







ECTU Central Office SOP_OP_21: Project Closure Planning

Version No:	1.0
Issue Date:	27 May 2024
Effective Date:	17 Jun 2024

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Kat Oatey Senior Trial Manager	Author	16-May-2024	 Kat Oatey (May 16, 2024 14:08 GMT+1)
Michael Main Business Coordinator	Reviewer	16-May-2024	 Michael Main (May 16, 2024 11:00 GMT+1)
Gina Cranswick Senior Trial Team Manager	Approver	27-May-2024	 Gina Cranswick (May 27, 2024 12:19 GMT+1)
Tanya Tharakan QA Manager	QA Authorisation	27-May-2024	 Tanya Tharakan (May 27, 2024 13:34 GMT+1)

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	17 Jun 2024	Initial creation

The user of this document is responsible for ensuring it is the current version.

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for implementing a Project Closure Plan for an Edinburgh Clinical Trials Unit (ECTU) adopted project.

2.0 SCOPE

This SOP applies to all staff members within ECTU responsible for projects adopted by ECTU. Projects include ECTU full-service studies (with oversight from the ECTU trial management team) or partial service studies (involving at least one or more ECTU team, with oversight from the Business Coordinator).

3.0 RESPONSIBILITIES

This SOP defines the responsibilities staff members within ECTU have when closing out an adopted project in a timely manner.

4.0 PROCEDURE

4.1 Timelines for Close Out

At least six months before the documented grant end date, a Project Closure Plan (PCP) should be put in place if close out is proceeding as planned.

For full-service studies, the Trial Management Team Lead will be responsible for reviewing the Portfolio Management system and notifying the Trial Manager by email that a PCP should be drafted.

For partial service studies, the Business Coordinator will be responsible for reviewing the Portfolio Management system and initiating the circulation of the draft PCP (see process in Section 4.3)

Sufficient time should be built in to accommodate the portfolio and PCP review, for example one month. This can be initiated earlier if appropriate (for example, the project has a longer defined close out period or ECTU funded staff time ends before the final 6 months is reached).

In the case of early project closure, where less than 6 months is remaining, the PCP will be put in place as soon as possible to support the close out.

4.2 Full-Service Studies

4.2.1 Drafting Project Closure Plan

The Trial Manager or designee will draft the PCP and circulate it to the ECTU teams involved in the project.

Each ECTU Team will include any key tasks required to complete the project, define the anticipated date of completion and who is responsible.

The user of this document is responsible for ensuring it is the current version.

Any tasks anticipated to occur after the grant end date should primarily be those required to meet Sponsor/Regulatory requirements.

The Trial Manager or designee should review the Table of Responsibilities in the Co-Sponsorship Agreement and the Grant Award Terms and Conditions (if applicable) against the draft PCP to ensure it is consistent with the responsibilities defined at the beginning of the project.

The PCP should be drafted to ensure as much activity as possible is completed before the grant end date.

4.2.2 Project Closure Plan Review

The draft PCP should be sent to the Senior Trial Manager (STM) responsible for the project and the TM Team Lead for review. If significant additional ECTU time/resources are required to complete any of the activity this will be referred to the Portfolio Management Group to discuss potential solutions.

If it is established that additional external funding is required, this will be escalated to the Senior Research Development Manager to discuss with the CI and ensure appropriate funding is put in place.

Once the STM/TM Team Lead have approved the draft PCP for circulation, the Trial Manager will send it to the CI (and any other external key responsible parties) for review. External parties may include other departments or organisations who have been delegated tasks (for example, if the Process Evaluation Team is at another institution).

The CI/other parties will be asked to notify the TM of any amendments required to the proposed PCP or approve it for sign off.

In case of disagreement around any of the timelines/responsibilities this should be escalated by the Trial Manager to the STM/TM Team Lead who will refer it to the Portfolio Management Group for discussion.

4.2.3 Project Closure Plan Sign off

Once the contents of the draft PCP are agreed, it can be finalised by the TM and circulated for sign off by a representative from each team.

The signed PCP will be circulated by the TM to all parties.

4.2.4 Implementing the Project Closure Plan

An 'End of Trial Meeting' is specified in the ECTU Central Office SOP ECTU_SOP_TM_14: End of Trial Notification and Close-out. Progress delivering the tasks on the PCP should be discussed at this meeting.

The user of this document is responsible for ensuring it is the current version.

The PCP should also form part of the ongoing agenda during the close out period so progress can be discussed on the key responsibilities of each party.

