ECTU Central Office SOP TM_19: Study Guidance and Handover

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	28th January 2019	Initial creation/New document
2.0	5th June 2019	Addition of risk assessment to Study Management Guidebook Template guidance
3.0	14th April 2020	Updates made as a result of Audit findings. Information added about where to file documentation. Other minor revisions. Updates to revision history of Study Management Guidebook and Essential Study Information document. SOP Author changed
4.0	25 Jun 2021	Addition of new process when all or some of ECTU responsibilities are transferred out with ECTU. Risk assessment updated and removed from SOP. Details of new form and processes to document handover process to external parties added (External Handover Form).
5.0	20 Nov 2023	Revisions throughout to reflect TM co-working and need for SMG for all new studies. Removal of references to partial service studies. Transferred to template v3.0

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedures to follow when preparing guidance documents in the event of a change of Trial Manager or co-working in studies managed by ECTU. This document also provides guidance in preparing for periods where the Trial Manager may be absent (unexpected or planned for example, maternity leave) and when ECTU responsibilities are transferred to staff external to ECTU.

2.0 SCOPE

This SOP applies to all studies that are managed by an ECTU Trial Manager (TM). This is also applicable where studies are managed by an ECTU Assistant Trial Manager (ATM) with oversight and in that case, ATMs should follow the guidance given for TMs. For the remainder of this SOP, TM references refer to both TM and ATM. This SOP should also be followed when trial management responsibilities are shared/ handed over by the Trial Management Team to either internal or external staff.

3.0 RESPONSIBILITIES

It is the responsibility of the delegated Trial Manager/ATM to ensure that study guidance is created and maintained for the studies they manage and for Senior Trial Managers (STM) and the TM Team lead to have oversight of this in the case of handover

4.0 PROCEDURE

4.1 HANDOVER MANAGEMENT – CHANGE OF TRIAL MANAGER

4.1.1 A new Trial Manager may be appointed to a study if the current Trial Manager leaves ECTU employment the incumbent Trial Manager is redeployed to work on another study; is absent long-term (for example, on maternity leave); or a co-working arrangement is in place with more than one Trial Manager appointed to a study

4.1.2 In the event of a planned handover the Senior Trial Manager will ensure that the guidance documents are fully updated before the incumbent Trial Manager hands over the study. The Senior Trial Manager should arrange a handover meeting(s) between the incumbent Trial Manager and their successor. Brief minutes of the handover discussion(s) will be documented in an email and agreed by the parties involved (incumbent TM, incoming TM and Senior TM) and filed in TMF Section 10 ‘Meetings’. A subfolder will be created to contain the documents related to the handover.

4.1.3 If the incoming Trial Manager is a new ECTU/ UoE employee, the Study Management Guidebook will be provided to them as part of their induction process. The Senior Trial Manager will be responsible for providing this and

documenting that it has been handed over in an email and filing this in TMF Section 10.

4.1.4 If possible, the incumbent Trial Manager will inform all relevant parties of their departure (including last day of service). If this is not possible, the Senior Trial Manager or Trial Management Team Lead will inform the relevant parties. This may include:

- ECTU Trial Office Team
- Chief Investigator
- Sponsor
- Funder
- Site Research Teams

4.1.5 The incumbent Trial Manager should ensure they handover/ remove access from any project-specific systems (for example CPMS, clinicaltrials.gov, IRAS, database) and sign themselves off any centrally held delegation logs and other documentation.

4.1.6 Once a successor has been identified, all relevant parties should be notified as appropriate. The Senior Trial Manager or Trial Management Team Lead should inform the Chief Investigator and ECTU of a new Trial Manager in advance of their start date with all other parties informed once the individual is in post, if this is practical. The same process for notifying relevant parties is applicable should the Trial Manager be external to ECTU.

4.2 Guidance Documents

The Trial Manager(s) will be responsible for preparing and maintaining all study management and handover guidance for all studies that they manage for the duration the grant is active and once Operations handover is complete. A Trial Management Support Officer (TMSO) or an Assistant Trial Manager (ATM) can help prepare these for the TM to review and sign off.

