York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
SOP
R&D/S113

R&I Closeout Process

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&I Department's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&I Department SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&I Department website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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	Name/Position:	Sarah Sheath, SOP Controller
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This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewer	Details of significant changes
1.0	24th December 2024		New SOP

Contents

1 Introduction, Background and Purpose

Upon conclusion of local activity on a research study there can be numerous administrative and contractual processes within the R&I management and governance function that are needed to be concluded or checked prior to a study being sent to Archiving.

For example, there may outstanding invoices that need raising. Or their may be external researchers with Honorary Contracts who now need these contracts concluding.

Failure to complete such checks can sometimes result in damages or loss to the R&I Department, such as missing earned income or inappropriate access remaining in place for external staff.

Whilst a Study Sponsor may host their own Site Closeout visits with our Research Delivery Teams in relation to the closedown of participant follow-up activity, finalisation of the Investigator Site File and data queries; these reviews will not relate to the above local R&I considerations. As such a YSTH R&I Closeout Process has been developed to monitor and close-off these local R&I management and governance considerations and checks.

The purpose of this SOP and it's associated EDGE workflow (Appendix A) is to describe the R&I Closeout Process that will be followed after a Study Closure notice and prior to the studies Archiving.

2 Who Should Use This SOP

This SOP is for all R&I Staff involved in study management, governance, and administration of ongoing research studies. This includes Trust-Sponsored and External-Sponsored Studies and all study types and designs.

Principal Investigators, Research Delivery Teams and Support Departments should also take note of these actions as a requirement ahead of future Archiving of their research study. Their input may also be sought as part of the process.

3 When this SOP Should be Used

This SOP should be used at the point at which a research study has reached the end of its local delivery activity, i.e. 'Study Closure'.

Please refer to Section 4.1 for a definition of this timepoint.

4 Procedure(s)

4.1 Identifying Closed Studies

The R&I Project Support Team monitor study end dates as part of regular EDGE Data Quality meetings and reviews. Upon noticing that a 'Planned Study End Date' has expired they will contact the Research Delivery Team to confirm that study activity has now concluded.

Where no Research Delivery Team support is required for a study, the Project Support team will instead contact the Study Sponsor directly to confirm the end of local activity.

Dependant on the role of the Trust for the research study alongside how the study is being managed and delivered by its Study Sponsor, Study Closure may be defined by a number of different confirmations;

- Close-Out Visit/Review confirmation email/letter from Study Sponsor
- Email/letter from Study Sponsor confirming conclusion of local delivery activity for the research study and that no formal Close-Out Visit/Review required.
- Where Study Sponsor is unresponsive or out of contact, and alternative confirmation is received from R&I Management that we are stopping activity.
- Where R&I Management make the decision to close Study Activity early with immediate effect and no plan to restart
- *Where Trust Sponsored*, confirmation from Project/Programme Manager of end to local activity.
- *Where Trust is a Participant Information Centre (PIC) only*, confirmation from Recruiting Site that their Recruitment Activity has ended and will not restart.

Upon confirmation of the above R&I will commence the EDGE Workflow named 'R&I Closeout' as detailed in Appendix A with the purpose of processes described in the subsequent sections.

The assigned individual responsible for commencing the R&I Closeout Workflow will vary based on delivery plans for the study;

- Hosted-Study **with** Delivery Team support: Clinical Trials Assistant
- Hosted-Study **without** Delivery Team support: Project Support Team (Hosted Studies)
- Trust Sponsored Study: Project Support Team (Sponsored Studies)

4.2 R&I Closeout Workflow

The detailed process for the R&I Closeout Workflow is described in greater detail under Appendix A and within the EDGE workflow itself.

The following sections are to describe the purpose and context for each process and to advice further with regards what needs to be reviewed within

4.2.1 EDGE Status Updates

Upon Study Closure notification R&I will update the status of the research project to 'Closed' on the Project Site Page within EDGE.

