SOP 320, Developing a Research Protocol

For Use in:	Research & Development
By:	All staff
For:	All staff involved in the conduct of research
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SOP 320 v2.2

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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SOP 320 Writing a Proposal and Developing a Research

1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CTA	Clinical Trials Agreement
CTIMP	Clinical Trial of an Investigational Medicinal Product
EU	European Union
GCP	Good Clinical Practice
HRA	Health Research Authority
NCTU	Norwich Clinical Trials Unit
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
R&D	Research and Development
SOP	Standard Operating Procedure
UEA	University of East Anglia

3. Scope

This SOP describes the process for writing health care research proposals and protocols by researchers at NCTU, UEA and NNUH

4. Introduction

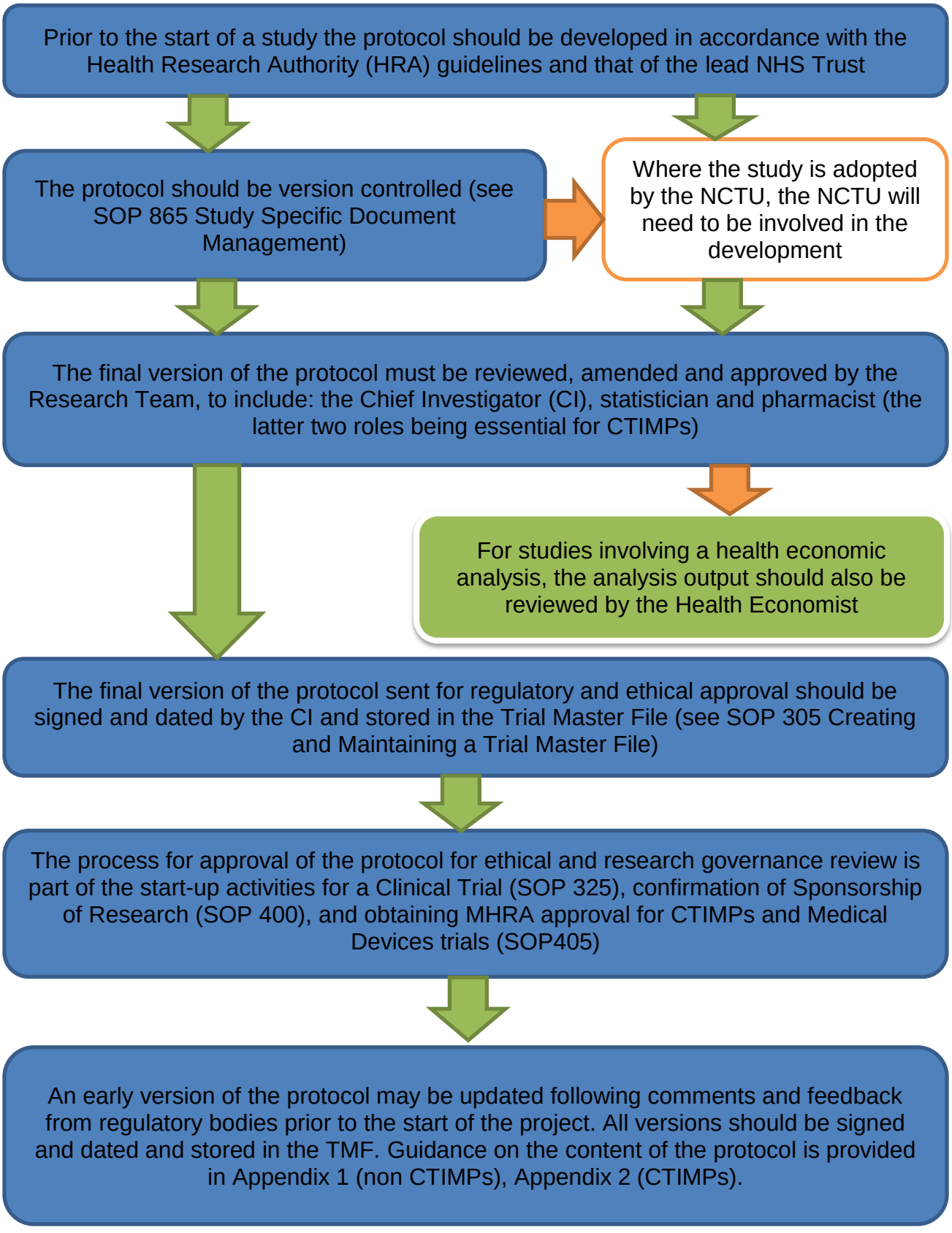
This process aims to ensure the research team has the correct guidance to enable production of protocols for research studies. Research is carefully designed to safeguard the health and safety of the participants in compliance with the conditions and principles of Good Clinical Practice (GCP) and the applicable EU guidelines and regulations.

