UNIVERSITY OF LEEDS

Standard Sponsorship Guidance for Non-CTIMP Research Applications Requiring NHS Ethical and/or HRA Approval

Contents

The University of Leeds will act as Sponsor in principle for research involving the NHS as defined in the UK Policy Framework for Health and Social Care Research (2017), where the Chief Investigator is either a substantive employee or a registered doctorate level student of the University. If this is not the case and University Sponsorship is appropriate for the research, it should be discussed with Emma Armstrong, Head of Research Regulatory Compliance (see contact details page 4 below) and any decision to sponsor in principle will be made on a case-by-case basis.

1. HRA Approval

HRA Approval is the approval process that is required for research to commence in the NHS in England. It brings together an assessment of governance and legal compliance undertaken by dedicated HRA staff, with an Independent Research Ethics Committee (REC) opinion provided through the UK Health Departments' Research Ethics Service (where required).

HRA Approval replaces the need for local checks of legal compliance by each participating NHS organisation and supports and complements local processes relating to assessing, arranging and confirming local capacity and capability to undertake the study. Once HRA Approval has been issued and the site has confirmed capacity and capability to undertake the research, the site will confirm with the Sponsor their readiness to recruit, and the study will start at that site.

Applications for HRA Approval must use the single application form in IRAS, enabled by selecting IRAS form in question 4 in the project filter on IRAS. Guidance on how to apply for HRA Approval using the IRAS system can be found on;
http://www.hra.nhs.uk/research-community/applying-for-approvals
If you are new to IRAS you will find clear instruction on the use of IRAS on,
https://www.myresearchproject.org.uk/ELearning/index.html.

In addition to completing the HRA form in IRAS, the application to the HRA may need to include additional documents the ***Organisation information Document (OID)*** and if your study is classed as an investigational clinical trial, a **model noncommercial agreement (mNCA)** and the ***Schedule of Events* (SOE) *or SoECAT***. These forms are intended to capture all information around study activities being undertaken at a local level and are used as part of the local information pack send to participating sites to allow sites to confirm capacity and capability to undertake the study.

Please note, if your study requires a SoECAT, it will require review and approval of the research costs generated by the form, by the grants team at the University and the NHS costs by the lead NHS R&D office according to their local process before we can provide an email confirming it can be submitted to the CRN for validation.

The SoECAT is completed online and you can find guidance on this on the NIHR website on, https://www.nihr.ac.uk/documents/online-soecat-guidance/30396.

If you have questions regarding the SoECAT, whether your study needs one and the process for validation etc. then you can contact the early contact and engagement service in the CRN, Yorkshire and the Humber, please see,
https://www.nihr.ac.uk/online-soecat-guidance

It is advised that you contact your lead R&D office early in the process of applying for HRA approval so that they are aware of your study. The research team will need to send the HRA initial assessment letter (and the full HRA Approval letter when they receive this) along with the UK local information pack to the local research teams, R&D offices and as appropriate the NIHR LCRN as soon as they have received them from the HRA. This pack is the UK- wide mechanism for setting up participating NHS/HSC sites.

You will find further information on the UK local Information pack and the OID/mNCA documents on the IRAS website in the site-specific information section within the help section of IRAS.
(https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx).

We would advise that you read the guidance on the contents of the UK Local Information Pack to familiarise yourself with the documents required as part of this pack.
A template email is available on the IRAS website, which will need to be used when you send the Local Information pack to the relevant R&D offices.
Please note, the sponsor delegates the responsibility to the research team to send the UK Local Information Pack with the localised Organisation Information Document to the R&D offices and study delivery teams at participating NHS organisations using the appropriate email, after receipt of the Initial assessment Letter from the HRA

If your study includes non-NHS sites an assessment of the suitability of the site and Principal Investigator will be undertaken in a proportionate way depending on the study type. Please refer to the guidance on the IRAS site, which can be found in, https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-Sharing.

2. Applying for Sponsor Review

2.1 IRAS Applications

Up to 10-15 working days are required for initial Sponsor review to be undertaken. Therefore, before booking into the HRA you should send a draft copy of the IRAS form, attached to an email to governance-ethics@leeds.ac.uk. In addition, please attach copies of your protocol and all documents you will be submitting to the HRA for approval including information sheets, consent forms, Data Management Plan (DMP template can be found here https://library.leeds.ac.uk/info/14062/research-data-management/62/data-management-planning) topic guides if required etc. As above, you will also need to complete an Organisation Information Document and Schedule of Events (or SoECAT) document required under the HRA Approvals process for studies taking place in the NHS so please send these with your other documents for sponsor review.