This will indicate for R&I records that study activity and participant follow-up has now concluded and will allow it to be excluded from Portfolio and Prioritisation reviews when considering follow-up burden and research delivery team capacity.

Upon the later completion of the R&I Closeout process the Project Site Status will later be updated to 'Completed' and will act as an indicator that the above review has concluded and that the project may now be sent for Archiving. Please refer to Section 4.3.

4.2.2 Sponsor Closeout Visits & Checklists

Some study Sponsors may request that the Research Team attend a formal Closeout Visit at the end of patient and data collection visits, or alternatively may request completion of their own Closeout Checklist

As part of the R&I Closeout process Research Delivery Teams will be asked to confirm if this has been completed or to confirm that the Sponsor will not require one

4.2.3 Invoicing

Many projects include an element of financial income, or in some cases expenditure, in relation to our local delivery activity or wider partnerships and responsibilities; such as payment of staff time or research grant income.

When income and expenditure is present as confirmed by the project's EDGE record, upon the conclusion of the project it is imperative that it is confirmed whether any outstanding invoices are to be expected and to ensure this income/expenditure is not missed prior to Archiving a project.

The R&I Project Support team have a rigid process for monitoring ongoing invoicing timelines via EDGE attributes and at this point of the R&I Closeout workflow they will be asked to confirm that the final invoice has been raised and received.

4.2.4 Honorary Contracts and Letters of Access (LOAs)

Some projects may require researchers and staff external to the Trust to be granted an Honorary Contract or Letter of Access which is a signed agreement which will allow them access to the Trust premises for the purposes of delivering elements of the research project.

Honorary Contracts/LOAs are not terms of Trust employment and are very specific as to the activity they are granted access to perform and will tend to expire upon the conclusion of study activity at the site, unless otherwise stated. They will also be assigned a Trust Supervisor, sometimes the Principal Investigator, to take responsibility for their oversight when in the department.

Where such agreements are present it is important that upon conclusion of study activity that such named individuals and their assigned Trust Supervisor are notified by R&I that their activity has concluded and that their access to the Trust has now ended.

A template email 'Notice of End to Honorary Contract/Letter of Access' (R&D/F06) has been provided for this purpose.

Should the named individual also have been granted IT or Security Access within the Trust, these must also be revoked by contact to the Trust Security and/or Systems & Network Services departments;

- The named individual will be requested to return their name badge to the R&I Department and handed to the Project Support Team Management Administrators

- The Project Support Team Management Administrators will contact Trust Systems & Network Services to request the revocation of IT access

4.2.5 Sub-Contracted Services

At times it may be necessary for R&I to arrange for a Sub-Contract or Collaboration agreement with an external organisation to deliver an aspect of the study on behalf of the Trust (known hereafter as a Service Provider) For example, providing laboratory services or radiology scanning when Trust capacity is limited.

Upon conclusion of local study activity R&I will contact such Service Providers to provide confirmation that study activity has now concluded and that no further support will be required.

A template email 'Notice of End to Sub-Contracted Services Agreement' (R&D/F86) is provided to notify such Service Providers of this news.

It should be noted that at times a Sub-Contract with a Service Provider may go beyond the local study delivery date. For example, a Service Provider may be contracted for writing up of data publications for Trust Sponsored studies, or for long-term archival tissue storage that may expand into future projects.

As such R&I governance staff will be asked to review the agreements upon Study Closure and confirm to the Project Support Team that this Sub-Contract is acceptable to end. The R&I role responsible for this review will vary based on study type;

- Externally-Sponsored projects: the assigned Research Delivery Facilitator (RDF)
- Trust-Sponsored projects: the assigned Project/Programme Manager

If the Service Provider activity is required to continue beyond the end to local delivery activity;

Based on the nature of the Service Provision the assigned RDF or Project Manager may determine that the R&I Closeout process may need to await the conclusion of the Sub-Contract Agreement and as such the EDGE Workflow will be put on hold.

