SOP number	**50.028**	Version	**1.0**
Title	**Signatures & Approvals Process for Research and Innovation Documents**		

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SOP category	NHS GG&C General
Staff category	

Staff Category	**R**	**A**	**C**	**I**
R&I Systems & Operations Manager		X		
All R&I Staff	X			
Chief Investigator				X
Principal Investigator				X

1. Scope

This Standard Operating Procedure (SOP) applies to all documents that require formal approval, including but not limited to policies,, protocols, agreements, guidance documents, and supporting governance documentation generated or approved by NHSGGC R&I in support of sponsored, co-sponsored, hosted and innovation activities.

2. Purpose

This (SOP) defines the requirements and process for the signing, approval and authorisation of formal documents within NHSGGC R&I and/or Greater Glasgow Health Board. It outlines acceptable forms of signature, responsibilities of signatories and the principles to be followed to ensure documents are approved in a consistent, auditable and traceable manner.

3. Procedures

3.1. Background

Signatures applied to documents represent confirmation that the content has been reviewed, approved and authorised by appropriately delegated individuals and that the document is accurate, complete and compliant with relevant policies, procedures and regulatory requirements.

The use of controlled signatures provides assurance of accountability, governance and transparency, and supports compliance with applicable legal, ethical and regulatory frameworks. Signature control also ensures that documents are formally endorsed before implementation and that changes to approved documents are appropriately managed.

3.2. Documents for Signature

For avoidance of doubt, any documents that require a signature and is produced or approved by a member of NHSGGC R&I Staff must be signed in accordance with this SOP.

See Table 1 for list of documents and appropriate signature method and by which signatory

Please refer to WI 52.028A for further guidance on specific documents that would fall under the scope of this SOP.

3.3. Process for Signing Documents

Once a document has been reviewed by all relevant stakeholders and has been accepted for Signatures, the Research Coordinator, Research Facilitator or Innovation Project Coordinator, or document author in some cases, will inform the authorised DocuSign user that a document can be signed. The authorised DocuSign user will then follow either of the two steps below depending on the type of signature requested. All signatures must be applied and retained in a manner that complies with ALCOA+ data integrity principles and provides an auditable record of approval.

Two forms of signature are acceptable for NHSGGC R&I documents.

3.4. Wet Ink Signature

A document can be printed and a wet ink signature added with the date and any other required details (e.g. role), in black ink only. This will then be shared with the relevant stakeholders for their signatures. The original paper document will then need to be saved in the corresponding TMF/ISF. Scanned copies of the document must be in full, not the signature page only and stored in the e-folder. If the scanned copies are to act as the original and replace the paper copy, they must be verified as an accurate representation of the original document by the individual scanning it.

In cases where a wet signature is used, not all other signatures need to be wet signatures. The scanned document with Wet Ink signature included can be uploaded for electronic signature. Where the document is sent for signatures by NHSGGC, especially to individuals who are not co-located, the preference for signature methods will be electronic (DocuSign/Adobe). In instances where a location has instigated the signature process, and wet signature has been used from their side, NHSGGC will sign electronically and the electronic signature can act as the verification of the document where scanning is required.

In cases where a location has completed a wet ink signature, a file note can be added to the TMF to note where the original wet ink signature is. However, the original document will be considered at the fully executed version.

3.5. Electronic Signature

NHSGGC R&I approved electronic signature platforms (currently DocuSign and Adobe Sign) may be used. All NHSGGC R&I Documents that require signatures via electronic signature will be completed this way, where possible. For DocuSign, the reviewed and approved document will be sent to the authorised DocuSign user. The authorised DocuSign user will request the names and email address of all those who need to sign the document from the Document provider (for sponsor projects). A link will be sent to the appropriate stakeholders for signatures. A completed version of the Signed Document along with either the DocuSign Certificate of Completion or Adobe Sign Audit Report will be saved in the corresponding E-folder, and where relevant Trial Master File (TMF) and Investigator Site File ((ISF), locations to record and file via their standard local processes).