5. Rules

A research protocol is an essential document which provides the research team with a plan for undertaking the study

- A protocol is a legal document that, once approved by regulatory and ethical bodies, all parties and organisations involved in the study agree to comply with
- Investigators should sign and date the signature page of the current protocol and organisations should refer to the protocol in their agreements about the study
- The protocol must be written by the Research Team prior to applying for any approval and prior to starting the study

6. Procedure for Research Protocol Development



The process for seeking approval for amendments to the research protocol is

Detailed in:

- SOP 215 (Research Study Amendments)
- SOP 405 (Obtaining and Maintaining Medicines and Healthcare Products Regulatory Approvals Agency (MHRA) Approval for a Clinical Trial).

7. Procedure for UEA and CTU

Procedure will be as defined in the local working practice documentation.

Where the CTU has delegated responsibility for developing the research protocol; the CTU research protocol template maybe used; with Sponsor approval.

8. Appendix 1 Guidance for protocol structure for non CTIMPs

Protocol Identification, code number, version numbers and dates, signatures

Protocol code number

- A protocol code number is unique for each study and required on each protocol
- The Sponsor must have input into the code used

Protocol version number and dates

- Allocate version numbers and dates for protocols during the drafting process
- The final protocol that is submitted to the ethics committee should be numbered as version 1.0 and dated with the date of finalisation
- If protocol amendments are made, the protocol version number and date must be updated

Protocol signature

- The protocol and amendments must be signed by the Sponsor
- Provide name and title of person(s) authorised to sign the protocol and a signature and date block

Protocol requirements:

a) Title:

The title clearly identifies the study and contains a brief description of the study design and objectives.

b) Investigators:

List everyone who has made a material contribution to the design of at least one component of the study.

Include name and contact details.

c) Abstract/Summary

Summarise the objectives of the study.

Give a brief outline of the design and methods.

d) Introduction

Outline the background to the research; include a critical review of the current knowledge or literature, including published and unpublished work in the area.

Gaps in the evidence should be identified; as should the potential value of furthering knowledge in this field, such as theoretical or practice based applications of the potential research outcomes.

An explanation of the reasons for undertaking the work should be included in this section, incorporating a reflective stance whereby the researcher/s reflect upon their reasons for undertaking the research and interest in the field.

e) Objectives:

Outline broad objectives that should follow on from the identified gaps in the literature and rationale for the study.

Stated objectives should allow for unexpected emergent findings to be incorporated as part of the research findings.

f) Study Design:

Provide summary of study design which will answer particular research question.

g) Location of study:

What is the location of the study and any specific tasks.

f) Participants:

Information regarding participants should be provided:

- Expected study population, including a rationale of why they are relevant to your research question(s).
- Methods by which participants will be identified and recruited and what criteria will be used for deciding whether or not individuals are eligible to participate.
- Expected sample size and justification.
- Nature of expected adverse events along with the reporting procedures that will be used.
- Assessment and follow up requirements
- End of the study schedule and requirements
- Consent process and relevant timelines
- Issues such as the potential transferability of results to alternative populations.

h) Sampling methods:

Sampling methods and justifications may be framed in terms of gaining access to particular populations, or in terms of fit with the research design.

i) Methods of data collection:

- What data will be collected
- Reason for data collection
- Method of collection
- Schedule for collection

j) Data Management & Analysis

- Method of data recording
- Collection
- Management and access
- Statistical Analysis Plan (SAP) including assumptions of analysis
- Data analysis package
- Reporting of data and statistical analysis results
- Electronic data capture, analysis and reporting

k) Study Administration & Ethical Issues

- Arrangements for the day-to-day management of the study.
- Methods by which the participants' interests will be safeguarded. For example; the process of risk limitation; how you will maintain confidentiality or anonymise participants' data and how you will deal with any apparent psychological harm
- State whether there has been user involvement in design of the study, and whether user involvement will be incorporated as an ongoing aspect of the research.
- State whether you have adhered to any set of ethical guidelines
- Any proposal should clearly state who is funding the research study and what interest they have in its outcome.
- Confirm the sponsorship arrangements for the study.

l) Resource Requirements:

- Resource implications to the host organisation
- Other departments
- Outline the timetable/schedule of the research and costs.

m) Study Plan:

A study plan or flow chart showing a brief summary of the order, site and timing of all procedures may be included.

n) Supervision for student projects:

The protocol should name any individual(s) who will supervise the research project and the intended arrangements for the supervision.

o) Dissemination & Outcome (SOP 340 Clinical Trial reporting):

Reporting of study findings:

- Publish or present the findings including any report of findings to the participants.
- Any implications for future practice and theoretical knowledge advancement should also be suggested.

p) Archiving of study records and data (SOP 900 Archiving, retrieval and destruction of Research Documents):

- Location of archive for principal location, vendor and site locations
- Period of archiving

9. Appendix 2 Requirements for a protocol structure for CTIMPs and/or Medical Device Trials and Further Guidance

The contents of a trial protocol for a CTIMP and/or Medical Device Trial should include the following information:

- General background information
- Trial objective and purpose
- Trial design
- Selection of sites/clinicians
- Selection and withdrawal of participants
- Randomisation and Unblinding
- Treatment of participants
- Assessments and Follow-Up (efficacy, safety and quality of life)
- Safety Reporting and Follow-Up
- Statistics
- Direct access to source data/documents
- Quality control and quality assurance (risk assessment, monitoring)
- Regulatory issues (Clinical Trials Agreement) CTA, ethics, consent, confidentiality, indemnity, sponsor, funding, audit & inspection))
- Data handling and record keeping
- Archiving location and period
- Trial Management
- Publication and reporting
- References
- Appendices

Protocol identification: code number, version number and dates, signatures

Protocol code number

- A code unique number is required on each protocol
- The protocol code number should be in place when the EudraCT number is issued
- Previous code numbers for other trials must not be used; e.g. trial acronym and year (MAG98) or the ISRCTN number

Protocol version number and dates

- Allocate a version number and version dates to protocols during the drafting process
- The final protocol that is submitted to the ethics committee should be numbered as version 1.0 and dated with the date of finalisation
- If protocol amendments are made, the protocol version number and date must be updated

Protocol signature

- The protocol and amendments must be signed by the Sponsor
- Provide name and title of person(s) authorised to sign the protocol and a signature and date block

a) Other General Information:

- Provide names & addresses of key study personnel
- Provide names & addresses of clinical laboratories, drug supply organizations and any other institutions involved in the trial.

b) Other guidance for good protocol development:

Include Risk Assessment for the study (SOP 700 Risk Assessment and SOP 725 Capacity, Capability and Risk Assessment).

c) Safety Reporting:

ICH GCP requires that both investigators and sponsors follow specific procedures when reporting adverse events/reactions in clinical trials involving

IMPs. These procedures should be described un-ambiguously in the safety section of the protocol and may require additional documents that should be referred to in this section e.g.:

- The trial safety management plan (SmPC)
- Reference Safety Information (RSI)
- The Sponsor is responsible for providing this information for this section.

See SOP 205 Adverse Events: Identifying, Recording and Reporting for CTIMPs and Device Trials.

d) Protocol amendments:

See SOP 215 Research Study Amendments.

10. Approval

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11. Reason for Update and Training Implication

This replaces SOP 320 v 2.1

Update	Reason	Training Implication	Action
Section 7 updated to clarify CTU and UEA process General update and reformatting	Response to regulatory inspection and new template update	Yes	Review SOP and update training matrix