You will be informed by email when the Sponsor review has taken place. Should amendments or checks be required before sponsorship can be signed off, you will be informed as soon as possible and up to a further 5 working days should be allowed for final sponsorship sign off to allow for re-review. At this point, you will be sent an email confirming sponsorship in principle and a copy of the University Indemnity certificate,

which you will need to include with your submission to the HRA. We will provide you with a sponsor reference number for your study which you can add to A5-1 in the IRAS form and to your study protocol.

2.2 Research that has University of Leeds ethical approval

For projects involving the NHS that have undergone University of Leeds ethical review, in most cases, HRA Approval will be required so once you have received confirmation of University of Leeds ethical approval, please send a draft copy of your completed IRAS Form, your protocol and other approved documents, along with a copy of your ethical approval letter to governance-ethics@leeds.ac.uk for sponsorship review and sign off. This will take up to 7 working days.

Most of these studies will also need a completed Organisation Information Document and Schedule of Events document for submission for HRA Approval, which we will also review as part of the sponsorship process.

2.3 Submitting for HRA and NHS REC approval

Once you have received all your electronic authorisations on the IRAS form and uploaded your documents to the checklist on IRAS you need to book for NHS REC and HRA review.

For guidance on how to make a booking navigate to the e-submission tab on IRAS which provides a detailed step-by-step process and a direct link to the booking portal. A separate login is required for the portal unless you have used the service before, but guidance is provided on IRAS on how to create a new account. Applicants will be required to answer a series of questions online before they can book a review slot. This is in order to direct them to the appropriate REC.Once the online HRA booking is completed, the application can then be submitted using the submission tab on IRAS. For studies applying for NIHR CRN Portfolio a request should be made for inclusion on the NIHR portfolio prior to the application to HRA Approval. The HRA will share information about the application with the CRN to allow them to make a decision on NIHR CRN Portfolio eligibility. Further information can be found at: https://www.nihr.ac.uk

3. Additional information for completing the IRAS form

3.1 *Student Research*

The supervisors of students should be named as Chief Investigator in almost all cases (with the exception of PhD and doctoral level students).
The HRA introduced eligibility criteria for review of standalone student research. (Standalone research at undergraduate level that requires NHS ethics and/or HRA review cannot take place. Some Masters level students will be able to apply for NHS ethics and HRA Approval. To find out if your study qualifies for review please see the HRA guidance on; https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research.
The review of PhD research studies is unchanged.

Master's level: Applicants should complete the student research toolkit in the first

instance, to check eligibility.
Students and their supervisors will need to use this toolkit before proceeding with their IRAS (Integrated Research Application System) application. For eligible student research, there may be a supplementary declaration form that needs to be completed before being able to submit an application through IRAS.

The toolkit has been designed to pull together the resources required to understand what approvals may be needed to carry out a study. It contains links to existing HRA decision tools as well as new ones developed especially for students. It provides access to five different decision tools designed to provide answers to the questions below:

- Is my study research?
- Is my research taking place in the NHS and does it need NHS Approval?
- Does my study need NHS REC review?
- What type of NHS REC review will I need?
- Can I carry out my research?

3.2 *NHS Ethics Proportionate Review Service (PRS)*

If you consider the study, does not raise any material ethical issues, please check the criteria and consult the guidance on PRS at: http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service.
The HRA strongly recommend that researchers use the proportionate review toolkit to consider whether their study might be suitable for proportionate review. The tool kit can be accessed via the link above.
The application and submission process is the same as for full NHS research ethics committee review, however, the final opinion is issued within 14 days of submission of a valid application and there is no requirement to attend the REC meeting.

3.3 *Standard Sponsorship and Indemnity responses*

The standard sponsorship in principle and indemnity responses for the relevant sections on IRAS generated forms and Sponsor review submission guidance are as follows (*please note*, the following are not definitive answers – this will depend on the specifics of your research). Please contact the sponsor governance office at governance-ethics@leeds.ac.uk if you have any queries.

3.4 *Sponsor contact details*

3.4.1 A4

Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project? Please enter, Jean Uniacke, Research Ethics and Governance Officer, Governance and Compliance Directorate, The University of Leeds, Woodhouse Lane, Leeds, LS2 9JT. Email: governance-ethics@leeds.ac.uk Telephone 0113 3437587

3.4.2 A64-1

Sponsor SP1 status is 'Academic'. *Name of organisation* is 'University of Leeds'. *Contact person* is Emma Armstrong, Head of Research Regulatory Compliance, Governance and

Compliance Directorate, The University of Leeds, Woodhouse Lane, Leeds, LS2 9JT.
Email: governance-ethics@leeds.ac.uk Telephone 0113 3437587

There will only be one Sponsor (the University); as a general rule, the University of Leeds does not co-Sponsor unless by specific agreement with relevant parties and/or appropriate Faculty and University of Leeds representatives (contact Emma Armstrong, at the above email address if you are unsure).

