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SOP 725 Capacity, Capability and Risk Assessment of Trials Hosted by NNUH

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Capacity, capability, risk assessment of trials
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Product
CTU	Clinical Trials Unit
HRA	Health Research Authority
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
PI	Principal Investigator
R&D	Research and Development
RGC	Research Governance Coordinator
RSM	Research Services Manager
RSO	Research Study Officer
SOP	Standard Operating Procedure
UEA	University of East Anglia

3. Objectives

To confirm the arrangements for risk assessments and capacity and capability assessments for hosted studies.

4. Scope

This SOP applies to all healthcare research hosted by NNUH, regardless of who the study sponsor is. External sponsors may require use of their own SOPs; this will be specified in site agreements. It is the responsibility of the local Principal Investigator (PI) to ensure that study-specific SOPs can be operated without conflict with this SOP and in accordance with all organisational polices related to research.

5. Introduction

When the Trust is hosting a study, a capacity, capability and risk assessment will be conducted to assess the Trust's capacity and capability to deliver on a study, in line with the Health Research Authority (HRA) approval process. Follow-up actions will be dependent on the outcome of the assessment.

The risk assessment is based on the Trust's capacity and capability to deliver on a study, identifying the potential hazards associated with the trial and an assessment of the likelihood of those hazards occurring and resulting in harm. Appropriate management/mitigation strategies should then be identified and implemented to bring any harm identified to within an acceptable limit.

The Medicines for Human Use (Clinical Trials) Regulations 2004 allow for risk-adapted approaches to the management of clinical trials of investigational medicinal products (CTIMPs). Norfolk and Norwich University Hospitals NHS Trust (NNUH) has adopted the risk-adaptive approach for the management of all studies it hosts, including CTIMPs, clinical investigations of medical devices and all other research.

6. Definition of Risk

Low Risk Likelihood

- Likely to be safe or without problem
- Documentation and relevant experience / training in place

Medium Risk Likelihood

- Concern of a possible effect on safety and/or possible problem arising, but evidence presented to address possible safety issues / problems
- Majority of essential documentation and training in place with evidence of a plan to acquire missing documentation / training in place

High Risk Likelihood

- Issues identified regarding safety and/or problems arising, with no evidence presented to address safety issues / problems
- Essential Documentation missing with no plan in place for acquiring documents. Evidence of relevant experience and/or training not demonstrated, or documented, with no plan in place to acquire necessary training / experience

7. Procedure NNUH

Which Assessment is required?

If it is unclear whether NNUH is the potential study Sponsor or Host, the Research Study Officer (RSO) should discuss with the RSM prior to conducting the assessment.

If NNUH is the Sponsor for a study, please refer to SOP 720 Risk Assessment of Trials Sponsored by NNUH or UEA.

If it is unclear what type of research is being undertaken (i.e. clinical trial) the RSO, Chief Investigator (CI), or Principal Investigator (PI) should seek confirmation by contacting the study Sponsor.

The RSO will co-ordinate the capacity, capability and risk assessment process (see Appendix 1).

Acceptable limits

- If any section is rated high risk, after mitigating factors have been taken into account, NNUH will not host the study
- The decision to host a study rated high risk will be re-evaluated by the Research Services Manager (RSM) or Research Governance Coordinator (RGC) once it has been demonstrated by the PI and / or Sponsor that appropriate mitigating factors has been implemented to reduce the likelihood of risk to at least a medium risk level

Completing the Capacity and Capability Assessment Workflows

The Capacity and Capability Assessment workflows on Edge have been created as a result of the HRA Approval process, and in line with current guidelines.

- The workflow can be updated by the RSO for the duration of the capacity and capability (C&C) assessment period. If the study is a CTIMP or clinical investigation of a medical device, additional workflows may need completing also.
- RSO to complete parts of the workflow prior to the initial feasibility meeting based on the study information available
- Early in the C&C assessment process, the RSO will meet with the PI, and members of the study team, to conduct the initial feasibility meeting. At the meeting the team should discuss any issues relating to the delivery of the study.
- After the meeting the RSO will document discussions in the C&C workflow and email notes from the meeting to the study team.
- Concerns arising from the initial feasibility meeting should be discussed with the study team, and when necessary the Sponsor, to see if they can be resolved. If issues cannot be resolved, and the study team

wishes to go ahead with the study, the RSO should discuss the concerns with the RSM or RGC so an appropriate course of action can be decided.

- Actions resulting from the feasibility meeting should be entered into the workflow and completed during study set-up.
- All associated documentation should be saved to the project folder on the R&D shared drive and document the C&C Assessment on Edge.

Capacity, Capability and Risk Assessment Review

For hosted and sponsored studies, capacity and capability to deliver the study will be reviewed whenever an amendment to the study is made (see SOP 215 Research Study Amendments).

