SOP number	**51.014**	Version	**5.0**
Title	**Preparation and Initial Submission of Research Studies to the Research Ethics and Regulatory authorities IRAS/Combined Review Forms for Sponsored & Co-sponsored Studies**		

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SOP category	NHS GGC Sponsor R&I

Staff category

Staff Category	**R**	**A**	**C**	**I**
Systems & Operations Manager		X		
Chief Investigator	X			
R&I Sponsor Pharmacy	X			
Project Management	X			
Sponsor R&I Co-ordinators	X			
Sponsor Research Facilitator	X			
Senior Research Administrators	X			
Biorepository Team	X			
Information Governance Team	X			
R&I Pharmacovigilance			X	
University of Glasgow Research Regulation and Compliance team			X	
R&I Monitoring Team			X	

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) staff who are responsible for reviewing submissions made via the Integrated Research Application System (IRAS) for research studies requiring approval from Research Ethics Committees (REC) and regulatory authorities. This includes submissions made through the Combined Review (CR) process for Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of Medical Devices (CIMDs), which are submitted directly to both REC and the Medicines and Healthcare products Regulatory Agency (MHRA)

2. Purpose

To describe the process for reviewing and authorising IRAS and CR submissions to the REC and regulatory authorities such as the MHRA when NHSGGC is acting as the Sponsor or Co-Sponsor of a research study and submission to local R&I departments.

3. Procedures

3.1. Background

All research involving NHS patients, staff, or facilities must comply with UK legislation and ethical standards, including the UK Policy Framework for Health and Social Care Research, the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, for CTIMPs, the Medical Devices Regulations 2002, as amended, for CIMDs. Studies requiring approval from a REC or the MHRA must be submitted via IRAS. CTIMPs, CIMDs or a combined trial of an investigational medicinal product and an investigational medical device will be referred to as CTIMPs/CIMDs and all other study types will be referred to as non-CTIMPs in this SOP. For CTIMPs/CIMDs, the CR process enables simultaneous submission to both REC and MHRA. As Sponsor or Co-Sponsor, NHSGGC is responsible for ensuring submissions are complete, accurate, and compliant. Local R&I management review and approval is covered separately in SOP 52.001.

3.2. Non-CTIMP Research Studies

3.2.1. IRAS Form Review

The Chief Investigator (CI) or delegate (e.g. Project Manager (PM)) will complete the IRAS form, for more guidance on completion, please refer to GUI 51.014A: IRAS Form Completion Guidance for Non-CTIMP Studies. Supporting documents must also be complete and accurate. The documents required for submission can be found here: https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx.

The Sponsor R&I Co-ordinator or Facilitator will review the complete document set along with IRAS form and provide feedback to the CI in line with SOP 51.001 and SOP 51.002, ensuring consistency across all documents, correct selection of project filter questions, and alignment with the study protocol, they will then highlight any inconsistencies or potential feasibility, pathway or governance issues. They will also ensure activities are consistent with what was costed at the grant submission stage (see SOP 51.010).

3.2.1.1. Radiation and Imaging (if applicable)

For studies including the use of ionising radiation or non-standard imaging protocols, Part B – Section 3 of the IRAS form will also need to be completed, the definition of a research exposure can be found here:
https://www.myresearchproject.org.uk/help/hlpradiation.aspx

Part B – Section 3 of the IRAS form will also need to be reviewed and signed by Clinical Radiation Expert and Medical Physics Expert via Radiation Assurance process which takes place before IRAS submission and Sponsor authorisation. For multi-site studies, it is advised HRA-managed route is taken (this is a requirement if there are any English sites), please note this incurs a fee and should be costed for at grant stage (see SOP 51.010). More information on applying for radiation assurance can be found here:
https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/technical-assurances/radiation-assurance/applying-radiation-assurance/

3.2.1.2. Radioactive substances (if applicable)

For studies involving administration of radioactive substances, e.g. a radiotracer, Administration of Radioactive Substances Advisory Committee (ARSAC) approval is required. Details of when ARSAC approval is required and how to apply can be found here:
https://www.myresearchproject.org.uk/help/hlparsac.aspx

3.2.1.3. Pharmacy (if applicable)

For studies involving a medicinal product, the Sponsor R&I Co-ordinator should also share the IRAS form with the Sponsor Pharmacist to review and provide input where necessary.

