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SOP 605 Sample Size Calculation

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Sample Size
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To be reviewed before: This document remains current after this date but will be under review	09/02/2026 (3 years, unless legislation or process changes)
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

1. Contents

2. Definitions of Terms Used / Glossary

CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
NNUH	Norfolk and Norwich University Hospital
PI	Principal Investigator
R&D	Research and Development
RIN	Research & Innovation Services, UEA
SSC	Sample size calculation
SOP	Standard Operating Procedure
TMF	Trial Master File
UEA	University of East Anglia

3. Objectives

To define procedures for Sample Size Calculations for clinical trials.

4. Scope

This SOP defines the procedure for the production of Sample Size Calculations (SSC) for clinical trials. Whilst the detailed procedure of this SOP relates to clinical trials, the principles of this SOP should be adopted for non-trials healthcare research by the member(s) of the research team with responsibility for statistical design and analysis.

5. Rules

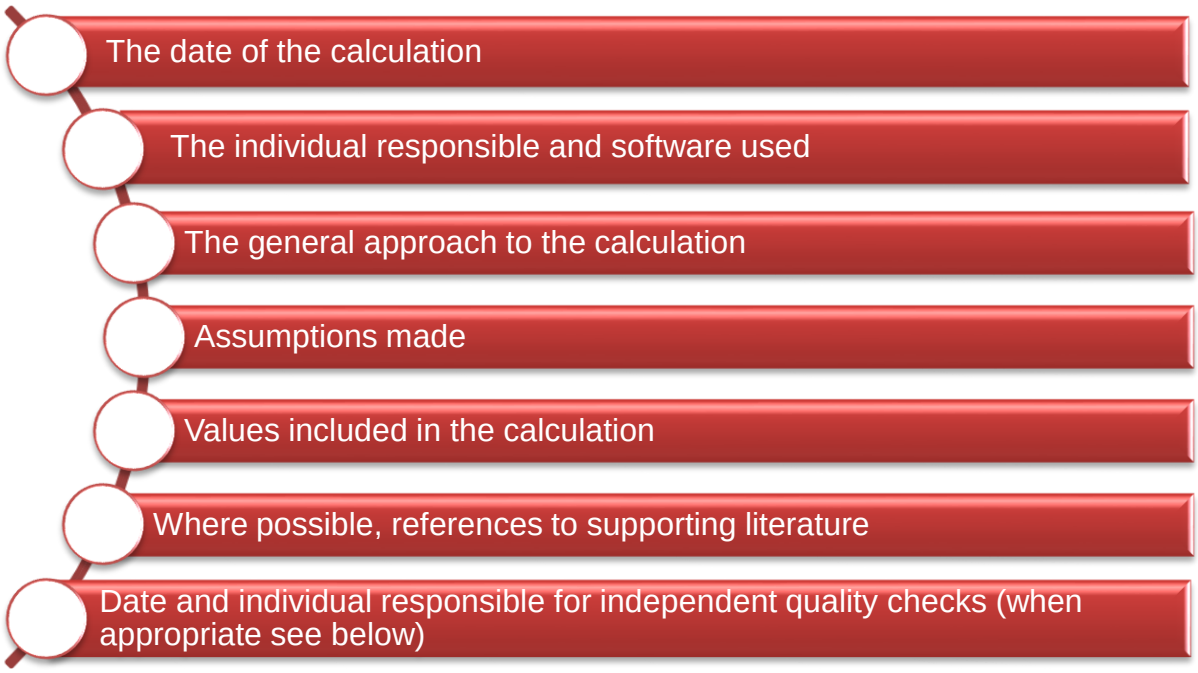
Sample size calculation (SSC)
• Should be carried out by an appropriately qualified individual, usually the nominated trial statistician, and using appropriate software. • Should be based upon information provided by the trial Chief Investigator and other members of the trial team.

6. Producing Sample Size Calculations

⇩	SSCs should be considered at a very early stage of clinical trial development. They are required for funding and governance applications and need to be justified in detail.
⇩	It is recognised that there are differing approaches to SSCs depending on trial types and objectives. Generally, an SSC will be based around a degree of precision in a parameter estimate, often involving the notion of statistical power and statistical significance (or, equivalently, Type I and Type II errors). However, for some studies, such as feasibility or pilot studies, such an approach will not be appropriate, but the sample size still needs to be justified on alternative grounds.
⇩	The basis of the SSC will often be the agreed primary efficacy end-point. Typically, a minimal clinically relevant effect will need to be agreed upon amongst the trial team. Ideally, there should be some justification that this is achievable. An estimate of between group variation will typically be required. The source for this needs to be documented.
⇩	Statistical errors (Type I and Type II) to be tolerated need to be stated and where 'not typical' should be justified. Typical values would be a 'two-sided' Type I error of 5% and Type II error of 20% or 10%, i.e., a Statistical Power of 80% or 90%.

7. Documentation of Sample Size Calculations

It is recognised that there may be a degree of iteration and different versions of SSCs should be documented. Refer to **SOP 865 Study Specific Research Documentation Management** for further guidance. Documentation for SSCs should clearly state:



8. Quality

When an application is being made for funding, a quality check on the SCC should be made prior to the submission for funding. When changes to the sample size are made e.g., as a result of peer review during the funding application, an additional quality check should be made.

9. References and Related Documents

References	
ICH GCP E6 / SI 2004/1041	
SOP No.	**SOP Title**
SOP 865	Study Specific Research Documentation Management

10. Approval

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Date	16 February 2023 | 2:04 GMT

11. Reason for new version and Training Implication

This SOP replaces the previous version number V1.4

Changes made	
Reason	• New template • Removal of '*prior to the submission for ethical approval'* after additional quality check (Section 8)
Training Implication	**No**
Actions required	• NA