York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
SOP
R&D/S107

Delegation of tasks to a named person CTA Support and the role of the Clinical Trials Assistant (CTA)

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

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Author:	Mark Aldous & Mags Szewczyk
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Approved by:	Name/Position:	Cate Laven, Head of Clinical Research Delivery
	Date:	3rd September 2025
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	11th August 2025

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	14th July 2021		New SOP resulting from internal R&D restructure
2.0	16th September 2021		Addition of associate form – R&D/F125
3.0	6th September 2025	Jonathan Hawker	New process put in place. SOP update to reflect these changes

Contents

1 Introduction, Background and Purpose

This SOP outlines the updated process for delegating routine administrative tasks to Clinical Trials Assistants (CTAs) within York and Scarborough Teaching Hospitals NHS Foundation Trust. The aim is to streamline delegation of duties within the CTA Support Team, reduce administrative burden, and ensure efficient delivery of research support across all Care Groups.

CTAs operate as a single, coordinated team, in which each CTA is primarily assigned to a specific Research Care Group. Within these groups, CTAs work closely with Research Nurses, Research Practitioners, Research AHPs, Research Midwives and clinical teams to support a portfolio of studies led by Principal Investigators. CTAs provide administrative support throughout the full lifecycle of research projects—from expressions of interest and site selection through to study delivery, close-out, and archiving. They also provide flexible support across other Care Groups as needed, depending on workload demands. Their work is supervised by a Study Coordinator who oversees the CTAs weekly rota for staff cover, processing of modifications to research projects (amendments), research record maintenance (hard copy ISFs, Q drive, EDGE), and data quality between LPMS and CPMS systems.

2 Who Should Use This SOP

This SOP should be used by staff within York and Scarborough Teaching Hospitals NHS Foundation Trust who are involved in research studies and who have responsibility for ensuring that research staff delegated to provide CTA support for studies are appropriately qualified and trained to carry out their role.

The primary point of contact for enquiries and CTA support is:

CTA Coordinator

R&I Department, Learning and Research Centre,

York Hospital, Wigginton Road, York, YO31 8HE

CTASupport@york.nhs.uk or 01904 72 5867.

3 When this SOP Should be Used

This SOP applies to all research studies supported by the CTA Team and to staff responsible for delegating and overseeing CTA activities.
It should be referred to when new CTA staff are appointed, when a new research project begins, and/or when amendments have training implications.

4 Procedure(s)

4.1 Core CTA Tasks:

Core CTA tasks include:
- Filing documents
- Transcribing data from paper to electronic CRFs
- Scheduling meetings
- Email correspondence
- Maintaining Investigator Site Files (ISF)
- Updating EDGE and CPD systems
- Preparing recruitment packs
- Implementing amendments
- Supporting research delivery operations

These tasks:
- Do not involve clinical judgement or direct patient care
- Do not require study-specific decision-making
- Are covered by the CTA's standard job description and the R&I departments training & competencies framework for research delivery staff (including GCP training and internal SOPs)

Because these tasks are generic and non-clinical, any trained CTA can perform them across studies without needing to be individually named on each study's Delegation Log.

To ensure accountability and provide a clear point of contact, each study must have one named CTA listed on the Delegation Log. However, all other trained CTAs may support the study by performing core administrative tasks without needing to be individually named on the log.

4.2 Named CTA Oversight:

Each study must have a named CTA on the Delegation Log to ensure accountability, oversight, and a single point of contact for CTA-related queries. The CTA Team's line manager regularly reviews each team member's training needs and competency to ensure that core CTA duties can be appropriately delegated. Any study-specific training that extends beyond standard CTA responsibilities—but remains within the scope of administrative support—must be completed as required by the study sponsor on a study-by-study basis.

4.3 Delegation of Duties for CTAs:

The primary assigned CTA signs the study delegation log, which is authorised by the Principal Investigator (PI). Study-specific training is required only if tasks exceed standard CTA duties (e.g., direct data collection from patients' medical records, assisting in clinics). Such training must be documented before the CTA undertakes any study-specific responsibilities.