At the grant end date, the Trial Manager or designee will update the 'Actual date of completion' column to confirm each ECTU task is complete or mark it as 'ongoing at handover'. The final section of the PCP will then be signed off by the Trial Manager or designee and sent to the CI and other responsible parties in a handover email which indicates the formal end of the project.

The TM will file the final signed PCP in the Trial Master File (TMF) in Section 2.4 'End of Trial'.

Each party will then be responsible for ensuring all their tasks are followed up until completion.

Any tasks completed by ECTU staff after the project handover should be documented in the TMF by updating the PCP with 'Actual date of completion' and/or filing correspondence indicating the tasks are complete.

4.3 Partial Service Projects

4.3.1 Drafting Project Closure Plan

Partial Service Projects have a non-ECTU trial manager (i.e. the TM is external to ECTU) who will coordinate the overall close out of the project. The ECTU Business Coordinator will instigate the PCP, primarily to define the close out activities ECTU staff are responsible for. The CI and external teams will be offered the opportunity to contribute to this plan and use it as a resource for their project planning. The Business Coordinator will enter the project details on the PCP template and circulate it to the ECTU teams involved in the project to populate.

Each ECTU Team will include any key tasks required to complete the project, define the anticipated date of completion and who is responsible.

The Team Lead from each ECTU team should review the tasks listed and if significant additional ECTU time/resources are required to complete any of the activity this will be referred to the Portfolio Management Group to discuss potential solutions.

If it is established that additional external funding is required, this will be escalated to the Senior Research Development Manager to discuss with the CI and ensure appropriate funding is put in place.

Any tasks anticipated to occur after the grant end date should primarily be those required to meet Sponsor/Regulatory requirements.

The PCP should be drafted to ensure as much activity as possible is completed before the grant end date

4.3.2 Project Closure Plan Review

Once the Business Coordinator has received approval from each Team Lead for the draft PCP to be circulated, the Business Coordinator will send it to the CI (and any other external key responsible parties) for review. External parties may include other departments or organisations who have been delegated tasks (for example, the Trial Manager responsible for the project).

The CI/other parties will be asked to notify the Business Coordinator of any amendments required to the proposed PCP or approve it for sign off.

In case of disagreement around any of the timelines/responsibilities this should be escalated by the Business Coordinator to the Portfolio Management Group for discussion.

If the CI/other parties do not wish to contribute to, or sign off the project closure plan, then the Business Coordinator will document this on the project closure plan and proceed to sign off/implementation.

4.3.3 Project Closure Plan Sign off

Once the contents of the draft PCP are agreed, it can be finalised by the Business Coordinator and circulated for sign off by a representative from each team.

The signed PCP will be circulated by the Business Coordinator to all parties.

4.3.4 Implementing the Project Closure Plan

It is recommended that the PCP should form part of the ongoing agenda during the close out period so progress can be discussed on the key responsibilities of each party. ECTU staff involved in the project are responsible for ensuring progress on their actions are communicated at these meetings.

At the grant end date, the Business Coordinator will ask each ECTU team to update the 'Actual date of completion' column to confirm each ECTU task is complete or mark it as 'ongoing at handover'. The final section of the PCP will then be signed off by the Business Coordinator and sent to the CI and other responsible parties in a handover email which indicates the formal end of the project.

The Business Coordinator will file the final signed PCP on the ECTU drive.

Each party will then be responsible for ensuring all their tasks are followed up until completion.

Any tasks completed by ECTU staff after the project handover should be documented by updating a copy of the PCP with 'Actual date of completion' or filing correspondence indicating the tasks are complete in the study-specific folder on the ECTU drive.



5.0 RELEVANT DOCUMENTS AND REFERENCES

[On ECTU Website](#)

- ECTU Central Office SOP ECTU_SOP_TM_14: End of Trial Notification and Close-out

On ECTU Shared Drive

- OP-T05 Project Closure Plan Template

The user of this document is responsible for ensuring it is the current version.





ECTU_SOP_OP_21 Project Closure Planning v1.0 - unsigned

Final Audit Report

2024-05-27

Created:	2024-05-27 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAA6icpUHG2R1yi54TZOgvaieFkf3x_y2hG

"ECTU_SOP_OP_21 Project Closure Planning v1.0 - unsigned" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-05-27 - 13:33:01 GMT+1- IP address: 192.41.114.230
-  Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2024-05-27 - 13:34:16 GMT+1
-  Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Signature Date: 2024-05-27 - 13:34:35 GMT+1 - Time Source: server- IP address: 192.41.114.230
-  Agreement completed.
2024-05-27 - 13:34:35 GMT+1