There are three types of study management guidance documents that are applicable when considering study guidance. ECTU templates are available on the shared drive for this purpose. These are:

- Essential Study Information document – all studies
- Study Management Guidebook – all studies
- External Handover Form – selected studies only

Other guidance documents may be prepared at the discretion of the Trial Manager if appropriate to the study and the location of these should be documented in the Study Management Guidebook.

4.2.1 Essential Study Information

The Essential Study Information document is a crib-sheet that provides basic trial information so that urgent enquiries can be dealt with when the Trial Management Staff are unavailable.

4.2.1.1 The Essential Study Information document will be prepared for all studies ECTU manages. For new studies, this should be completed before recruitment begins. Once prepared, a copy will be placed next to the phone on the Trial Managers' and ATM/ TMSO desks (where one is employed on the study) so that it can be accessed when the individual is unavailable.

4.2.1.2 The Essential Study Information document should be signed, scanned and saved in section 0 of the study folder on the ECTU shared drive. The original paper copy should be filed in the TMF (Section 0).

4.2.1.3 The Trial Manager or designee will ensure that the Essential Study Information document is up-to-date prior to any planned absence. This will also be formally reviewed every six months from the effective date until the grant end date by the Trial Manager or Designee to ensure that it is up-to-date in the event of an unplanned absence. If no changes are required, the version number will remain the same but a new date given and it should be noted in the 'Summary of Revisions' that there were no changes. Updates will be filed as per section 4.2.1.2.

4.2.2 Study Management Guidebook and Risk Assessment

The Study Management Guidebook provides comprehensive information relating to the management of the study. It should be in place before recruitment starts and be updated regularly to ensure it remains current.

4.2.2.1 A Study Management Guidebook will be prepared for all studies ECTU manages.

4.2.2.2 Once a Study Management Guidebook is created, this should be signed, scanned and saved into section 0 of the study folder on the ECTU shared drive. The original paper copy should be filed in the TMF (Section 0).

4.2.2.3 The Study Management Guidebook will be updated by the Trial Manager or designee as required and will be formally reviewed every 6 months from the effective date to ensure accuracy. If no changes are required, the version number will remain the same but a new date given and it should be noted in the 'Summary of Revisions' that no changes were required. Updates will be filed as per section 4.2.2.2.

4.2.2.4 It is recommended that where an initial draft is created or major revisions are made, the Study Management Guidebook is also reviewed by a Senior Trial Manager or a Trial Manager not associated with the study in order to ensure its efficacy as a training/ handover document. Any reviews should be recorded in the Document Revision History.

4.2.3 External Handover Form

The External Handover Form is a checklist that is to be used where studies or certain responsibilities within a study have commenced within ECTU but are transferred outwith ECTU prior to completion of the study. This form documents the status of the study at the point of handover and details discussions and transfer of responsibilities at this point. This is used in addition to the Study Management Guidebook in these cases.

4.2.3.1 Where ECTU responsibilities are being transferred to those outside of ECTU the relevant sections of the External Handover document should be completed.

4.2.3.2 The Trial Manager or designee will be responsible for creating the External Handover Form and (if applicable) asking the relevant Data Manager and Statistician to complete their sections. Once completed it should be sent to the Trial Management Team Lead and any other relevant Team Leads for review (for example, OPs team)

4.2.3.3 Where trial management responsibilities are handed over to external staff the same processes should be followed as those for an internal transfer. In addition, the External Handover document should be completed. Further instructions on the process for transferring responsibilities to external parties are given in the External Handover document.

4.2.3.4 Once an External Handover document has been completed, this should be signed. The signed document should be saved into section 0 of the study folder on the ECTU shared drive prior to transfer of the filing system. The original paper copy should be filed in the TMF (Section 0).)

5.0 RELEVANT DOCUMENTS AND REFERENCES

- TM-T25 Essential Study Information
- TM-T26 Study Management Guidebook Template
- TM-T27 Study Management Risk Assessment
- OP-T01 ECTU External Handover