3.2.2. IRAS Form Authorisation

Once all documents are confirmed as compliant with R&I standards, the Sponsor R&I Co-ordinator or Research Facilitator will acknowledge this by email. The Chief Investigator (CI) or delegated team member must then submit the IRAS application and complete the e-booking process on the same day. Research Ethics Committee (REC) review is arranged via the Central Allocation System (CAS) using the CAS Booking tool. It is essential that the study is reviewed by the appropriate REC type (e.g. for studies involving adults lacking capacity). This can be discussed with local ethics contacts, but final allocation will be confirmed by CAS at the point of submission.

A full copy of the submitted documents must be sent to the R&I Co-ordinator by the CI or delegate so it can be saved in the electronic TMF. Authorisation via IRAS is electronic, the R&I Co-ordinator or Research Facilitator will electronically sign the form on behalf of the Sponsor once all checks are complete.

3.2.3. IRAS Form Response

All approvals received, e.g. a favourable ethical opinion, as well as any updated documentation must be retained in the Sponsor e-TMF. Follow guidance on SOP 51.021 for managing post-approval changes.

3.3. CTIMP/CIMD Research Studies

3.3.1. Combined Review Form Review

For CTIMPs/CIMDs, submissions are made through the Combined Review (CR) service within IRAS. The CR forms are completed by the CI or a delegated team member (e.g. PM), Radiologist, Pharmacist). The preparer must understand the study and IRAS system. Expert input is required for specific sections as described in Section 3.2.1.1 – 3.2.1.3 (e.g. Pharmacy for IMP handling and accountability and Radiology for non-standard imaging protocols). Sponsor representatives must review for regulatory alignment, risk management, and legal compliance and must ensure appropriate insurance is in place. The Sponsor R&I Co-ordinator ensures all relevant sections are completed, including input from Pharmacy, Medical Physics, and Clinical Engineering where appropriate. Additional documents (e.g. sIMPD, SmPC, device details) must be reviewed by the appropriate experts. The full list of documents required for IRAS submission under the CR process is available on the HRA website: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-review/document-management-combined-review-applications/.

3.3.2. Combined Review Form Authorisation

The R&I Co-ordinator authorises the CR form on behalf of the Sponsor after confirming all expert reviews have been completed and documented via email. The R&I Co-ordinator must confirm that all study documentation has been reviewed by relevant stakeholders, including Pharmacy, Radiation Assurance, Imaging, and any other applicable departments. The R&I Co-ordinator will save all correspondence of reviews and all submission documents in the e-folder and note on the Sponsor checklist when the application was signed as per SOP 51.020. The Senior Research Administrator (SRA) will then add all submission documents and relevant correspondence to the Sponsor Trial Master File (TMF) as per SOP 51.016. Guidance on completing and submitting CR applications is available via the IRAS Help site and the HRA Combined Review Guidance.

3.4. Combined Review Response

All approvals received, including favourable ethical opinions, MHRA approvals, and R&I acknowledgements, all ethics correspondence as well as any updated documentation or responses must be retained in the TMF in accordance with SOP 51.016. Where applicable, Grounds for Non-Acceptance (GNA) documentation must also be filed. Follow guidance on SOP 51.021 for managing post-approval changes.

3.4.1. Grounds for Non-Acceptance (GNA)

If a GNA is received after a CR submission, the R&I Co-ordinator Sponsor should promptly circulate the feedback issued jointly by the MHRA and REC to the CI and all relevant stakeholders for review. The stakeholders should address the points raised promptly, ensuring that any revised documents or clarifications meet regulatory expectations. Once the response is prepared, the CI or a delegated team member must re-submit the CR application through IRAS as done, following the process outlined in Section 3.2., referencing the GNA and ensuring all updates are clearly documented. Timely and co-ordinated action is essential to avoid delays in authorisation.

3.5. Tissue Banks

For studies involving research tissue banks, the R&I Research Facilitator or Sponsor Co-ordinator will refer the researcher to the Biorepository team, who hold delegated ethical approval and manage sample storage. The Biorepository is responsible for completing all costings and uploading these studies to SReDA. Review of the protocol, consent documents, and governance arrangements is carried out by the Biorepository team and authorisation of the IRAS form is provided by the NHSGGC Biorepository Manager.

3.6. Research Databases

For research databases hosted within NHSGGC, the submission process via IRAS includes the Sponsor Research Facilitator to co-ordinate costing and review any associated documents and the SRA to assign a project reference and update SReDA. Review of the governance arrangements is carried out by the Information Governance team and authorisation of the IRAS form is provided by the NHSGGC Data Protection Officer. For full procedural details, refer to SOP 52.018: NHSGGC R&I Process for Research Database.

