ECTU Central Office SOP ECTU_OP_18:
Applying for Project Extensions

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Authorship and Approval			
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Tanya Tharakan, QA Manager	QA Authorisation	15 Dec 2023	Retained email approval dated 15 Dec 2023

Document Revision History		
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1.0	15 Jan 2024	Initial creation. Formerly ECTU_SOP_TM_13, Converted to SOP_OP_18 due to change in responsibility. Transferred to SOP template V3.0. Author, reviewer, approver, QA authorisation details updated. Substantial changes made throughout.

1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines the procedure for applying for project extensions both for full-service projects managed by ECTU, as well as for partial service projects managed by other CTUs or organisations where ECTU has a supportive role.

Projects are defined as clinical trials or any other type of research study within ECTU's portfolio.

2.0 SCOPE

This SOP applies to all projects within ECTU's portfolio where an extension is required.

If alternative funding needs to be sought to continue a project, then this is considered a new project, not an extension, and this SOP does not apply.

3.0 RESPONSIBILITIES

3.1 It is the responsibility of the Trial Manager (TM), Research Development Team (RDT) and the Business Coordinator (BC) to:

- Follow this SOP when discussions about a project extension take place.
- Monitor and facilitate the progress of key steps, as identified below.

4.0 PROCEDURE

4.1 Initial decisions for projects with an ECTU trial manager

[Note: Any indication of an extension during the course of a project, whether it is during formal meetings or informal conversations, should be escalated at the earliest opportunity to a senior Trial Manager/ Team Lead for discussion by the Operations Team.

The possibility of extending a project should be discussed with the Chief Investigator, Trial/ Project Statistician and the Trial Steering Committee (TSC, if applicable). To assess the need for a project extension, alternative solutions, such as reviewing the sample size or adjusting the exclusion criteria should be explored in the first instance.**]**

The Trial Manager and CI should discuss the extension with the Trial Management Group (TMG) to identify any potential impact. It may also be useful to ask the Trial/Project Statistician to provide a comparison of the power calculations with and without the extension.

The decision-making to extend a project should be agreed upon by the key stakeholders, including the original co-applicants (where appropriate), the Sponsor, Trial Management Group, Trial Steering Committee and Data Monitoring Committee (DMC, if applicable). Some funders will request written approval for an extension from the TSC and DMC chairpersons.

4.1.1 Once the need for an extension has been agreed upon and the general requirements discussed, the Trial Manager should contact the ECTU Research Development Team (RDT) by email (ECTU-new.proposals@ed.ac.uk) to make them aware of the need for an extension.

4.1.2 An "Intent to Submit" (ITS) form is required (found in the web portal on the University's Research Office (ERO) webpage) to proceed with extension requests. The responsibility for this submission in most cases lies with the lead unit (CI/ CI's unit). RDT or the TM can remind the CI of this responsibility in an email.

4.1.3 Where additional financial support is required (see section 4.3), the funding body that funded the original grant should be approached by the CI, unless there are conditions disqualifying the project from extension requests.

[**Note:** If alternative funding needs to be sought to continue a project, then this is considered a new project, not an extension, and this SOP does not apply.**]**

4.1.4 Documentation around the project extension decision-making and outcomes should be included in the Trial Master File (TMF) and this will be fulfilled by the Trial Manager. On occasion, if required by the funder, ECTU may provide a letter of support to the CI. RDT will facilitate obtaining a signed letter of support from the ECTU Director.

4.1.5 Extension requests related to studies in ECTU's portfolio will be added to the Portfolio Management meeting agenda for discussion/oversight. These meetings occur on a weekly basis, and are attended (when available) by the ECTU Operations Team, consisting of the unit Director, Clinical Director, Chief Operating Officer, Business Manager, Senior Research Development Manager, QA and delivery team leads (or their delegates).

