Clinical Directorate Clinical Research Governance Team

Standard Operating Procedure

Completing an IRAS Application for Non-CTIMP Research

SOP013

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1. Introduction

The UK Policy Framework for Health and Social Care Research states that no research study within the NHS involving individuals, their organs, tissue or data may begin until it has a favourable opinion from a Research Ethics Committee (REC). The NHS REC is a core function of the Health Research Authority (HRA) and review all applications for research taking place within the NHS[1] and consider any adverse risk to participants.

The Medical Devices Regulations 2002 requires that require that before a Clinical Investigation a Medical Device can commence a Notice of No Objection is given from the MHRA and favourable opinion is given by an NHS REC.

Research that falls under the remit of the Human Tissue Act 2004 or the Mental Capacity Act 2005 also require ethical review by an appropriate body, normally an NHS REC.

Approval may be required from additional regulatory bodies depending on the nature of the clinical trial or study.

The Integrated Research Application System (IRAS) provides a single system for applying for the permissions and approvals for health and social care/community care research in the UK. It enables trial information to be recorded once instead of duplicating information in separate application forms.

IRAS captures the information needed for the relevant approvals from the following regulatory/review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) and Health and Care Research Wales (HCRW) for projects seeking HRA & HCRW Approval
- Medicines and Healthcare products Regulatory Agency (MHRA) – Devices Division
- NHS / HSC R&D offices
- NHS / HSC Research Ethics Committees
- Her Majesty's Prison and Probation Service (HMPPS)
- Social Care Research Ethics Committee

[1] Please note, NHS REC are also responsible for reviewing non-NHS research in certain cases. Please refer to http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/ for further information

2. Scope of Procedure

The purpose of this standard operating procedure is to outline the process of using IRAS, provide details of where further help can sought and provide advice on answering local questions. This SOP covers the process for non-CTIMPs only. Please see SOP031 for advice on CTIMP applications.

3. Who

This SOP is aimed at Chief Investigators (CI), students, trial coordinators and other members of University Staff involved in IRAS application process for University Sponsored research.

Completing the data set is ultimately the responsibility of the CI, however, the Sponsor recognises this this is often done with the support of other members of the study team e.g. the student conducting the research, a research nurse or trial coordinator. When signing the form, the Chief Investigator is confirming they have full knowledge of the data contained in the form and will abide by the conditions set out in the declaration.

The form also requires the signature of the Sponsor's representative. If this is the University, the study must have approval from the University following review at either the Liverpool Health Partners (LHP) Joint Research Office (JRO) Sponsorship Committee or Non-Interventional Sponsorship Sub Committee (NISSC) at least in principle in writing before the Clinical Research Governance Team can authorise the IRAS form on behalf of the University. This signature confirms that the sponsor will abide by the conditions set out on the declaration. For further information regarding Sponsorship Approval please refer to SOP004[2].

4. When

It is beneficial to start the IRAS process as early as possible when setting up a research project. However, the form should not be submitted until sponsorship has been confirmed with either an Intention to Sponsor or Sponsorship Approval letter. The process of obtaining required approvals must be completed, and approvals received from the relevant governing bodies prior to the study opening for subject recruitment. As the MHRA and the REC have a 30-day period to respond to applications it is advised that this is taken into consideration when planning the study timelines.

5. Getting Started

IRAS can be accessed at: https://www.myresearchproject.org.uk/SignIn.aspx

New users can create an account by clicking on the 'Create Account' tab at the top of the page and setting a user name and password. When setting up a new account is it advised that a regularly accessed email account is used as this is the account that all notifications are sent to.

E-training for the IRAS system can be accessed by the tabs at the top of the page and it is recommended that all users complete training before use of the system.

[2] Sponsorship Application and Approval Process

The answers given in the first section of the form 'IRAS Project Filter' (questions 1-10) will determine the data set required for the project. The system will generate only those questions and sections which apply to your study type and are required by the bodies reviewing your study. These questions will automatically appear on all forms and only need to be answered once.

Once the required data set has been generated the navigate feature can be used to access the Integrated Dataset for all project forms which lists all the questions required on 2 or more forms, or to select an individual form and answer all the relevant questions to that form.

When completing the form comprehensive help can be found at https://www.myresearchproject.org.uk/Help/UsingIRAS.aspx.

