# ECTU Central Office SOP ECTU_OP_04: Site Initiation and Sponsor Authorisation

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## Authorship and Approval

<table>
<thead>
<tr>
<th>Name and Designation</th>
<th>Author/Reviewer/Approval</th>
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<tr>
<td>Anna Heye, Trial Manager</td>
<td>V2.0 Reviewer</td>
<td>05/09/2019</td>
<td>Signature on File</td>
</tr>
<tr>
<td>Kat Oatey, Trial Manager</td>
<td>V2.0 Reviewer</td>
<td>05/09/2019</td>
<td>Signature on File</td>
</tr>
<tr>
<td>John Norrie, ECTU Director</td>
<td>V2.0 Approver</td>
<td>03/10/2019</td>
<td>Signature on File</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>15th May 2017</td>
<td>Initial creation/new document</td>
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<td>Updated at scheduled review. Document moved to new template. Addition of Regulatory Green Light process and Regulatory Green Light checklist. Sections 4.3 4.4.2 and 4.6 updated. Other minor changes made throughout.</td>
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1. PURPOSE

A Site Initiation Visit (SIV) and Sponsor authorisation are required to prepare and set up a research site to conduct a clinical research study. Training will be provided to site staff on required Standard Operating Procedures (SOPs), and it will be ensured that the study team have access to the appropriate SOPs and related documents, and that there is appropriate resource in place to begin the trial. The study protocol and Good Clinical Practice (GCP) will also be discussed. The SIV will be scheduled according to the monitoring plan and the SIV procedures must be complete before Sponsor authorisation can be granted and the site opened for recruitment.

SIVs and Sponsor authorisation will take place for new study sites where the risk assessment has deemed that an SIV is required.

This SOP describes the procedure for SIVs and Sponsor authorisation for sites that will participate in studies selected for monitoring and managed by ECTU.

2. SCOPE

This Standard Operating Procedure (SOP) applies only to studies where the Sponsor does not provide their own SOP for this task. Where a Sponsor SOP is available, this will supersede this SOP. This SOP applies to the Clinical Trials Monitor or any other individual, who will conduct and document SIV and facilitate the Sponsor authorisation to commence the study.

3. RESPONSIBILITIES

3.1 The Clinical Trials Monitor, or designee, is responsible for conducting the SIV (including reporting and follow up) and for ensuring that Sponsor authorisation to open the trial site is facilitated in accordance with this SOP.

3.2 The Clinical Trials Monitor is responsible for liaising with the Sponsor and Trial Manager, or designee, throughout the facilitation process.

4. PROCEDURE

4.1 Collaboration between Trial Manager and Clinical Trial Monitor

4.1.1 The Trial Manager, or designee, will liaise with the Clinical Trials Monitor to discuss when the SIV and Sponsor authorisation process should commence.

4.2 Before Site Initiation Visit

4.2.1 The SIV will be conducted prior to first participant being enrolled onto the trial.

4.2.2 The Clinical Trials Monitor, or designee, will liaise with the Principal Investigator (PI), or site contact, to arrange an SIV for each site, as required in the monitoring plan.

4.2.3 The Clinical Trials Monitor, or designee, will outline the requirements for the SIV, in terms of attendance of the study team and in terms of time and resources.

4.2.4 Prior to the SIV, the Clinical Trials Monitor, or designee, will ensure that all required approvals are in place or document clearly what approvals are outstanding at the time of the SIV.
4.2.5 Clear instruction will be given that sites cannot open to recruitment without confirmation of Sponsor authorisation to open trial site.

4.2.6 The Clinical Trials Monitor, or designee, will ensure that a Trial Master File (TMF) has been created for the study. It is the PI’s responsibility to ensure that an Investigator Site File (ISF) is in place for their site before the study starts.

4.3 During Site Initiation Visit

4.3.1 The PI and all relevant trial team members, as identified by the PI, will attend the SIV. Representatives from any supporting departments will attend as necessary e.g. pharmacy, radiology, laboratories. Attendance should be documented in the ISF (usually on the Training Log). For those who are unable to attend the SIV in person, training will be provided and documented in the ISF.

4.3.2 The PI is responsible for ensuring that the study team has received training on the protocol. Protocol training will be provided by the Chief Investigator (CI), or designee, and documented at SIV unless otherwise agreed in the monitoring plan. Protocol training must be provided prior to site opening to recruitment.

4.3.3 The Clinical Trials Monitor, or designee, will provide training with respect to the appropriate SOPs and will discuss the study protocol, study documents and GCP as documented in the monitoring and SDV plan.

4.3.4 In accordance with the monitoring plan and where deemed necessary by the Trial Manager, the Clinical Trials Monitor, or designee, will attend protocol training provided by the PI.

4.3.5 The Clinical Trials Monitor, or designee, will discuss and verify all items listed in the SIV report. The SIV report can be made study specific to remove non-applicable sections.

4.3.6 If there is a delay of 3 months or more between the SIV and start of the study, refresher training for the site will be considered. If training is provided this will be documented and filed alongside the SIV report. Where refresher training is not provided, this will be justified in a file note and filed alongside the SIV report.