Alternatively, they may confirm that the study can proceed through the remainder of the R&I Closeout process and is acceptable to be Archived without impacting the terms of the Sub-Contract agreement. If this is confirmed this section of the R&I Closeout Workflow may be marked as Complete with no further actions necessary.

4.2.6 Supporting NHS Treatment & Continuous Care Sites

Similar to Sub-Contracted Services some projects may require that study activity for Trust participants is delivered by an additional NHS Organisation, this will be the case when the clinical pathway for the patients is delivered across multiple Trusts.

Sometimes it may be the case that a certain treatment or procedure is delivered on the Trust's behalf by a neighbouring NHS organisation. For example, oncology patients attend Leeds Teaching Hospitals NHSFT for Radiotherapy treatments. Where this pathway is required for a research study such NHS sites are required by the Health Research Authority to fully open the study as a 'Treatment Site'.

Alternatively, some studies may have the scenario where the treatment or procedure is performed at our Trust with patients then referred back to their local NHS Trust where they will continue Follow-Up activity. In such cases they will be required to open the study as a 'Continuous Care Site'.

In either case where such support is present the R&I Department should notify such organisations upon the conclusion of the study activity. This is as a professional courtesy so that fellow NHS Organisations are aware to expect no further patients or follow-up activity and that they can start their own closeout activities.

A template email 'Notification of Study Closure to Treatment or Continuous Care Site' (R&D/F97) has been provided to give notice to such organisations when required.

4.2.7 Return of Loaned Equipment & Supplies

At times the Study Sponsor may be providing the Trust with loaned equipment or supplies.

When such is provided the studies assigned RDF will record this during study via an EDGE attribute under the 'C&C General Information' attribute set

As part of the R&I Closeout Workflow this attribute should be checked and if marked 'Yes' the staff member should confirm with the Research Delivery Team that any loaned equipment has been returned as planned.

At times Sponsors may agree for the Trust to keep such equipment either indefinitely or for further research studies they plan to continue with beyond the duration of the study in question.

4.3 R&I Closeout Confirmation

Upon confirmation all the above checks and notifications, the R&I Department will issue the Principal Investigator and Research Delivery Team with a 'Confirmation of R&I Closeout' (R&D/F104), this will take the form of an email sent on behalf of the R&I Department,

The email will act as confirmation that, alongside any separately required Study Sponsor notifications, the study may now be sent for Archiving. A copy should be filed within the Investigator Site File and the R&I File.

Upon this confirmation the Project Site Status on EDGE will be updated to 'Completed' to further reflect that this review is now completed.

The Quality Assurance Team will be copied into this correspondence as a notification that the project will be ready for Archiving.

4.4 Archiving

The completion of the R&I Closeout process will be a requirement ahead of study archiving. The individual completing the Workflow should ensure that the QA Mailbox is notified upon the sending of the R&I Closeout Completion Email.

This will prompt the named Archivist that the study is now ready for archiving and will follow the standard R&I Department Archiving SOP (R&D/S52)

Upon full archiving of the study the Named Archivist will complete the final step on the R&I Closeout Workflow as detail in Appendix A

Related SOPs and Documents

Cross-reference any other SOPs, documents or forms that are related to the SOP you are writing.

- R&D/S52 - R&I Department procedure for archiving clinical research documents – Role of the Named Archivist
- R&D/F06 - Notice of End to Honorary Contract/Letter of Access
- R&D/F86 - Notice of End to Sub-Contracted Services Agreement
- R&D/F97 - Notification of Study Closure to Treatment or Continuous Care Site
- R&D/F104 - Confirmation of R&I Closeout