The Risk Assessment for sponsored studies may be reviewed at any time during the study taking into account new knowledge and experience, and may include reconsiderations for the acceptable limit of risks. This may occur as a result of any of the following (this list is not exhaustive):

- Monitoring findings
- Inspection of audit findings
- Safety review
- Serious breach or non-compliance
- Change to protocol, resources, personnel, facilities or external service providers

The Risk Assessment review will be completed as per the initial assessment. It may not be necessary to revise all sections of the Risk Assessment attribute on Edge.

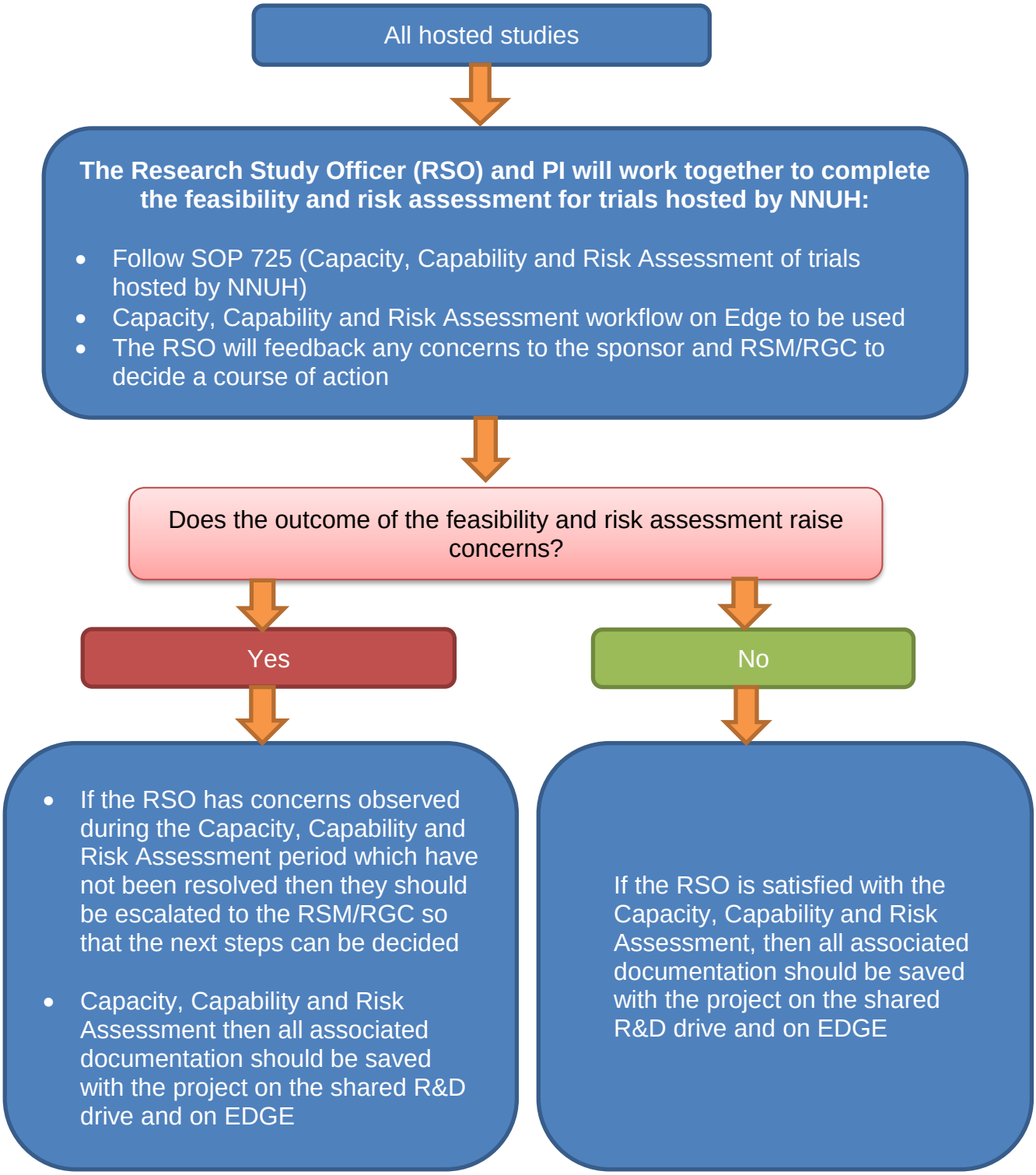
The RSO and / or RSM or RGC and the PI will agree which sections will be revised and whether a review meeting is required.

8. References and Related Documents

References
ICH GCP E6 / SI 2004/1041
Medicines for Human Use (Clinical Trials) Regulations 2004

SOP No.	SOP Title
SOP 215	Research Study Amendments
SOP 720	Risk Assessment of Trials Sponsored by NNUH or UEA.

9. Appendix 1: Flow chart of Responsibilities



10. Approval

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11. Reason for new version and Training Implication

This SOP replaces the previous version number V2

Changes made	What changes have been made to the contents of the document
Reason	• To add missing page information regarding C&C Workflow completion by R&D
Training Implication	**No**
Actions required	• NA