4.4 After Site Initiation Visit

4.4.1 Subsequent to the visit, the SIV report and follow-up letter will be prepared by the Clinical Trials Monitor, or designee, who conducted the SIV. The report will be completed with factual information only. No personal opinions or comments will be documented in the report.

4.4.2 If any issues are identified requiring a delay to the site opening or any concerns over conduct are raised, these will be communicated to the Trial Manager and PI immediately, and documented in the SIV report. The Trial Manager should communicate these to the Sponsor if they cannot easily be resolved.

4.4.3 The SIV report will be reviewed by the Trials Manager, or designee, in accordance with the monitoring plan, before being provided to the study site. The report cannot be reviewed by the person who prepared the report.

4.4.4 A signed copy of the completed report and follow-up letter will be sent to the PI and Trial Manager by the Clinical Trials Monitor, or designee. If supporting departments were involved in the SIV or the report and follow-up letter is relevant to the supporting department, they will be provided with a copy.

4.4.5 The PI will sign the PI statement on the SIV report and return a copy to the Clinical Trials Monitor, or designee. This signature is required for the SIV process to be complete. A copy will be provided to the Trial Manager.
4.4.6 Target times for completion of SIV report and sending report to PI are outlined in the monitoring plan. Where target times were not met, justification will be documented in a file note and filed alongside the monitoring report.

4.4.7 The SIV report, follow-up letter and a copy of all training materials used for protocol specific training during the SIV will be filed in the TMF and ISF as appropriate.

4.4.8 Actions identified during the SIV will be followed up to resolution using the Monitoring Visit Actions Log.

4.5 Remote Site Initiation Visits

4.5.1 If appropriate, the monitoring plan will specify that remote site initiation will be completed. The Clinical Trials Monitor, or designee, will discuss the necessary items in SIV report over the telephone (or via another remote communication method) with the study team, provide training with respect to the Sponsor’s SOPs and discuss GCP and the study protocol as required.

4.5.2 Remote SIVs must document that all items in the SIV report have been verified. Evidence should be provided by the site where required.

4.5.3 The Clinical Trials Monitor, or designee, who conducted the remote SIV will complete the SIV report using the information provided by the study team. Where all requirements for the SIV report cannot be verified remotely, an on-site SIV will be performed.

4.6 Sponsor Authorisation

4.6.1 Before a site can commence study recruitment, authorisation must be granted on behalf of the Sponsor by the Clinical Trials Monitor, or designee.

4.6.2 Where applicable according to the risk assessment or monitoring plan, the Clinical Trials Monitor, or designee, will provide authorisation to release IMP to the site (‘Regulatory Green Light’) by completing the Regulatory Green Light Checklist.

4.6.3 Regulatory green light will only be provided once all approvals are in place. In addition to local approvals, this may include the Sponsor’s authorisation to start the trial (if applicable according to the risk assessment or the Sponsor’s SOPs).

4.6.4 The Clinical Trials Monitor, or designee, will confirm (or verify remotely) all actions in the Sponsor authorisation form and document them as completed or non-applicable. The Sponsor authorisation form should be completed by the Clinical Trials Monitor, or designee who attended the SIV. In circumstances where this is not possible, the form will be signed by a member of the Trial Management team and the reasons for this documented.

4.6.5 If the SIV has been performed remotely, evidence should be provided by site to verify actions have been completed as required.

4.6.6 If any issues are identified requiring a delay to the site opening for recruitment, these will be escalated to the Trial Manager and the PI immediately.

4.6.7 The completed Sponsor authorisation form will be subject to review by the Sponsor representative, who signs off the form.

4.6.8 Once the Sponsor authorisation is reviewed and finalised, the Clinical Trials Monitor, or designee, will send the completed document to the PI to convey permission to open the study at the trial site. Relevant members of the study team and supporting departments such as pharmacy will also be provided with a copy.

4.6.9 For studies with a long screening period, initial authorisation can be granted to begin screening participants before IMP has arrived at site. For authorisation to begin screening to be granted, all other actions except IMP in place, shipping records verified and drug labels
accurate and consistent with MHRA approval must have been completed in the Sponsor authorisation form, and written confirmation received that IMP will be onsite before end of screening period.

**4.6.10** A second authorisation to begin dosing will be granted once IMP is confirmed as on site and remaining actions in the Sponsor authorisation form have been confirmed or verified remotely.

### 5. RELEVANT DOCUMENTS

**Sponsor Authorisation Form**  
ECT Unit/SOPs/Finalised SOP and WPD/OP/Supporting Documents and Templates

**Site Initiation Visit Report Template**  
ECT Unit/SOPs/Finalised SOP and WPD/OP/Supporting Documents and Templates

**Monitoring Visit Actions Log**  
ECT Unit/SOPs/Finalised SOP and WPD/OP/Supporting Documents and Templates

**Regulatory Green Light Checklist**  
ECT Unit/SOPs/Finalised SOP and WPD/OP/Supporting Documents and Templates