6. Application Specific Advice

6.1 NIHR Research Delivery Portfolio

The NIHR Research Delivery Network (RDN)[3] Portfolio of studies consists of clinical research studies that are eligible for support from the NIHR RDN in England.

All high-quality research studies, eligible for NIHR RDN support in England, are included on the NIHR RDN Portfolio. NIHR RDN supported studies benefit from the following:

- Access to the NIHR RDN Study Support Service - a standard national framework for supporting the planning, set-up and delivery of high-quality clinical research in England
- Provision of NHS support as defined by AcoRD and/or the equivalent of NHS Support in other settings (e.g. research carried out in social care, care homes, hospices, or public health settings)
- Access to relevant research delivery training, including Good Clinical Practice training
- ISRCTN registration via the Central Portfolio Management System.

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 the RDN and will be used alongside the study protocol and grant award letter(s) to determine eligibility. You will be notified of the outcome, via email.

Please note, if your study is eligible for NIHR Research Delivery Network support and included on the NIHR RDN Portfolio the study team must adhere to the Portfolio Terms and Conditions to maintain access to NIHR Research Delivery Network support in England, and for continued inclusion on the NIHR RDN Portfolio. These Terms and Conditions apply at the point of acceptance onto the NIHR RDN

[3] Formally Clinical Research Network (CRN)

Portfolio until a study closes to recruitment. Failure to adhere to the Terms and Conditions may result in the study being removed from the NIHR Portfolio[4].

The Sponsorship Team will maintain oversight of the performance of studies on the NIHR RDN Portfolio, via the NIHR Sponsor Engagement Tool, and will request updates from Study Teams on the progress of recruitment. If a study is consistently underperforming, and mitigation strategies have not worked, the Sponsor may direct the study be removed from the NIHR portfolio and Sponsorship support may also be withdrawn.

6.2 Application for Notice of No Objection for CIMD

Once a study has been identified as a CIMD it must be identified as such on the IRAS Project Filter page. The requirements for MHRA application differ depending on the type of planned investigation, which are detailed in Part 2a of the project filter questions. For further guidance on the classification of CIMDs please refer to the MHRA[5] for further information.

If required, IRAS will create the MHRA Devices form to apply for a Notice of No Objection to allow the CIMD to be carried out.

Applications to the MHRA do carry a fee, please refer to the MHRA[6] for more information and ensure these costs are included in the research funding.

6.3 HRA and Health and Care Research Wales (HCRW) Approval

HRA and Health and Care Research Wales (HCRW) Approval[7] is the process for the NHS in England and Wales that comprises a review by a NHS REC (where required – see the HRA[8] for further information) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA staff. It replaces the need for NHS permission by each participating organisation in England.

You should apply for HRA Approval if:

- The lead NHS R&D Office for your project is in England or Wales; and
- Your research is described by any of the IRAS filter question 2 categories (except those for "Research Tissue Bank" and "Research Database").

To apply for HRA Approval you should select the option for "IRAS Form" at project filter question 4.

[4] See https://www.nihr.ac.uk/terms-and-conditions-nihr-research-delivery-network-support-frequently-asked-questions and https://www.nihr.ac.uk/media/25616/download
[5] https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device
[6] https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees#clinical-trials-for-devices-fees
[7] https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/
[8] http://www.hra.nhs.uk/research-community/before-you-apply/determine-which-review-body-approvals-are-required/

6.4 Supporting Documentation

Each application form created within IRAS has a related 'Checklist' which details supporting documentation for the application.

You must attach your supporting documentation to this checklist before submitting your application.

The Sponsor Responsible Officer will also ensure that HRA specific requirements for documentation are met before providing signatory on the IRAS form. This may include;

a) Validated SoECAT (Schedule of Events Cost Attribution Tool[9]) or SoE (Schedule of Events)[10]

b) Final draft of Organisation Information Document

c) Draft mNCA or Research Site Agreement, as applicable and as required

d) CI signed eligibility declaration for standalone Masters student research studies only[11]

e) Confirm all Study documentation has;

   Version numbers and dates

   IRAS number inserted

f) Confirm that all participant information sheets follow the HRA Transparency wording for all sponsors

g) Confirm HRA Participant Information Quality Standards and Design and Review Principles have been adhered to (using FORM023[12] if needed)

The Sponsor Responsible Officer will provide drafts or templates of required documents as needed.