4.2 Initial decisions for projects without an ECTU trial manager

[Note: ECTU's expectation is that the same processes as described in the Note in section 4.1 have been undertaken by the research team prior to notifying ECTU of the requirement for a project extension.**]**

4.2.1 Once the need for an extension has been agreed upon and the general requirements discussed, the Trial Manager or Project Manager should contact the ECTU Research Development Team (RDT) by email (ECTU-new.proposals@ed.ac.uk) to make them aware of the need for an extension.

4.2.2 An "Intent to Submit" (ITS) form is required (found in the web portal on the University's Research Office webpage) to proceed with extension requests. The responsibility for this submission in most cases lies with the lead unit (CI/ CI's unit).

In the case where ECTU is the only unit participating in the project within CMVM, then the Business Coordinator will complete and submit this form.

4.2.3 Where additional financial support is required (see section 4.3), the funding body that funded the original grant should be approached by the CI, unless there are conditions disqualifying the project from extension requests.

[Note: If alternative funding needs to be sought to continue a project, then this is considered a new project, not an extension, and this SOP does not apply.**]**

4.2.4 On occasion, if required by the funder, ECTU may provide a letter of support to the CI. RDT will facilitate obtaining a signed letter of support from the ECTU Director.

4.2.5 Extension requests related to studies in ECTU's portfolio will be added to the Portfolio Management meeting agenda for discussion/oversight. These meetings occur on a weekly basis, and are attended (when available) by the ECTU Operations Team, consisting of the unit director, clinical director, chief operating officer, business manager, senior research development manager, QA and delivery team leads (or their delegates).

4.3 Extension requirements and considerations

[Note: ECTU's expectation is that for projects without an ECTU trial manager, equivalent/ similar processes as described below are undertaken by the research team (i.e., external trial/ project manager and/ or Chief Investigator).**]**

4.3.1 The ECTU Trial Manager or RDT should identify the funder requirements (procedures may differ for studies not sponsored by NHS Lothian/UoE) regarding the process for the extension applications and any applicable criteria that must be met regarding funding extension requests.

4.3.2 The ECTU Trial Manager, together with the Chief Investigator, should develop a revised project timeline incorporating the extension period (e.g., on a Gantt chart). It may be useful to detail 2-3 options for completing the project. RDT and the statistics team (if applicable) can help with this, if required. The CI is ultimately responsible for deciding on the length of the extension request but should be guided by the data and the recommendations from ECTU in terms of feasibility.

4.3.3 An up-to date summary of spending on the project grant should be prepared. Submission of the ITS form (sections 4.1.2 or 4.2.2) triggers this activity from ERO.

[Note: The standard approach would be that upon receiving an ITS form, ERO will assign a Research Funding Specialist (RFS) to the request, who will collate the information from: (1) the grant reconciliation; (2) the committed costs to the current grant end-date from all units involved; and (3) the extension costs from all units involved. Once collated, the RFS will prepare a variation to contract (VTC), which contains the financial figures for the extension request. The RFS will send these official financial figures to the Chief Investigator, and other relevant colleagues, including RDT (full-service studies) or the Business Coordinator (partial service studies).**]**

4.3.4 RDT (full service) or the Business Coordinator (partial service) should collate the ECTU resource requirements for the extension. For this, RDT or the Business Coordinator will contact (by email) all of the ECTU teams involved in the project (via the Team Leads) to

request that they identify the resource requirements for (1) committed costs covering the period from the date of the grant reconciliation to the end of the current award; and (2) extension costs. Resource requirements include: staff posts, consumables, travel, further IMP supply (if applicable) and data entry costs. This list is not exhaustive, and other costs can be included based on the project's unique requirements.

[Note: While RDT or the Business Coordinator are collating the ECTU costs, the RFS from ERO should be liaising with the CI to identify costs for the other centres, external partners and the NHS involved in the grant.**]**

4.3.5 Once ECTU committed and extension costs have been collated, RDT (full service) or the Business Coordinator (partial service) will email the RFS with this information. In the case that the trial manager is within ECTU (full service), they should be copied into this email. In the case that the trial manager in not within ECTU (partial service), then the email to the RFS should not include them, to protect ECTU financial information.

