Standard Operating Procedure			**51.005**
R&I - End of study procedures			
Version	**4.0**		
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Released by	Julie Brittenden	Signature	Date

1. SOP Category
NHS GG&C Sponsor R&I

2. Staff Category

Staff Category	R	A	C	I
Systems Manager		X		
Senior Research Administrator	X			
Research Administrators	X			
Research Information Officer	X			
Innovation Project Manager	X			
Sponsor Research Co-Ordinator				X
Commercial Research Co-Ordinator				X
Sponsor Pharmacy				X

3. Scope
This procedure applies to NHS Greater Glasgow and Clyde (NHS GG&C) R&I Department.

4. Purpose
This SOP describes the procedures which the R&I Office must follow on receipt of notification of end of trial/study by Sponsor/Co-ordinating Centre.

5. Procedures
5.1. End of Study Acknowledgement
When an End of Study Declaration Form and/or Declaration of the end of a Clinical Trial form is sent by the research team to R&I, the Research Administrator (RA)/Senior Research Administrator (SRA)/Innovation Project Manager (IPM) will follow SOP 51.022.

A monthly end date report is generated by the informatics team for active and in-follow up studies which are past their study end date to ensure R&I have visibility of all project statuses. An email is sent to the PI asking for an update on the project status. SReDA will be updated when the PI has responded and the SRA/RA will be informed of the project status. If no response from the PI then this should be chased twice more times. If there is no response after all 3 emails then this will be escalated to the Project Coordinator to confirm if the study should be marked as completed (Refer to Guideline 51.022A).

The RA/SRA/IPM will issue an email to the PI/CI (Principal Investigator/Chief Investigator) to acknowledge receipt of an End of Study Declaration form and/or Declaration of the end of a Clinical Trial form. Any such emails will then be stored in the Enterprise Vault within Outlook as well as in the e-folder in the common drive.

At the same time, the RA/SRA/IPM will request the REC end of study acknowledgment email from the PI/CI for our records. For all CTIMP/device studies, the RA/SRA/IPM must collect and store the end of study declaration acknowledgment from REC as this is an essential document in the TMF. The RA/SRA/IPM may need to chase the study team or REC for this

acknowledgment. For all non CTIMP/device studies, the RA/SRA/IPM will make efforts to ensure the CI/PI returns this document and it is appropriately stored in the ethics section of the e-folder in the common drive, along with the End of study form. The RA/SRA/IPM will also cross-check the form against SReDA (Scottish Research Database Application) to ensure study information is correctly recorded (See SOP 51.022).

5.2. Trial Close Out

When an End of Study Declaration Form and/or Declaration of the end of a Clinical Trial form has been received the RA/SRA/IPM notifies the Information Officer (IO) in the event the study is Sponsored/Led by GG&C, and they notify the relevant Research Co-ordinator and the process described in SOP 51.017 will be followed. The IO will then update CPMS portfolio database and makes archiving arrangements with the study team as detailed in SOP 51.024 and SOP 51.025. If the trial is a CTIMP and/or R&I pharmacy involves dispensing medicines pharmacy must also be notified to close the study (as per SOP 22.026).

6. Referenced documents

- SOP 51.017 - Registration of research projects on public databases
- SOP 51.022 - Data & Administration tasks
- Guideline 51.022A – SReDA End Date Process
- SOP 51.024 - Archiving Essential Documents from Clinical Research – Process for a Sponsored Clinical Trial of an Investigational Medicinal Product (CTIMP)
- SOP 51.025 - Archiving Essential Documents from Clinical Research – Process for a Sponsored Non CTIMP
- SOP 22.026 - Closure of a clinical trial – pharmacy process

7. Related documents

- None

8. Document History

Version	Date	Description
1.0	14/07/2016	Release of first version
2.0	10/06/2019	Updated to template v2.0, change of author and releaser
3.0	04/10/2021	Updated to R&I from R&D and to include innovation staff. Updated section 5.2
4.0	10/03/2023	Administrative changes (change of author, removal of 5 years for SOP review, addition of cross-checking end of study form against SReDA, information added about study past end date reports, addition of SOPs 51.024 and 51.025 and Guideline 51.022A in referenced documents). Minor change to processes (addition of requesting REC end of study acknowledgment email and saving in e-folder)