Glasgow Clinical Trials Unit Standard Operating Procedure

SOP number	**50.011**	Version	**5.0**
Title	**Setting up and Maintaining Research and Innovation project files (for R&I office approvals)**		

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	Date

SOP category	NHS GG&C General
Staff category	

Staff Category	R	A	C	I
Research & Innovation Systems & Operations Manager		X		
Sponsor Research Coordinator	X			
Commercial Research Coordinator	X			
Innovation Contracts Manager	X			
Research Facilitator	X			
Innovation Project Manager	X			
Senior Research Administrator	X			
Research Administrator	X			
Information Officer			X	

1. Scope

This SOP applies to all R&I staff responsible for establishing and maintaining an electronic file (e-file) for a research or innovation project in the R&I department (e.g. Research Administrators, Senior Research Administrators, Innovation Project Managers).

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 (excluding NHS Greater Glasgow and Clyde (NHSGGC) sponsored or co-sponsored Clinical Trial Investigational Medicinal Products (CTIMPs) and Clinical Investigations of Medical Devices (CIMDs).

3. Procedures

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 research or innovation portfolio team (commercial or non-commercial). Within this main folder a further 10 e-files are made using the e-folder index (Form 50.011A) for research projects. Staff can use the template e-folder (Form 52.009C) to create the e-file, which can be found in the common drive and comprises all the sections of the e-folder index. For innovation projects, 8 e-files are made using the innovation projects e-folder index (Form 50.011B). Documents are to be saved electronically into the relevant e-files and the project checklist (Form 52.009D) updated as necessary.

Glasgow Clinical Trials Unit Standard Operating Procedure

Documents should be saved in the e-folder with an appropriate name, following the naming convention on Form 50.11A or Form 50.11B for innovation projects. Any superseded documents should be stored in a folder named 'Superseded' for auditing purposes.

For NHSGGC sponsored CTIMP and CIMD studies, refer to SOP 51.016 for guidance on the preparation and maintenance of the Trial Master File (TMF). 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.

4. Referenced documents
- SOP 50.009 – Project Numbering
- SOP 51.016 – Preparation and Maintenance of a Trial Master File
- Form 50.009A – Project ID Log
- Form 50.011A – E-Folder Index
- Form 50.011B – Innovation Projects E-Folder Index
- Form 52.009C – Template E-folder
- Form 52.009D – Project e-File Checklist

5. Related documents
- None

6. Document history

Version	Date	Description
1.0	02/07/2012	Release of first version
2.0	14/07/2016	Updated to template v1.4.
3.0	16/04/2019	Updated to template v2.0, change of releaser
4.0	08/07/2021	Updated to change to R&I and include innovation projects
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).

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