4.3.6 The Chief Investigator should review the costs together with the Trial Manager, RDT (full service) or Business Coordinator (partial service), and the ERO RFS. RDT (full service) or the Business Coordinator (partial service) should arrange a meeting to facilitate this review.

4.3.7 On occasion, the costs received will not be acceptable to the Chief Investigator. In these instances, the ECTU Trial Manager should escalate the issue to the Trial Manager Team Lead or the Senior Research Development Manager at the quickest opportunity, so that they can raise it for discussion at the next Portfolio Management meeting, or if urgent, convene a meeting with relevant parties to discuss.

For studies where the trial manager is not within ECTU (partial service), the Business Coordinator should raise any issues around costs for discussion at the next Portfolio Management meeting, or if urgent, convene a meeting with relevant parties to discuss.

4.4 Writing/ use of reports to support an extension

When preparing the report, the Trial Manager or designee should give significance to the financial aspect along with the content of the extension. The RDT and/ or Business Team can support with the design of the financial section of the report.

There are several types of reports that could be used:

- Recent progress report
- Recovery plan
- Grant reconciliation, financial commitments and extension costs
- Any other funder templates

On notification of request for a recovery plan or an extension, please follow the key steps below.

[Note:
1) For partial service studies, the Business Coordinator will complete certain tasks instead of RDT.

2) Typically, a Review Team (consisting of the TM, Trial Statistician, and members of the ECTU Management team, as appropriate) is formed either following request from the Funder for a progress review, or if there are budgetary concerns recognised by ECTU**]**

TM Responsibilities	Team Leads / Ops Team Oversight
Notify the Senior TM in a timely way, ensuring consideration is given to time sensitivities and deadlines. (STM will then relay to appropriate Team Lead(s) providing any deadline, specific requests or concerns)	The **RDT Team** adds this to the subsequent Portfolio Management meeting agenda, and requests financial reconciliation from ERO (see section 4.1). The **key ECTU reviewer** of the report must be decided prior to submission.
Invite the Senior TM / TM Team Lead/ Statistics Team Lead(s) (and others) to the regular PMG / Trial team meetings during this period to provide oversight and support.	The Senior TM / TM Team Lead/ Statistics Team Lead(s) **must** be invited to the PMG/Trial team meetings to be able to provide advice and support.
Identify the requirements for the report, and whether the funder has provided guidance. Ensure the current Trial Gantt Chart of timelines and milestones is up to date.	
Create a shared space (for example, Teams or SharePoint) to ensure tracked changes are captured, and/or version control is accurately kept for the recovery plan documents, as required. Ensure all parties have access to the shared space.	
1. Recovery planning to be added to Team meeting agenda. Team meeting to review current status (for example, progress against stop/go criteria, barriers to progress etc) and then consider recovery / extension options (typically 2-3 scenarios). 2. Establish a clear timeline to prepare for submission of recovery plan, taking into account time to discuss options, collate data (for example, stats to review recruitment projections, sample size, power, screening data etc) and further refine scenarios. 3. Clearly outline timelines and review at each meeting to keep to schedule. Ensure there is enough time for the report to be written, financial details included, and for the review to be undertaken within the trial	**STATS Team** to consider data to support the creation of scenarios (for example, sample size, power and recruitment projections) if required. The Review Team is involved throughout this process. All relevant teams, including external to ECTU, will require sufficient time to review, and must have knowledge of the deadline.