3.5 *Insurance/ indemnity questions to meet potential legal liabilities*

A copy of the University Indemnity certificate will be provided as an attachment to the formal email confirming sponsorship in principle.

3.5.1 A76-1
Re: M*anagement* of the research - usually, response is 'other insurance or indemnity arrangements will apply' and details should be given as follows 'University of Leeds indemnity applies'.

3.5.2 A76-2
Re: *design* of the research - as above

3.5.3 A76-3
Re: *conduct* of the research - usually, response is NHS where relevant to study (i.e., where participants are NHS patients). If research is undertaken on non-NHS sites, University indemnity would usually apply unless other arrangements are in place, such as for private practices.

For all studies falling under the clinical trial category in IRAS, the University (via the Sponsor governance team) is required to notify the University of Leeds insurance office about any potential claims against the University clinical trials policy.
To meet this obligation**, all researchers are required to notify the Sponsor governance office of any queries or communications they have had with a patient, their family or legal representative regarding the indemnity cover in place for a University of Leeds sponsored trial.** This could be a general enquiry about the type of indemnity in place for a trial, queries about the process to make a claim or questions following a particular event or complaint.
If in doubt whether to discuss a specific query with the Sponsor governance team please get in touch, we ask researchers to 'err on the side of caution' and potentially over report to us in this circumstance.
This notification should be made to governance-ethics@leeds.ac.uk and detail the following:

- Study name and IRAS number
- Participating site
- Status of participant on study
- Summary of the query received
- Details of any related, adverse events or incidents

3.6 *Protection of Intellectual Property (IP) in Ethics Applications*

The advice from the NHS Research Ethics Service in relation to this issue is as

follows:

All ethics applications are reviewed under a confidentiality agreement.
However, NRES is committed to publishing research summaries in the public domain. You can opt out of the research summary citing IP reasons. NRES use the lay summary from the IRAS form for research summaries. You should indicate in the lay summary your reasons for not completing this section.

4. Study Protocol

A research protocol is an essential part of a research project and is a requirement for HRA submissions. A research protocol should contain a full description of the research study allowing the researcher to plan and review the projects steps and it should serve as a guide throughout the research to ensure everyone involved in delivery of the study adheres to the methods outlined.
No two research protocols are the same, but the HRA have produced template protocols as a guide for researchers which contain the headings that most protocols would be expected to contain, and we would advise researchers to consider those templates when developing their protocol using the headings as appropriate to their study. The HRA template protocols can be found on, https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/.

5. Participant Information Sheets and Consent Forms

In July 2023 the HRA introduced new quality standards to improve information given to research participants. The quality standards have been launched alongside Design and Review Principles which show researchers and the REC what important ethical considerations are for participant participation.

From December 2023 the quality standards and design and review principles will become mandatory and will be applied by research ethics staff when a study is submitted for REC review to check if the information sheet is compliant when validating the study for REC review. Using the guidance will increase the likelihood of receiving a favorable opinion from the REC. if the guidance is not used then an application will receive a provisional REC opinion.

You will find the quality standards on, https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-quality-standards/.

You will find the Design and review Principles on, https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-design-and-review-principles/.

Please familiarise yourself with the new quality standards and the Design and review principles to ensure your information sheet conforms to the quality standards required by the HRA.

We would also highly recommend, based on our experience of the feedback given to researchers by the HRA and Research Ethics Committees that you read the guidance for Researchers and Reviewers on the design of information sheets and consent forms provided by the HRA on, https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/.

(Please note, the HRA require the inclusion of the IRAS reference number for your project on all your study documents including information sheets and consent forms). You will find further guidance at: http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information.

Following the introduction of the General Data Protection Regulations in May 2018 the HRA have published recommended transparency wording for participant information sheets to ensure they are GDPR compliant. The recommended wording can be found on; https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/.

The link to the University privacy statement for research participants is:
https://dataprotection.leeds.ac.uk/research-participant-privacy-notice/
The link to the HRA generic patient data and research leaflet which the HRA recommend is available to all patients involved in research is,
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
Please add both links to the participant information sheet as part of the HRA transparency wording. (Note the generic leaflet is directed at patient participants only).
Please also add the contact details for the University data protection officer which is dpo@leeds.ac.uk to your information sheet.

6. Managing your study post REC and HRA Approval:

Once your study has received HRA Approval, as a condition of sponsorship the Chief Investigator is expected to keep copies of all the HRA approved documents for the study in the Site File to be made available to the sponsor for audit or monitoring when requested. In addition, please send copies of all the HRA approved study documents to governance-ethics@leeds.ac.uk along with a copy of the HRA Approval letter as soon as you receive them.

