Health Research Authority Approval for Research Studies

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Approved by: Gary Roper Date: 18/03/16

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<th>Version</th>
<th>Date</th>
<th>Reason for Change</th>
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<td>1.0</td>
<td>26 May 2015</td>
<td>New SOP</td>
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<tr>
<td>1.1</td>
<td>25 Nov 2015</td>
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<td>Full process implementation</td>
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</tbody>
</table>
Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Purpose</td>
<td>3</td>
</tr>
<tr>
<td>2. Introduction</td>
<td>3</td>
</tr>
<tr>
<td>3. Procedure</td>
<td>3</td>
</tr>
<tr>
<td>4. References</td>
<td>8</td>
</tr>
</tbody>
</table>
1. PURPOSE

This procedure describes the approvals process for all NHS involved research studies as defined by the Health Research Authority (HRA).

Please Note: This SOP is subject to change as and when the HRA continue to develop their process. The JRCO will communicate any changes and developments to researchers via SOP’s, the JRCO website, JRCO newsletter and Divisional Research Managers.

Please Note: At present HRA approval only applies to research sites in England. For any new studies that are led from outside England but have English sites, the NHS permissions coordinating function of the lead nation (Wales, Scotland, Northern Ireland) will share information with the HRA Assessment team, who can issue HRA Approval for English sites and thereby retain existing compatibility arrangements.

2. INTRODUCTION

The Health Research Authority has implemented a new programme to manage the way research approvals are processed. There has been a rolling programme during 2015/16 to centralise ethics and regulatory approvals via the HRA with the aim of streamlining procedures to speed up research implementation and research site activation.

The HRA are centralising ethics and regulatory review so that research sites 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 statement of activities form or research agreement depending on the research type.

The studies can be commercial or non-commercial, eligible for the NIHR CRN Portfolio or not and may have an educational component.

3. PROCEDURE

3.1 Sponsor Review and Approval

For projects where Imperial College London and Imperial College Healthcare NHS Trust are research sponsors, you will need to 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

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 a ‘statement of activities’ as part of your submission which provides details needed for HRA review and for a site to assess capacity and capability. This replaces the Site Specific Information (SSI) from. In addition to this you will need to complete a Schedule of Events spreadsheet detailing what research activity will occur at research sites.

The HRA has defined research sites as ‘types’ so you will only need to submit one Statement of Activities for each type rather than for each individual research site. If all research sites are carrying out the same activity only one Statement of Activities will be required, but if activity varies between sites e.g. additional imaging or investigations, additional statements will be needed for each variance.

For single site studies sponsored by the AHSC and only occurring at ICHT a Statement of Activities and Schedule of Events will not be required.


If any of your UK research sites are outside England you will need to complete an SSI form for these sites.

### 3.1.1 NIHR CRN Portfolio Studies

If you wish to apply to the NIHR CRN Portfolio you will still be required to electronically submit a Portfolio Application Form (PAF) to the NIHR via IRAS before you submit your application for HRA Approval.

The PAF is created in IRAS and electronically submitted via IRAS to the CRN. A PAF will be generated when your responses to questions in the IRAS filter question indicate that the study is led from England and you will to apply to the NIHR CRN for support. The HRA will share information about your application with the CRN to allow them to make a decision on NIHR CRN Portfolio eligibility.

Further guidance can be found at: [http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/applying-for-hra-approval/#2](http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/applying-for-hra-approval/#2)

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 ‘HRA Approval’. Note: when you select this option, the options for separate application forms for NHS R&D and NHS Research Ethics Committee will disappear.
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 Statement of Activities 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.
9. You will receive an email confirming that your application has been booked for 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.

10. 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 statement of activities 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. If any conditions are applied to the approval they will need to be reviewed and approved by the HRA before commencing the study.
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 for the first phase of implementation 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 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 ‘Statement of Activities’ 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 Confirmation of Capacity and Capability

For projects sponsored by organisations other than Imperial, the sponsor will contact the JRCO or Trust Divisional Research Managers to inform them of the study and its status of approval. For non-commercial projects a Statement of Activities (SoA) should 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 will also provide study related documents (valid document set) that are applicable to the site. Submissions will be made via the JRCO generic email address – jrco@imperial.ac.uk or to the appropriate Trust DRM (contact details in Appendix 1).

The sponsor will be notified within 3 working days of receipt of the valid document set, and the Trust has 40 calendar days to confirm capacity and capability to the sponsor.

Valid Document set:

- Copy of IRAS Form (combined REC and R&D form) as submitted for HRA Approval
- Protocol
- Any amendments
- Participant information and consent documents
- Statement of Activity relevant to the participating NHS organisation (non-commercially sponsored only) or delegation log (commercially sponsored only) – only containing information known to sponsor
- Relevant template contract/model agreement (if needed in addition to Statement of Activity)
- Costing template (commercially sponsored only) or Schedule of Events (non-commercially sponsored only)
- Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study*
- Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions

*ICHT also requests that copies of the study Case Report Forms are included in the document set to allow for accurate assessment of visit workload and timelines.

Once the document set has been received the JRCO and DRM’s will liaise with each other to confirm commencement of capacity and capability assessment.

The DRM’s will liaise with the local research teams, support services such as Pharmacy, Imaging and Contracts (as applicable) as part of the capacity and capability assessment. Upon completing the assessment the DRM will notify the JRCO.

Once the assessment process is completed the JRCO is required to confirm organisational readiness with the sponsor via email (this confirmation replaces the Trust R&D approval letter).

When HRA approval and JRCO confirmation have been completed the CI/PI and DRM will be informed via email and the study can commence.

For studies where Imperial AHSC is sponsor the JRCO will contact the DRM at the sponsor assessment stage to begin our local capacity and capability process.
4. REFERENCES

Health Research Authority –  

HRA Assessment Criteria and Standards -  

JRCO/SOP/009 - Sponsorship and Insurance Approval
## Appendix 1

### Divisional Research Managers and Feasibility Officers:

<table>
<thead>
<tr>
<th>Division</th>
<th>Name</th>
<th>Directorates</th>
<th>Contact</th>
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<tbody>
<tr>
<td>A</td>
<td>Saddaf Shaheen Research Manager</td>
<td>Renal Specialist Medicine Emergency Medicine / Medicine for the Elderly HIV/Sexual Health/ Infection/TB Stroke and Neurosciences</td>
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<td></td>
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<tr>
<td>B</td>
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<tr>
<td></td>
<td>Najma Ahmed Margarita Durkina Richard Turner Laura Eshmene (Feasibility Officers)</td>
<td></td>
<td>Ophthalmology: <a href="mailto:najma.ahmed@imperial.nhs.uk">najma.ahmed@imperial.nhs.uk</a></td>
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<td></td>
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<td>Cluster 1 of cancer (lung/urology/head, neck &amp; brain) ENT/audiology Orthopaedics: <a href="mailto:margarita.durkina@imperial.nhs.uk">margarita.durkina@imperial.nhs.uk</a></td>
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<td>Haematology (including haematological) Critical care, pain and anaesthetics Major Trauma: <a href="mailto:laura.eshmene@imperial.nhs.uk">laura.eshmene@imperial.nhs.uk</a></td>
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<td></td>
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<td>Cluster 2 of cancer (breast/radiotherapy/colorectal) Surgery: <a href="mailto:richard.turner@imperial.nhs.uk">richard.turner@imperial.nhs.uk</a></td>
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<td>James Severin (Feasibility Officer)</td>
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