TM Responsibilities	Team Leads / Ops Team Oversight
team and by the named reviewer in advance of the deadline.	
When notified by the STM, the TM should arrange an **INTERNAL ECTU** meeting with the Senior Team (TBC attendees required by the TM Team Lead & include the trial Statistician, RDT & STM). The considerations for this meeting must include (list not exhaustive): 1. Whether the remit of the Progress review is adhered to (for example, if a funder requests a plan for early withdrawal of funding). 2. Whether the scenarios are realistic. 3. Whether the proposal incorporates a recruitment rate more than 50% of the existing rate (carefully consider whether this is feasible / based on available screening data). 4. Whether the number of sites has been increased (carefully consider if this is feasible). 5. Consider changes that are required to the protocol / documents, reducing the participant burden etc, and has time for these changes to be implemented been included. 6. Whether the CI is experienced or additional support in decision making is required.	Senior Team (TBC attendees required by the TM Team Lead & include the trial Statistician, RDT & STM

TM Responsibilities	Team Leads / Ops Team Oversight
Finalise the recovery plan. This must include: 1. Separate Gantt chart for each scenario, indicating timelines and including actual dates. 2. Separate recruitment projections for each scenario, prepared by the trial statistician, clearly indicating existing recruitment to date. 3. If required, a letter of support. For each scenario, it must also be clear what changes are required/proposed, such as substantial amendments, changes to operational delivery, drug supplies, etc.	
The proposal, including the report, Gantt chart and recruitment projections, must be circulated to the CI via email. The TM should also arrange a recovery plan meeting with the ECTU Review Team, ensuring the CI is included (and other key members of the non ECTU team as necessary, for example, ERO, Sponsor representative) to discuss the plan and any concerns. Agreement needs to be reached in good time and costing to be requested once each scenario is agreed.	**RDT** to provide costings once options are finalised
Arrange review by nominated ECTU Reviewer. This must be done in advance of submission and allow time for any edits. (Refer to: ECTU_SOP_OP_17 Review of External Reports)	The Reviewer can be decided based on the membership of the ECTU Review Team
Circulate final version as required, ensuring those involved in the review and the CI are copied in. Documents should be placed in the TMF Section 3.	
Following feedback relay information to those involved in the review and the CI. Document should be placed in TMF Section 3. Further discussions about implementing recommendations will then be required.	Consider feedback and support the implementation of agreed proposal. RDT to request any updates to the Worktribe record.

4.5 Funder Queries

On occasion, the funder will respond with queries around the extension request/ proposal. In these instances, the Trial Manager should notify the Senior Trial Manager and RDT (full service), or the Business Coordinator (partial service), who will provide support to the Trial Manager and Chief Investigator in clarifying the funder's queries.

4.6 Outcomes

4.6.1 ECTU's expectation is that the Chief Investigator should inform the Trial Manager, who in turn should notify RDT (full service) or the Business Coordinator (partial service) of the outcome. Once notification of the outcome is received by RDT or the Business Coordinator, they will then notify the ECTU Operations Team at the Portfolio Management Meeting, update the project record in the portfolio database, and notify the RFS in ERO by email.

4.6.2 The CI is responsible for informing any other relevant parties (e.g., PIs, researchers at sites, drug companies) with regard to the outcome of the extension application. In some cases, these communications may be delegated to the Trial Manager following discussion with the CI.

4.6.3 RDT and the Business Team should work with ERO to ensure that a copy of the formal written notification of extension from Funder is added to the Worktribe record. This will then enable ERO to update the project end date on Worktribe and arrange for the People and Money (P&M) project record finish date (end date plus 3 months) to be amended.

4.6.4 Extension applications that prove unsuccessful should be dealt with on a case-by-case basis with input from the Chief Investigator and all relevant stakeholders to determine the course of action for the project.

5.0 RELEVANT DOCUMENTS AND REFERENCES

- CMVM Intent to Submit Form: https://www.ed.ac.uk/research-office/winning-research-funding/craft-application/cmvm-intent-to-submit-a-research-funding-applicati
- NIHR Guidance for recovery plan: ECTU Current Trials\4 TRIAL MANAGEMENT\Guidance docs and training\Suggested NIHR Recovery Plan Content.docx
- ECTU_SOP_OP_17 Review of External Reports (on ECTU shared drive)