Research teams will need to adhere to all HRA reporting requirements following receipt of HRA Approval.
This will include submitting annual progress reports if required for the study and sending the end of study declaration and final report within the required HRA timelines. Further information can be found on:
https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/.
https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/.

HRA requirements for safety reporting and serious breaches of protocol will need to be adhered to.
Please see, https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/.

The REC standard conditions that need to be followed after REC approval can be found on the HRA website on, Non-CTIMP Standard Conditions - Health Research Authority (hra.nhs.uk).

N.B. In all cases, you are required to notify the Sponsor of any amendments to your study and to supply a copy of the completed amendment tool, as well as copies of progress reports and end of study declarations to this office, via governance-ethics@leeds.ac.uk

7. Amendments for NHS REC and HRA approved studies

For all project-based research, an Amendment Tool which can be downloaded from a link on the IRAS website is now used for notification of both substantial and non-substantial amendments. You will find the amendment tool and guidance on how to complete it on, IRAS Help - Maintaining your approvals Amendment(myresearchproject.org.uk)

A pdf copy of the completed Amendment Tool and supporting study documents will need to be uploaded and submitted for review via an online amendment submission portal which is available via a direct link on IRAS. The link is on, https://www.myresearchproject.org.uk/help/hlpamendments.aspx#Online-Submission.

For any technical queries about accessing or using online amendment submission you can contact helpdesk@myresearchproject.org.uk.
For queries on the amendment itself you are advised to contact the REC who approved the study or amendments@hra.nhs.uk.

At the same time as completing the Amendment Tool, please notify the sponsor of your amendment and send all supporting documents, including a copy of the completed Amendment Tool to governance-ethics@leeds.ac.uk for sponsor review which will take up to 5-7 working days. We will then complete the sponsor declaration on the Amendment Tool and lock it, prior to you submitting the amendment online to the REC/HRA. It is a sponsor decision as to whether amendments are classed as substantial or non-substantial.

Where it says sponsor reference number on the tool, please use your sponsor number followed by the number of the amendment distinguishing between non substantial (NSA) and substantial (SA) amendments. For example, if your sponsor number is 2023-NCT01 and the amendment is substantial amendment one, then the number for the amendment tool would be 2023-NCT01-SA01. It is the responsibility of the research team to keep track of the numbering of their substantial and non-substantial amendments so that the correct number is added to the amendment tool.

Please note, once approved by the HRA, the sponsor delegates to the research team the responsibility to inform the relevant R&D departments at participating NHS organisations of any study amendments following HRA guidance, which can be found on, IRAS Help - Maintaining your approvals - Amendments for projects conducted in NHS/HSC (myresearchproject.org.uk)

8. HRA, Make it Public Research Transparency Strategy

The HRA have implemented a reporting process to support Health and Social Care researchers in fulfilling their responsibilities in making their research open and transparent. Please see, The Health Research Authority moves to make research

transparency the norm - Health Research Authority (hra.nhs.uk) for more information.

As part of this reporting process the HRA have developed a standard dataset on research transparency that will be collected in a new final study report which will be completed and submitted online to the HRA by the research team.

Researchers are also expected to submit a lay summary of results which the HRA will publish on its website.

For further information and to see the new final report form please see: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/.

9. Other relevant links

a. *A step-by-step guidance on uploading documents and storage of documents on IRAS:* https://www.myresearchproject.org.uk/help/hlpdocumentstorage.aspx.

b. *IRAS step by step guidance on electronic authorization:* https://www.myresearchproject.org.uk/help/hlpsignatures.aspx.

c. *HRA eLearning Modules* – the HRA have produced eLearning modules designed to support the research community. These training on research involving human tissue, research involving exposure to ionizing radiation and research involving participants lacking mental capacity etc.
You can access the eLearning modules at: https://www.hra.nhs.uk/planning-and-improving-research/learning/e-learning.

d. *Data Protection information* – information for researchers on management of research data can be found on the University website: https://dataprotection.leeds.ac.uk/information-for-researchers.

e. Further information on research data management including data archiving can be found on the University library website: https://library.leeds.ac.uk/info/14062/research_data_management/61/research_data_management_explained/1.

f. User guide for accessing CPMS to complete Online SoECAT, https://www.nihr.ac.uk/documents/getting-started-and-logging-in-to-cpms/11462.

g. Eligibility criteria for NIHR clinical network support https://www.nihr.ac.uk/documents/eligibility-for-nihr-clinical-research-network-support/23746.