5 Appendix A

R&I Closeout Workflow

Stage	**Query**	**Process**	**Assigned Teams(s)**
1. **EDGE Status Update**	Has the Closing Date and Status been updated on EDGE?	- Update the field “Closing Date (Actual)” with the confirmed Closing Date - Update the field “Project Site Status” to ‘Closed’ ***If Trust Sponsored***, also update the Green Project Page with Status and Date confirmations	CTA/ Project Support
2. **Study Sponsor Closeout Checklist**	Has the Sponsor requested a Site Close Out Visit or Checklist? And has this been completed?	- Ask if the Research Team if they have completed a Closeout Visit/Checklist for the Sponsor or if one is not to be required by the Sponsor. - If Yes, or confirmed not one requested then please mark as complete	CTA/ Project Support Research Teams
3. **Invoicing**	Has the final invoice been raised for the project?	- Check the EDGE Project Page for Finance attributes. - If no Finance attributes added, mark this section as complete. - Where finance attributes are present, contact the Management Team Administrators (via RG Inbox) and ask if they will have any outstanding Invoices to request and complete. When confirmed mark this section as complete	CTA/ Project Support Management Team Administrators
4. **Letters of Access & Honorary Contracts**	Have all associated Letters of Access or Honorary Contracts been ended?	- Check Project Page attributes under C&C General Information for “Who has a Letter of Access?” - If N/A or blank mark this section as complete.	CTA/ Project Support Management Team Administrators

		- If named individual, contact the Management Team administrators whole will send template email ‘Notification of end of Honorary Contract to associated staff - Management Team Administrators will update “Have they finished their LOA?” attribute on EDGE <u>Note</u>*: Make sure external staff member doesn’t have additional projects associated to their Honorary Contract which may still be active*	
5. **Sub-Contracted Services**	Have all associated Sub-Contractors been notified of the end to their activity?	- Check the Project Site page attributes for ‘Partner Information’ Attributes and see if “Subcontracted Services” is marked Yes. - If ‘No’ or if no Partner Information attributes present, mark this section as complete. - If ‘Yes’, contact the assigned RDF (if External-Sponsored Study) or Project Manager (if Trust Sponsored) and ask them to confirm that the Sub-Contract can be ended. - RDF/Project Manager must check that there are no services that would need to continue beyond extent of Study End Date; - RDF/Project Manager may advise that Subcontract will continue beyond end of Study Date and at this point this section may be marked as Complete - If confirmed Subcontract to	CTA/ Project Support RDF/ Project Manager

		end, RDF or Project Manager to send Template email; 'Notice of End to Sub-Contracted Services Agreement'	
6. **Loaned Equipment**	- Have all loaned equipment & supplies been returned to the Supplier	- Check C&C General Information attribute 'Loaned Equipment from Sponsor' - If 'No', mark section as completed. - If 'Yes', check with Research Team to confirm any loaned equipment has returned to the Sponsor as requested.	CTA/ Project Support Research Team
7. **Treatment & Continuous Care Sites**	- Have all associated Treatment or Continuous Care Sites been notified of study end?	- Check C&C General Information attribute 'External Treatment or Continuous Care site assigned?' - If blank or N/A mark this section as complete. - If organisation listed, contact assigned RDF who will send template email 'Notification of End of Treatment/Follow-up site activity' to R&D contact listed.	CTA/ Project Support
8. **R&I Closeout Confirmation**	- Confirmation of R&I Closeout	- Once all above stages completed, request assigned RDF or Project Manager to send template email 'Confirmation of R&I Closeout Completion' to the PI, Research Team and any assigned Support Departments - Ensure QA Mailbox is copied in as a notification to start Archiving activities - The Research Team should file a copy of this email within the	CTA/ Project Support Research Team RDF/Project Manager

		ISF under the 'End of Study' section (or Sponsor equivalent) - Update Project Site Status on EDGE to 'Completed' ***If Trust Sponsored*** also update Project Page 'Study Status' to Completed	
9. **Study Archiving**	- Has the project been archived?	- Ensure QA inbox is notified of end to R&I Closeout process. - QA to follow the R&I Archiving process as standard and mark as complete	CTA/ Project Support Named Archivist

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