ECTU Central Office SOP ECTU_OP_17: Review of External Reports

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Authorship and Approval			
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Document Revision History		
Version No	Date	Summary of Revisions
1.0	18 Jun 2021	SOP Originally ECTU_SOP_TM_16 v 2.0. SOP ID updated to ECTU_SOP_OP_17. Addition of Checklist and general updates.

1. PURPOSE

It is ECTU procedure that reports required by a funder should be reviewed by a senior member of ECTU staff prior to submission. This Standard Operating Procedure (SOP) sets out the steps to meet this requirement.

2. SCOPE

This SOP applies to all studies fully managed by ECTU where the funder requires a report on an annual, interim or ad-hoc basis.

3. PROCEDURE

3.1 Responsibilities

3.1.1 The Trial Manager or designee will be responsible for requesting a funder report review, providing a draft report to the reviewer and ensuring that the reviewer is aware of the timeline for review and the deadline for completion.

3.1.2 The Trial Team Manager (Operations) or designee will be responsible for allocating a Reviewer to a report when requested by the Trial Manager.

3.1.3 The Reviewer will be responsible for ensuring that the review is completed for the specified deadline and that report is an accurate reflection of the study progress to date.

3.2 Review Request Procedure

3.2.1 The Trial Manager will request a reviewer allocation by adding details of the study/report to the Progress Report Schedule (see section 4 for location details). The Trial Manager should ensure that the request is added as soon as the report due date is confirmed by the funder.

3.2.2 The Trial Team Manager (Operations) or designee will check the Progress Report Schedule on a regular basis and allocate Reviewers where required.

3.2.3 Once allocated, the Trial Team Manager (Operations) or designee will confirm the allocation to the Reviewer by email, advising of the study name and the date the report is due. The Trial Manager will be copied into this email.

3.2.4 If the Reviewer knows at the time of allocation that they will be unable to complete the review by the due date, they must inform the Trial Team Manager (Operations) or designee and Trial Manager within two weeks of being notified of the allocation. The Trial Team Manager (Operations) or designee will then allocate another reviewer.

3.3 Review Procedure

3.3.1 The Trial Manager will provide the Reviewer with a final draft of the report to review. This should be provided as soon as possible; preferably at least two weeks before the due date, but there is flexibility around this depending on individual circumstances agreed between the reviewer and trial manager and documented.

3.3.2 If the Reviewer is unable to complete the review once they have received the final draft from the Trial Manager, they should make arrangements for another Reviewer to complete this on their behalf,

ensuring that the Trial Manager is made aware of the change. The Trial Manager will update the progress report schedule accordingly.

3.3.3 The final draft report should include all text / data fields completed (statistical input may be required) and conform to the funders requirements in terms of report content and presentation. In addition the report should be reviewed by the Chief Investigator (or appointed other). If CI review is not possible the reviewer can review the latest draft version and advise should further review be required following CI review.

3.3.4 If previous reports and corresponding responses are available these should be provided to the Reviewer along with the final draft report. If not provided to reviewer these should be requested if appropriate.

3.3.5 The Reviewer, on receipt of the report should read the report in full ensuring that:

- Any requirements / requests from last report (where appropriate) have been met
- All questions / fields have been completed where appropriate and are a fair representation of the data presented.
- Where targets have not been met this is stated along with clear justification
- Possible solutions are provided in circumstances where problems and/or issues have been identified.
- Consideration is made to dissemination (e.g. made publically available)

3.4 Review Feedback and Report Revisions

3.4.1 Any comments on the report should be fed back to the Trial Manager.

3.4.2 Comments relating to the above criteria should be provided via the checklist and additional comments can be added to the final draft of the report sent via track changes if appropriate.

3.4.3 The Trial Manager will edit the report as required. If there are any edits or comments that are unclear clarification should be sought.

3.4.4 Should any further substantial edits be made following the review process the Trial Manager should notify the Reviewer of this and it may be necessary for the report to be formally reviewed again.

3.4.5 Should there be any disagreement regarding suggested edits, the Reviewer can seek further advice or clarification from another reviewer or the Chief Investigator.

3.5 Statistical Review of Final Reports

3.5.1 Official Final Reports that contain results from statistical analyses must be reviewed by the Trial Statistician or designee to ensure accuracy against the final statistical report according to ECTU Statistical SOPs

4. RELEVANT DOCUMENTS AND REFERENCES

ACCORD SOP CR011 Clinical Study Report Preparation- CTIMPs
OP–F01 Review of External Reports Reviewers Checklist
Progress Report Schedule (ECT Unit/ECTU Current Trials/4 TRIAL MANAGEMENT)