For a step-by-step instruction of the process for obtaining signatures please see WI 52.028A – Electronic Signatures.

3.6. Authorised Signatories at NHSGGC R&I

There are selected NHSGGC authorised signatories who are permitted to sign contracts and agreements on behalf of the Board for R&I studies. These individuals are authorised under the NHSGGC Scheme of Delegation and currently include the R&I Director, the Senior R&I Manager, the R&I Systems and Operations Manager, the Innovation Lead and the R&I Lead Pharmacist. In principle, since 2017, the R&I Systems and Operations Manager signs the majority of Systems contracts, apart from Pharmacy related contracts as they are directed to the R&I Lead Pharmacist. For the Confidential Disclosure Agreements (CDA)/Non-Disclosure Agreements (NDA) authorisation to sign on behalf of the Board has been delegated to the Commercial Co-ordinators, Sponsor Research Coordinators or Sponsor Research Facilitators. The signatory signs once the contract or CDA/NDA has been reviewed and is ready for signatures in accordance with **SOP 51.039**. The signatory checks the contract is as described and that the name is correct for signature.

3.6.1. Signatories for other Documentation

The Sponsor Research Coordinators, Sponsor Research Facilitators and Innovation Sponsor Coordinators can approve sponsor oversight documents including protocol documents, file notes, risk assessments, lab categorisation forms, sponsor RGL letter, MHRA/REC cover letters/ CTIMP oversight checklist, modification checklist, grant application and award letters, and TMG/TSC charters.

Where appropriate, other study documentation may be approved and signed by authors or stakeholders with delegated responsibility for the preparation, review or oversight of the document (see Table 1).

3.7. Contingency Signatures

In the absence of the designated signatory, an alternative authorised signatory may sign, provided they are appropriately authorised and any required specialist review has been completed.. This is decided on a case-by-case basis, depending on availability.

In the absence of the R&I Lead Pharmacist, any other authorised signatory may sign a Pharmacy related contract as long as a Sponsor Pharmacist has reviewed and approved the document as ready for signing.

For Example:
When the R&I Systems and Operations Manager is unavailable due to annual leave or sickness, the default authorised signatory can change to the R&I Lead Pharmacist or Innovation Lead and similar

for all other signatory roles, noting any conditions to be applied, e.g. Sponsor Pharmacist review for pharmacy related contracts.

Table 1. List of Documents for signature by method and Signatory.

Document type	**Method of Signature**	**Signatory**
Contracts (e.g. mNCA, Site Agreements, Model Clinical Trial Agreement, Vendor Contracts)	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Collaboration Agreements	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Data Sharing/Processing Agreements	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Material Transfer Agreements	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Service Level Agreements	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Co-Sponsorship Agreements	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Protocol Sign Off	DocuSign/Adobe or Wet signature	Non-Authorised Signatory
End of Study Declaration	DocuSign/Adobe or Wet signature	Non-Authorised Signatory
Confidentiality Disclosure Agreements/Non-Disclosure Agreements	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Quality Technical Agreements	DocuSign/Adobe or Wet signature	Authorised Board Signatory
IRAS Application	Online System	Non-Authorised Signatory
Grant Applications	Online System/ DocuSign/Adobe or Wet signature	Non-Authorised Signatory
Grant Award Letters	DocuSign/Adobe or Wet signature	Authorised Board Signatory when award letter is acting as the research contract. Otherwise Non-Authorised Signatory.
Technical Agreements (IMP Related)	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Pharmacy Documents	DocuSign/Adobe or Wet signature	Authorised Board Signatory
Research Passport/ Letter of Access	Adobe	Non-Authorised Signatory
R&I Management Approval	Adobe	Non-Authorised Signatory

4. Referenced documents

- Work Instruction 50.028A – Electronic Signature
- SOP51.039 – Contracts Management for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow

5. Related documents

- SOP51.014 – Preparation and Initial Submission of Research Studies to the Research Ethics and Regulatory authorities IRAS/Combined Review Forms for Sponsored & Co-sponsored Studies

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	14/09/2026	First Release	No