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.	Effective 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.
2.0	19 Jun 2024	Updated to new template (v3.0). Edited to reflect current processes. Included section 4.3.6. Minor formatting changes

1.0 PURPOSE

It is ECTU's 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.

2.0 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 during the period of ECTU involvement. This may involve a recovery plan should an extension to the original award be required.

3.0 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 Senior Trial Team Manager or designee will be responsible for allocating an ECTU Reviewer to a report when requested by the Trial Manager.

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

3.1.4 The Chief Investigator (CI) will be ultimately responsible for sending an accurate report to the funder.

4.0 PROCEDURE

4.1 Review Request Procedure

4.1.1 The Trial Manager will request a reviewer allocation by adding details of the study/report to the Progress Report Schedule (see section 5 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.

4.1.2 The Senior Trial Team Manager or designee will check the Progress Report Schedule on a regular basis and allocate Reviewers where required.

4.1.3 Once allocated, the Senior Trial Team Manager 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.

4.1.4 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 Senior Trial Team Manager or designee and Trial Manager within two weeks of being notified of the allocation. The Senior Trial Team Manager or designee will then allocate another reviewer.

4.2 Review Procedure

4.2.1 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 by email.

4.2.2 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.

4.2.3 The final draft report should include all text / data fields completed (statistical input may be required) and conform to the funder's 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 in a timely manner, the reviewer can review the latest draft version and advise should further review be required following CI review.

4.2.4 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 the reviewer, these should be requested if appropriate.

4.2.5 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 (for example, recovery plan).
- Consideration is made to dissemination (for example, made publicly available)

4.3 Review Feedback and Report Revisions

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

4.3.2 Comments relating to the above criteria should be provided via the OP–F01 Review of External Reports Reviewers checklist and additional comments can be added to the final draft of the report sent via track changes if appropriate. Completed checklists should be filed in the study specific TMF in section 3.3.2 Funder Reports.

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

4.3.4 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.

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

4.3.6 Once finalized the Trial Manager sends the report via email to either the funder, or the CI, to then forward onto the funder, as agreed. The final report is saved in the TMF, Section 3.

4.4 Statistical Review of Final Reports

4.4.1 Official Final Reports, before being sent to the funder, that contain results from statistical analyses must be reviewed by an ECTU Statistician or designee to ensure accuracy against the final statistical report.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Shared Drive

- OP–F01 Review of External Reports Reviewers Checklist
- Progress Report Schedule

ACCORD

- ACCORD SOP CR011 Clinical Study Report Preparation- CTIMPs

ECTU_SOP_OP_17 Review of External Reports V2.0 and OP-F01 Review of External Report Checklist v2.0

Final Audit Report 2024-05-29

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