponsor for information on what processes will occur at site. For Commercially sponsored studies a study agreement will be provided by the sponsor.

The sponsor must also provide the local document pack that is applicable to the site. All external sponsor correspondence will be submitted to the divisional research mnagers

If received by the JRCO then the JRCO will forward the SoA and study documents to the appropriate DRM to commence the feasibility process.

Once the feasibility process is completed the divisional management team is required to confirm capacity and capability approval with the sponsor via email (this confirmation replaces the Trust R&D approval letter). When HRA approval has been received and all approvals in place the divisional management team will issue CCC
For studies where Imperial AHSC is sponsor the CI/PI must contact the DRM prior to HRA submission to begin the feasibility process. Once initial assessment (NHS costs, facilities, participant numbers etc) has occurred the DRM will inform the CI and JRCO that the study can be submitted to the HRA.

A list of the Research Managers for each Division can be found in Appendix 2.

4. REFERENCES

Health Research Authority –

HRA Assessment Criteria and Standards -

JRCO/SOP/038 - Obtaining ICHT Approval for Healthcare Research not requiring REC Review

JRCO/SOP/009 - Sponsorship and Insurance Approval

Appendix 1

Divisional Research Managers and Feasibility Officers:

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<tr>
<th>Division</th>
<th>Name</th>
<th>Directorates</th>
<th>Contact</th>
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Appendix 1
| A | Scott Mullaney Research Manager | Renal Specialist Medicine Emergency Medicine/ Medicine for the Elderly HIV/Sexual Health/ Infection/TB Stroke and Neurosciences | scott.mullaney@iinhs.net
Priscilla Owusu-Barnieh Stroke, Neuroscience (dementia, PD, mental health), Neurosurgery, Emergencies & Trauma HIV, Sexual Health & Infection Yojna.HandooDas@imperial.nhs.net Respiratory, Gasto, Dermatology, Heptology, Rheumatology, Therapies, Nurse led, Renal |
| B | Donna McLean Research Manager | Surgery Cancer Clinical Haematology Critical Care, Anaesthetics and Pain POEM: plastics, orthopaedics, ENT, major trauma, ophthalmology | Donna.copeland@nhs.net
Najma.ahmed@nhs.net Cancer CXH, Breast, Radiotherapy/colorectal, Head&Neck margarita.durkina@nhs.net Cancer CXH, Lung, Urology, Melanoma Christos.paliompeis@nhs.net Malignant, Haematology (white cell) Harriet.jones1@nhs.net Critical care & pain, theatres and anesthetics, trauma and plastics, orthopaedics, ophthalmology, surgery, including Upper GI, bariatric, urology, colorectal, ENT/Audiology M.martinez@nhs.net HH Cancer Fran.mautadin@nhs.net Cardiovascular, cardiology/cardiothoracic Julie.kidd@nhs.net Cardiovascular Benign Haematology (red blood cell) |
| C | Ella Johnson Louise George Research Facilitator | Paediatrics and Neonates Womens health (obs and gynae) Pathology Imaging | Ella.johnson@nhs.net Louise,george3@nhs.net James.severin@imperial.nhs.uk |
| OPD, Pharmacy and Therapies Theatres (inc. pre-op and decontamination) | Cardiovascular |