3.7. Staff-Only Studies

For studies involving only NHS staff as participants, IRAS form submission on the IRAS platform is still required but is typically made to R&I only. The SRA co-ordinates the local review process according to SOP 52.017, which depends on whether NHSGGC resources are involved. If study activities occur on NHSGGC premises or involve NHSGGC staff, a full local review is required. If all activities are remote and no NHSGGC resources are used, no local review is needed. The SRA confirms this via email and updates SReDA accordingly.

3.8. Submission to Local R&I Departments

Submission to local R&I departments is completed electronically, either via email or through the NHS Research Scotland Permissions Coordinating Centre (NRS PCC) in Scotland for multi-centre studies. The CI or delegate, such as a PM, is responsible for submitting the Local Information Pack (LIP), which includes the Organisational Information Document (OID), and all relevant study documentation. Full details of what should be included in the LIP can be found here:
https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-Content
The LIP is prepared outside the IRAS system and contains site-specific details required for local review. For sites outside Scotland, the LIP must be sent directly to each participating site. If no PM is assigned, the CI is responsible for distributing the LIP.

4. Referenced documents

- GUI 51.014A: IRAS Form Completion Guidance for Non-CTIMP Studies
- SOP 51.001 - Protocol Development for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 51.002 - Participant Information Sheet and Informed Consent Form Development for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 51.010 - Preparation and Review of Grant Applications and Costs
- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 51.020 - Sponsor Regulatory Green Light and Trial Oversight
- SOP 51.021 - Review and Approval of Amendments for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 52.018 - NHS GGC R&I Process for Research Database
- SOP 52.001 - Obtaining NHS Management Approval Non-Commercial
- SOP 52.017 - Process for Local Review of Non-Commercial, Hosted, Multi-Centre and Single-Centre PR Studies with NHS Staff as Participants
- https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-review/document-management-combined-review-applications/
- https://www.myresearchproject.org.uk/help/hlpradiation.aspx
- https://www.myresearchproject.org.uk/help/hlparsac.aspx
- IRAS Help - Preparing & submitting applications - Site specific information
- https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/technical-assurances/radiation-assurance/applying-radiation-assurance/
- Medicines for Human Use (Clinical Trials) Regulations 2004
- Medical Devices Regulations 2002

5. Related documents

- SOP 51.017 - Registration of research projects on public databases
- SOP 51.025 - Archiving Essential Documents from Clinical Research – Process for a Sponsored Non CTIMP
- SOP 51.003 - Peer Review
- SOP 58.010 – CRIF Local IMER Review
- IRAS Website (non-CTIMPs)- https://www.myresearchproject.org.uk
- Combined Review IRAS website (CTIMPs/non-CTIMPs) - https://id.nihr.ac.uk/authenticationendpoint/login.do?RelayState=187468d5-2a0f-484d-81bb-82ce08c9dcdc&commonAuthCallerPath=%2Fsamlsso&forceAuth=true&passiveAuth=false&tenantDomain=carbon.super&sessionDataKey=2aada6ab-f9f7-45d8-95e1-a2cccb2d5732&relyingParty=https%3A%2F%2Fhra-iras-prod1.pegacloud.net%3A443%2Fprweb%2Fsp%2F1544550718&type=samlsso&sp=HRA+-+IRAS&isSaaSApp=false&authenticators=GoogleOIDCAuthenticator%3AGoogle%3BAttributeBasedAuthenticator%3ALOCAL
- MHRA Website - http://www.mhra.gov.uk
- NRES Website - http://www.nres.nhs.uk
- NRSPCC - www.nrspcc.org
- HMA Website - http://www.hma.eu

6. Document History

Version	Date	Description	Retrospective Implementation
1.0	05/02/2013	Release of first version	No
2.0	14/07/2016	Updated to template v1.4, SOP renumbered and clarification of content	No
3.0	12/03/2020	Author amended Staff category updated Process and procedures updated Local submission information updated SOP version updated "Released by" updated	No
4.0	11/02/2022	Updated to include innovation team, clinical investigations of non-CE marked medical devices and to change R&D to R&I	No
5.0	04/12/2025	Updated to include Combined Review process and refer to other SOPs. Added GUI 51.014A: IRAS Form Completion Guidance.	No