

SOP number	50.011	Version	6.0
Title	Setting up and Maintaining Research and Innovation project files (for R&I office approvals)		

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SOP category	NHS GG&C General			
Staff category				
Staff Category	R	A	C	I
Research & Innovation Systems & Operations Manager		X		
Sponsor Research Coordinators	X			
Commercial Research Coordinators	X			
Innovation Contracts Manager	X			
Research Facilitator	X			
Innovation Project Manager	X			
Senior Research Administrator	X			
Research Administrator	X			
Project Managers	X			
Information Officer			X	

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) Research and Innovation (R&I) staff by providing instructions for Senior Research Administrators (SRAs), Innovation project managers (IPM) and Research Administrators (RAs) on how to establish and maintain an electronic file (e-file) for research projects undertaken within NHSGGC, including commercial and non-commercial studies.

2. Purpose

The purpose of this SOP is to document a clear process for creating an e-file for the electronic documentation source and how to electronically file these for Board-level approval.

3. Procedures

3.1. Commercial & Non-commercial Projects

A project number is issued using SOP 50.009. Using the project number, an e-file is then made up in the appropriate research portfolio team. Within this main folder a further 9 subfolders are created in accordance with the e-Folder Index (Form 50.011A). Documents should be saved electronically within the appropriate subfolder and the project file checklist (Form 52.009D) updated as necessary. Any superseded documents should be stored in a folder named 'Superseded' for auditing purposes.

3.2. Innovation Projects

A project number is issued using SOP 50.009, Form 50.009A. Using the project number, an e-file is then made up in the appropriate Innovation portfolio team. For innovation projects, excluding Clinical Investigation of a Medical device (CIMDs), 8 subfolders are created in accordance with the innovation projects e-folder index (Form 50.011B). Documents should be saved electronically within the appropriate subfolder and the project file checklist (Form 52.009D) updated as necessary. Any superseded documents should be stored in a folder named 'Superseded' for auditing purposes.

3.3. NHSGGC Sponsored Projects.

For NHSGGC Sponsored Clinical Trials of Investigational Medicinal Products (CTIMP)/ Clinical Investigations of Medical Devices (CIMD) studies. The e-files will be set up in accordance with SOP 51.016. The contents of the e-Folder do not make up the TMF but are intended for working copies which must also be stored in appropriate TMF either printed or electronically. For NHSGGC Sponsored Non-CTIMP studies, SOP 51.042 will be followed.

4. Referenced documents

- SOP 50.009 – Project Numbering
- SOP 51.016 – Preparation and Maintenance of a Trial Master File
- SOP 51.042- Preparation and Maintenance of a Non-CTIMP Sponsor e-File
- Form 50.009A – Project ID Log
- Form 50.011A – E-Folder Index
- Form 50.011B – Innovation Projects E-Folder Index
- Form 52.009D – Project File Checklist

5. Related documents

- None

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	02/07/2012	Release of first version	No
2.0	14/07/2016	Updated to template v1.4.	No
3.0	16/04/2019	Updated to template v2.0, change of releaser	No
4.0	08/07/2021	Updated to change to R&I and include innovation projects	No
5.0	06/09/2023	Change of author, version updated, minor admin changes (e-file index updated from 9 e-files to 10 e-files, innovation index updated from 7 e-files to 8 e-files, addition of word electronic to SOP title, addition of referenced documents - SOP 51.016, Form 52.009C and Form 52.009D).	No
6.0	19/10/2026	Change of Author, version updated Minor changes efiles to 9, change of wording from amendment to modification, addition of SOP 51.042	No

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