ECTU Central Office SOP ECTU_ST_01: Sample Size Calculation

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Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval	Date	Signature
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Steff Lewis, ECTU Stats Team Leader	V4.0 Approval	14 January 2021	See Retained approval email dated 14 January 2021

Document Revision History		
Version No	Date	Summary of Revisions
1.0	6th Aug 2012	Initial creation/New document
2.0	5th March 2015	Clarification that validation should involve two people in section 3.3
3.0	13th March 2017	Section 3.4 and 3.5 added after Sponsor audit recommendation
4.0	20th February 2019	Updated at scheduled review. Document moved to new SOP template. Minor wording alterations to section 1, 3 and 4.
4.0	14 January 2021	No changes required at periodic review. No change to version number and effective date. Periodic review extended.

1. PURPOSE

Most prospective studies will have a sample size calculation prior to commencing the study in order to maximise the chance that the study is large enough to estimate the primary outcome effect with sufficient precision and so that the study is not so large that far more participants than necessary are exposed to trial interventions. This Standard Operating Procedure (SOP) outlines the procedures for performing, checking and documenting the sample size calculations.

2. SCOPE

This SOP applies to all randomised trials with full statistical support provided through ECTU and is applicable to the statistician who performs the sample size calculation.

3. PROCEDURE

3.1 Detail the sample size, precision or power calculation, including dropout rates, relevant assumptions, justifications and methods in enough detail that the calculation can be repeated by someone else.

3.2 This information should go in the trial protocol but if necessary, a separate document containing extra detail can be prepared and kept with the trial data. The Sample Size Estimate Form can be used for documenting the full details (see Section 4).

3.3 For a clinical trial of an investigational medicinal product (CTIMP), the sample size derivation should be done independently by two statisticians and this should be documented.

3.4 If a study does not need a formal size sample calculation (e.g. a feasibility study), there should still be some justification for the sample size chosen. It is not necessary to validate such justifications but they should be documented on the Sample Size Estimate Form.

3.5 If exploratory additional sample size calculations are performed (e.g. when communicating with funders) but these do not form part of the protocol, then they should be clearly labelled as exploratory. No validation is necessary.

4. RELEVANT DOCUMENTS AND REFERENCES

Sample Size Estimate Form
ECT Unit/SOPs/Finalised SOP and WPD/ST/Supporting Documents and Templates/Current