Health Research Authority Approval for Research Studies

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Version	Date	Reason for Change
Version 1.0	26 May 2015	New SOP
Version 1.1	25 Nov 2015	Addition of cohorts
Version 2.0	25 Oct 2017	Scheduled Review
Version 3.0	11 Jun 2019	Updates to the use of Organisation information document
Version 4.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP. JRCO name change to RGIT.
Version 5.0	07 Apr 2022	Updates made to the NIHR CRN Portfolio Studies section
Version 6.0	14 Jun 2024	Scheduled review

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1. PURPOSE

HRA Approval is now HRA and Health and Care Research Wales (HCRW) Approval and now applies to all project-based research taking place in the NHS in England and Wales. If your project is led from Northern Ireland, Scotland or Wales and involves NHS/HSCsites then you will not apply to the HRA. You should apply through the appropriate NHS/HSC permission process for that lead nation. Studies with sites in Northern Ireland, Scotland or Wales are supported through existing UK-wide compatibility systems where each country accepts relevant centralised assurances from national coordinating functions to avoid duplication.

2. INTRODUCTION

HRA Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC) so that you only need to submit one application. It applies where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers. References to participants include people whose data or tissue is involved in a research project.

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.
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 RGIT_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 RGIT 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 RGIT before submitting your study to the HRA.

All HRA applications for studies will be made using the on-line IRAS system.

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 RGIT via RGIT@imperial.ac.uk for review. Details of the sponsor review and approval process are described in RGIT_SOP_009 'Sponsorship and Insurance Approval'.

You will need to complete an 'Organisation Information Document and schedule of events /SoECAT' where necessary 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 canbe downloaded from: IRAS - My Research Project - Site Specific Information and HRA NHS - Prepare Study Documentation

The SOECAT document can be created online via the NIHR Central Portfolio Management System (CPMS)

See RGIT_TEMP_062_Process Map for OID and SoECATs.pdf for further information around OID and SOECAT requirements for ICL/ ICHT sponsored studies.

3.1.1 NIHR Research Delivery Network (RDN Portfolio Studies

From April 2024, the CRN will transition to a new organisation, the NIHR Research Delivery Network (RDN).
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If your study is an English-led CTIMP and you are applying for HRA Approval through the HRA and MHRA's combined review service, you must apply for RDN support through the new Non-commercial Portfolio Application service in CPMS. If the study does not have funding secured by open competition, the Networks will not accept it for adoption.

The following study types can now apply for RDN support via the new service, which allows investigators to apply earlier and receive an eligibility decision sooner to benefit from the full range of support that our study support service offers:

- English-led CTIMP (clinical trials of investigational medicinal products) studies which are led in England and going through the Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency's (MHRA) Combined Review Service, and;
- English-led studies that do not need, and therefore are not applying for, HRA Approval in the Integrated Research Application System (IRAS)

Studies that require HRA Approval but are not being progressed through combined review: These studies should continue to apply for NIHR RDN support by selecting **'yes'** to **question 5b** of the IRAS Project Filter. This will ensure key information from your IRAS submission is automatically shared with us. The NIHR CRN will then review whether the project is potentially eligible by using the IRAS form, the study protocol and grant award letter(s) and confirm this to the Chief Investigator. Who will be notified of the outcome via email.

The RDN for Imperial AHSC is North London - hosted by Barts Health NHS Trust-
If you are unable to apply via either of these routes, contact your RRDN for

advice on how to proceed.

3.2 Submission to the HRA

**** Please note that COVID-19 studies are processed through fast-track approval process, please request fast-track approval via fast.track@hra.nhs.uk. Detail about the process is available on: HRA NHS - Fast track review guidance for Covid-19 Studies ****

An online Booking Service is now used for all IRAS form applications for research project in the NHS (or HSC in Northern Ireland and for Research Ethics Committee (REC) for tissue banks, databases and health research taking place outside of the NHS/HSC). The process is outlined 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 with the protocol and applicable documents to apply for HRA Approval.
4. Complete your dataset and prepare your supporting documentation as usual.

5. In the IRAS project the 'E-Submission' tab details the steps to submit the application into the system.
6. Check your application is ready for submission either by using online tools provided on IRAS or by printing a draft copy of your form for review. If you wish to make application for RRDN support, please ensure YES is selected to IRAS Filter question 5b.
7. Upload any supporting documents to the checklist tab which will be submitted electronically with IRAS form. For all documents uploaded the following information must be completed – subtitle, document version and date and if a document type is not uploaded, provide a reason. Please note that if all the necessary documents are not uploaded at the point of submission, your application may be rejected. Check guidance provided on the checklist tab for detailed.

IMPORTANT NOTE ABOUT SUPPORTING DOCUMENTATION: Your application to the HRA may need to include the Organisation Information Document and Schedule of Events/SoECAT, for each type of site in your study, if sites are performing different activities. Where this is required, please include each document in a new row in the 'other' section of theChecklist by using the 'add new row' button.

Obtain the required electronic authorisations. Electronic authorisation is mandatory for all declarations in IRAS form. Please check on the guidance provided on IRAS for details.

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

Therefore, check the application thoroughly before seeking authorisations. The verification tool should be used to check completion of the form prior to obtaining authorisations. If after using the tool the only items being flagged are the missing authorisations, you can proceed to obtain authorisations. When authorisations are in place you will then need to run the verification tool again to pass the checks.

8. Booking the application for review online is the next step after the application has passed verification check. This uses a separate login and as a result you will require to create and account when booking an application for the first time. You will be asked to provide the IRAS project ID and key information about the study as described in the application. When ready to book the application click the 'book' button and booking confirmation will be sent by e-mail.

9. Electronically submit your application – after making the booking, please add the booking information to page 1 of the form and enter the REC name, REC Reference Number and Submission. Please do not amend any other information or click in any other fields at this point as this could invalidate the booking.

10. When ready click on E-submission button to electronically submit application form. E-submission button will be disabled when the application is submitted and/or is being processed.
11. After application submission a point of contact should be allocated via email, if not this contact could be obtained from the REC. This is contact is important in the process where there is need for correct mistake in an application or withdraw application, send additional supporting documents or response to a request for further information during the review process.

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').

The HRA may issue an initial assessment letter where changes are required. Once the HRA has completed its review the Chief Investigator and RGIT will be informed.

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.
- 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 all projects an agreement must be provided by the sponsor for information on what processes will occur at site.

The sponsor must also provide the local document pack that is applicable to the site, this includes the HRA approval letter. All external sponsor correspondence will be submitted to the divisional research manager(s) (DRM).

If received by the RGIT then the RGIT will forward the Organisation Information Document and schedule of events/SoECAT (where necessary) and study documents to the appropriate DRM to commence the feasibility process.

Once the feasibility process is completed the divisional management team confirms capacity and capability to host the research with the sponsor via email.

For studies where Imperial AHSC is sponsor, RGITI will contact the DRM at the beginning of the sponsorship process to begin the feasibility process.

A list of the Research Managers for each Division can be found in RGIT_TEMP_009_Divisional-Research-Managers-and-Feasibility-Facilitators.docx

4. REFERENCES

Health Research Authority (HRA) - Approval

RGIT_SOP_038 - Obtaining ICHT Approval for Healthcare Research not requiring REC Review

RGIT_SOP_009 - Sponsorship and Insurance Approval

RGIT_TEMP_009_Divisional-Research-Managers-and-Feasibility-Facilitators.docx