ECTU Central Office SOP ECTU_TM_19: Trial Management Handover Guidelines

<table>
<thead>
<tr>
<th>Version No:</th>
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<tr>
<td>Effective Date:</td>
<td>19 May 2020</td>
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Authorship and Approval

<table>
<thead>
<tr>
<th>Name and Designation</th>
<th>Author/Reviewer/Approval</th>
<th>Date</th>
<th>Signature</th>
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<tbody>
<tr>
<td>Julia Boyd, Senior Trial Manager</td>
<td>V3.0 Reviewer</td>
<td>04 May 2020</td>
<td>See Retained Approval Email dated 04 May 2020</td>
</tr>
<tr>
<td>Kat Oatey, Trial Manager</td>
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<td>06 May 2020</td>
<td>See Retained Approval Email dated 06 May 2020</td>
</tr>
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<td>Gina Cranswick, Trial Team Manager</td>
<td>V3.0 Approver</td>
<td>30 April 2020</td>
<td>See Retained Approval Email dated 30 Apr 2020</td>
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Document Revision History

<table>
<thead>
<tr>
<th>Version No</th>
<th>Date</th>
<th>Summary of Revisions</th>
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<tbody>
<tr>
<td>1.0</td>
<td>28th January 2019</td>
<td>Initial creation/New document</td>
</tr>
<tr>
<td>2.0</td>
<td>5th June 2019</td>
<td>Addition of risk assessment to Study Management Guidebook Template guidance</td>
</tr>
<tr>
<td>3.0</td>
<td>14th April 2020</td>
<td>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</td>
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedures to follow when preparing guidance documents in the event of a change of Trial Manager in studies managed by ECTU. This document also provides guidance in preparing for periods where the Trial Manager may be absent (e.g. maternity leave).

2. SCOPE

This SOP applies to all studies that are managed by an ECTU Trial Manager. This is also applicable where studies are managed solely by an ECTU Assistant Trial Manager and they have the equivalent responsibilities to a Trial Manager as detailed below.

3. GUIDANCE DOCUMENTS

3.1 The Trial Manager will be responsible for preparing and maintaining all handover guidance for all studies that they manage. A Trial Management Support Officer (TMSO) can help prepare these for the TM to review and sign off.

3.2 There are two types of handover guidance that may need to be prepared from the ECTU templates provided. These are:
   - Essential Study Information document – all studies
   - Study Management Guidebook – selected studies only

3.3 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 Manager is unavailable.

3.4 The Study Management Guidebook provides comprehensive information relating to the management of the study and is to be used when a study is handed over (either permanently or on a short-term basis) or in other instances where it will be useful.

3.5 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 Key Study Information section of the Essential Study Information document.

3.6 Essential Study Information

3.6.1 The Essential Study Information document will be prepared for all studies ECTU manages. For new studies, this should be completed during set up and should be in place before recruitment begins. Once prepared, a copy will be placed 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.

3.6.2 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).

3.6.3 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 3.6.2.

3.7 Study Management Guidebook and Risk Assessment

3.7.1 A Study Management Guidebook may also be needed for some studies. To determine whether this is needed, a risk assessment should be completed for all studies with input from a Senior Trial Manager. The risk assessment is shown in Appendix 1. It will determine the level of detail required in the guidebook and whether it is needed at all. For new studies, this should be completed during set up and should be in place before recruitment starts.

3.7.2 Once completed, the risk assessment should be scanned and saved to section 0 of the study folder on the ECTU shared drive and the paper copy filed in section 7.1 of the TMF. Risk assessments should be
reviewed annually, or if requested by Senior TM, or when significant changes occur in Trial Management.

3.7.2 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).

3.7.3 The Study Management Guidebook will be updated by the Trial Manager or designee as required but will be formally reviewed annually by the Trial Manager or designee 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 3.7.2.

3.7.4 It is recommended that the Study Management Guidebook is also reviewed by 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. HANDOVER MANAGEMENT – CHANGE OF TRIAL MANAGER

4.1 A new Trial Manager may be appointed to a study if the current Trial Manager leaves ECTU employment or if the incumbent Trial Manager is redeployed to work on another study or is absent long-term (e.g. on maternity leave).

4.2 In the event of a resignation, redeployment or planned long-term absence the Senior Trial Manager will ensure that the guidance documents are fully updated before the incumbent Trial Manager leaves employment/study. Brief minutes of the handover discussion(s) will be documented in an email and agreed by the parties involved and filed in TMF Section 10 ‘Meetings’.

4.3 In the event of redeployment or planned long-term absence, if possible, the Senior Trial Manager should arrange a handover meeting(s) between the incumbent Trial Manager and their successor. These discussions should also be documented as described in per section 4.2.

4.4 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.

4.5 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 Team Manager will inform the relevant parties. Parties to be informed may include:
   - ECTU Trial Office Team
   - Chief Investigator
   - Sponsor
   - Funder
   - Site Research Teams

4.6 Once a successor has been identified, all relevant parties should be notified as appropriate. The Senior Trial Manager or Trial Team Manager may inform the Chief Investigator and ECTU Trial Office Team of a new Trial Manager in advance of appointment with all other parties informed once the individual is in post if this is practical.

5. RELEVANT DOCUMENTS AND REFERENCES

Essential Study Information Template (on shared drive)
Study Management Guidebook Template (on shared drive)
<table>
<thead>
<tr>
<th>Study:</th>
<th>Risk</th>
<th>Insert value</th>
<th>Study Management Guidebook (SMG) completion guidance</th>
</tr>
</thead>
</table>
|       | ACCORD Sponsorship | Y = 0  
N = 1 | If no – complete all sections of SMG |
|       | TMSO or ATM working on the trial with access to generic email inbox | Y = 0  
N = 1 | If no – complete all sections of SMG |
|       | Standard TMF structure followed | Y = 0  
N = 1 | If no – provide TMF index |
|       | Are we responsible for any supplies (drug, samples etc.) | Y = 1  
N = 0 | If yes – complete SMG including sections 7 and/or 8 |
|       | Are there any key functions delegated to non ECTU staff | Y = 1  
N = 0 | If yes – complete SMG including sections 2, 3 and 10 |
|       | Planned redeployment of the Trial Manager | Y = 1  
N = 0 | If yes – complete all sections of SMG |
|       | Other | Y = 1  
N = 0 | If yes please specify and discuss with STM |

**Total Risk score**

0 - completion of guidebook not required but review risk assessment annually or if requested by Senior TM or when significant changes occur in TM

1 – complete sections of the guidebook specified above

2 or more - completion of full guidebook required

STM Comments

Completed by

Name: ____________________________

Signature: _________________________

Date: ___________________________

Agreed by (STM)

Name: ____________________________

Signature: _________________________

Date: ___________________________

Completed Risk Assessments should be filed in Section 7.1 of the Trial Master File.