6.5 Other applications

Upon receipt of University Sponsorship Approval, the Clinical Research Governance Team will advise if applications to other regulatory bodies mentioned in Section 1 are required and will provide specific advice.

Applications to bodies such as University Ethics committees and International Ethics committees are not made via IRAS, and the Clinical Research Governance Team will provide specific advice as and when these applications are required.

[9] https://www.nihr.ac.uk/online-soecat-guidance
[10] https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-SoE-SoECAT
[11] https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/student-research-toolkit/
[12] FORM023 HRA Participant Information Quality Standards and Design and Review Principles Checklist

7. Specific Expertise

Each application form located within IRAS will require input from individuals with particular expertise. These individuals should be identified as early as possible to allow their review and authorisation (where required) before submission.

7.1 Sponsorship

If the study is co-sponsored between the University and an NHS Trust it should be determined between the co-sponsors who will be the lead sponsor.

Once University Sponsorship is approved GUI002[13] will be provided to the application for Sponsor specific details for insertion onto the form.

The co-sponsor should be added using the "Add Co-Sponsor" button at the bottom of the page and contact details should be obtained from the appropriate NHS R&D department.

The lead sponsor named in question A64-1 has the responsibility to sign section D.2. For applications sponsored by the University please send the electronic authorisation request to sponsor@liverpool.ac.uk; please note only electronic signatures will be provided in line with IRAS guidance.

Upon receipt of the Authorisation Request the Clinical Research Governance Team will undertake a review of the application form(s) to ensure the information provided is consistent with the information provided in the Sponsorship Application. Any inconsistencies will be notified to the applicant for review. Although applications for Research Tissue Banks do not have the requirement for Sponsor Authorisation, it is University policy that Sponsorship approval should be in place before the University Designated Individual for the Human Tissue Authority research licence will provide authorisation.

7.2 Lead Medical Physics/ Clinical Radiation Experts

Depending on the nature and procedures involved in a study a Lead Medical Physics Expert and/or a Clinical Radiation Expert may need to be involved in advising on the study. This includes any ionising radiation or radioactive medicinal products being administered as required in the protocol even if this is considered standard care. The CI need to contact the appropriate Trust Radiology department if this section is required.

8. Roles and Responsibilities

It is the responsibility of the CI to complete the required application forms within IRAS and although this may be delegated to another member of the study team, the CI retains responsibility for the content of the application. This is evidence by their authorisation on each application form.

[13] GUI002 IRAS Form Guidance

The Clinical Research Governance Team will support the CI or delegated person through this process as required and requested.

The Senior Clinical Research Governance Manager will be the authorised signatory on behalf of the University as Sponsor. Authorisation requests are to be sent to sponsor@liverpool.ac.uk and only electronic signatures will be provided in line with IRAS guidance.

9. Abbreviations

CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
IRAS	Integrated Research Application System
JRO	Joint Research Office
LHP	Liverpool Health Partners
MHRA	Medicines and Health care products Agency
NIHR	National Institute for Health Research
RDN	Research Delivery Network
REC	Research Ethics Committee

10. Associated Documents and References

SOP004 - Sponsorship Application and Approval Process

GUI002 - IRAS Form Guidance

FORM023 HRA Participant Information Quality Standards and Design and Review Principles Checklist

UK Policy Framework for Health and Social Care Research

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No. 1031)

HRA Approval

HRA Determine which review body approvals are required

Integrated Research Application System (IRAS)

Terms and Conditions for NIHR Research Delivery Network Support

HRA Transparency wording for all sponsors

HRA Participant Information Quality Standards and Design and Review Principles

SoECAT guidance

SoE guidance

HRA Student Research Toolkit

MHRA Guidance Clinical investigations for medical devices

NIHR RDN Study Support Service

AcoRD (Attributing the costs of health and social care research)

NIHR Research delivery training

ISRCTN registration

Integrated Research Application System (IRAS)

11. Training and Resources

All CIs, students, trial coordinators and other members of University Staff involved in completing applications within the IRAS system are expected to undertake the IRAS training modules. These are available at https://www.myresearchproject.org.uk/ELearning/index.html.

CIs, students, trial coordinators and other members of University Staff involved in completing applications in IRAS should be aware of and familiar with this SOP. Training can be provided by the Clinical Research Governance Team upon request.

12. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years.