4.4 Documentation and Traceability:

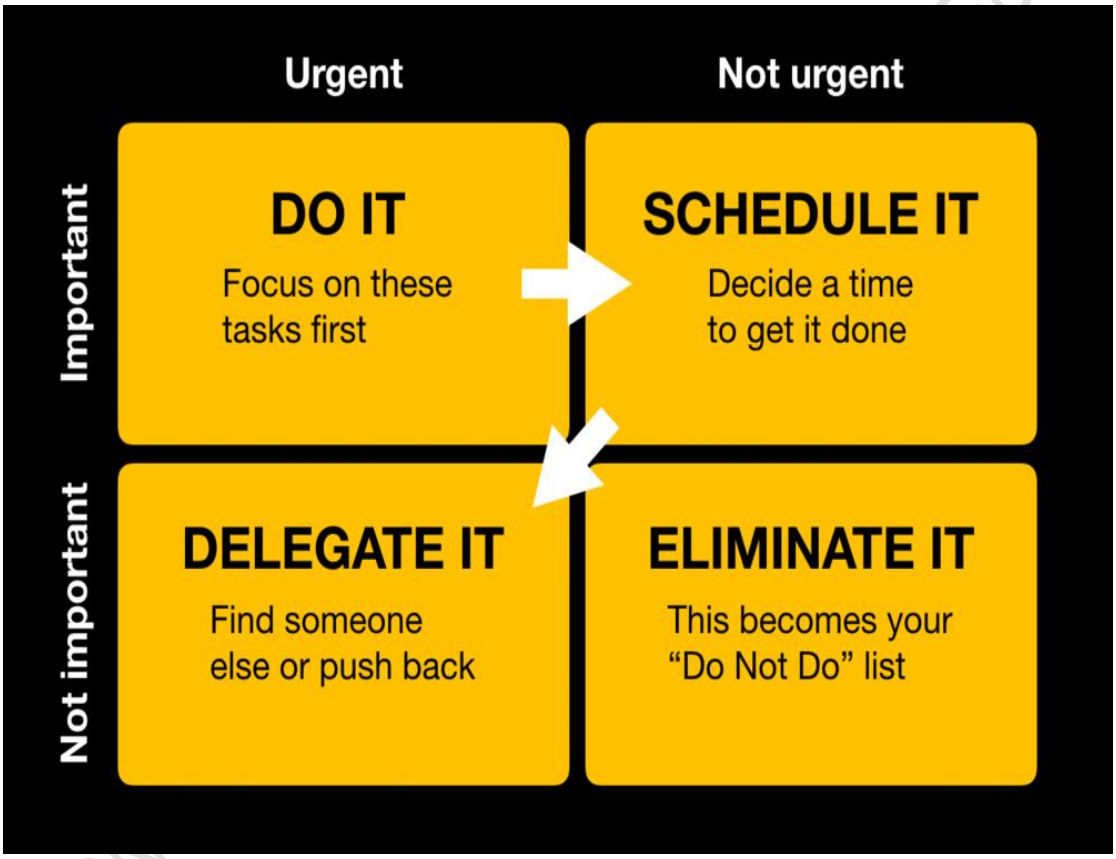
Delegated CTAs must sign the Delegation and Signature Log for studies within their portfolio of work. This ensures traceability and compliance with Good Clinical Practice (GCP) and regulatory requirements.

4.5 Flexible Team Working:

The CTA Support team operates as a flexible pool, responding to workload demands across Care Groups. CTAs are expected to manage their own caseloads, communicate regularly with their assigned Research Care Group team, and escalate capacity issues to the CTA Coordinator. This facilitates prioritisation and coordination of team resources.

5 Appendix A

Prioritising Workload - Time Management Matrix



Appendix B

Mastering Workflow