York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
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

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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Author:	Mark Aldous & Mags Szewczyk
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
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	Date:	19th August 2021
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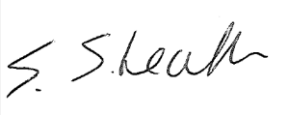
	Signature:	
	Date:	19th August 2021

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	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

Contents

1 Introduction, Background and Purpose

The main focus of the Clinical Trials Assistant (CTA) role is to provide a comprehensive administrative support for the R&D and research teams within the Trust. The role involves working closely with the CTA Coordinator and other CTA colleagues, with Research Nurses and study PIs, Support teams and all members of the multidisciplinary team to increase patient recruitment into clinical trials and to maintain holistic support for all research studies and R&D activities.

The CTA Coordinator and the CTA Support team will work flexibly within a pool of administrative support and across all Care Groups and Research teams providing support where/and when the clinical and service delivery needs arise.

To facilitate flexible support across all teams and specialities, and as per the MHRA GCP guidance, for larger teams/departments with team members working to the same job description, such as the CTA Support team, research activities will be delegated to a 'named person' who then takes responsibility for the conduct of that activity within the team. In the case of the CTA Support team, the CTA Coordinator will be responsible for assessing and determining the training requirements for individual trials in relation to the delegated tasks. For most members of the team the delegated study specific duties will not be different to their normal day to day duties as all CTA work is covered by the same job description and all CTA's receive the same induction training (GCP training and on the job training in core CTA duties), in addition to sponsor and Research Nurse lead study specific training.

For the majority of studies the typical CTA delegated tasks will consists of standard administrative support as outlined in the R&D Standard Operating Procedures. The standard CTA training must be documented and retained for the whole team (study training logs and individual training records as per the R&D SOP/S25).

The need for study specific training will have to be assessed by taking into consideration whether the study specific tasks differ from the typical CTA duties on different types of studies. This would be anything above the GCP training in record keeping (paper and electronic), implementation of amendments, administrative support for organising and tracking a patients journey on the study, reporting of deviations and adverse events to the study team and sponsor, study close out and archiving. These would be tasks such as study specific screening procedures, assisting in clinics, collecting IMP from pharmacy, blood taking and data collection directly from medical records/CPD where evaluation of results & medical entries is required.

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&D Unit, 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 should be referred to:

When new CTA staff are appointed.

When a new research project begins and delegation of duties is carried out.

When an amendment to an ongoing research project has training implications for CTA staff.

At annual appraisals of CTA staff.

4 Procedure(s)

4.1 Delegation of duties:

- For non-CTIMP research projects, including interventional studies - The CTA Coordinator signs the study delegation log which is to be authorised by the PI for all observational/data collection studies.

  If the CTA is delegated direct data collection from medical records/CPD (as opposed to data transcribing from paper CRFs to databases) or other research-intervention specific duties, a study specific training from the sponsor or/and the lead Research Nurse will be needed and will have to be documented prior to commencing any of the intervention related work.

- For CTIMP research projects - The CTA Coordinator signs the study delegation log which is to be authorised by the PI for CTIMPs or device studies for which CTA's are delegated the standard CTA tasks. For anything above these/for anything specific to the trial, study specific training from the sponsor or/and the lead Research Nurse will be needed and will have to be documented.

Once all training requirements are assessed and satisfied, the delegated CTA's will sign the R&D/F125 Delegation and Signature Log and the CTA Coordinator will authorise confirming full training and capability of carrying out the necessary CTA duties for the study.

Each study will have its own R&D/F125 which will be maintained and kept by the CTA Coordinator in the CTA Support office to ensure traceability and accountability of work completed.

This way the CTA Support team can flexibly provide the standard CTA support for any of the Trust research projects without delay and the need for individually signing the study sponsors' delegation logs.

Please always ensure that prior to any of the CTA colleagues commencing their work on your study, the CTA delegated duties are agreed and signed off by the CTA Coordinator on the sponsor's delegation log.

4.2 Flexible team working and the CTA service delivery:

The CTA Coordinator is responsible for coordinating all aspects of the day-to-day administrative duties within the CTA Support team including staff cover, problem solving, tracking and coordinating completion of delegated work. This is in addition to portfolio and quality related deliverables, such as providing regular reports on quality and progress, and working closely with the CTA team on forecasting incoming workloads based on the portfolio review meetings within each Care Group.

Clinical Trials Assistants are expected to manage their own administrative case-load while working as part of the multidisciplinary team, and report increasing demands to the CTA Coordinator via regular scanning of activities and close communication with their primary assigned Care Group's Research Nurses.

Due to variable demands for CTA support across Care Groups, the CTA Team will work flexibly across all projects according to the day-to-day requests and priorities.

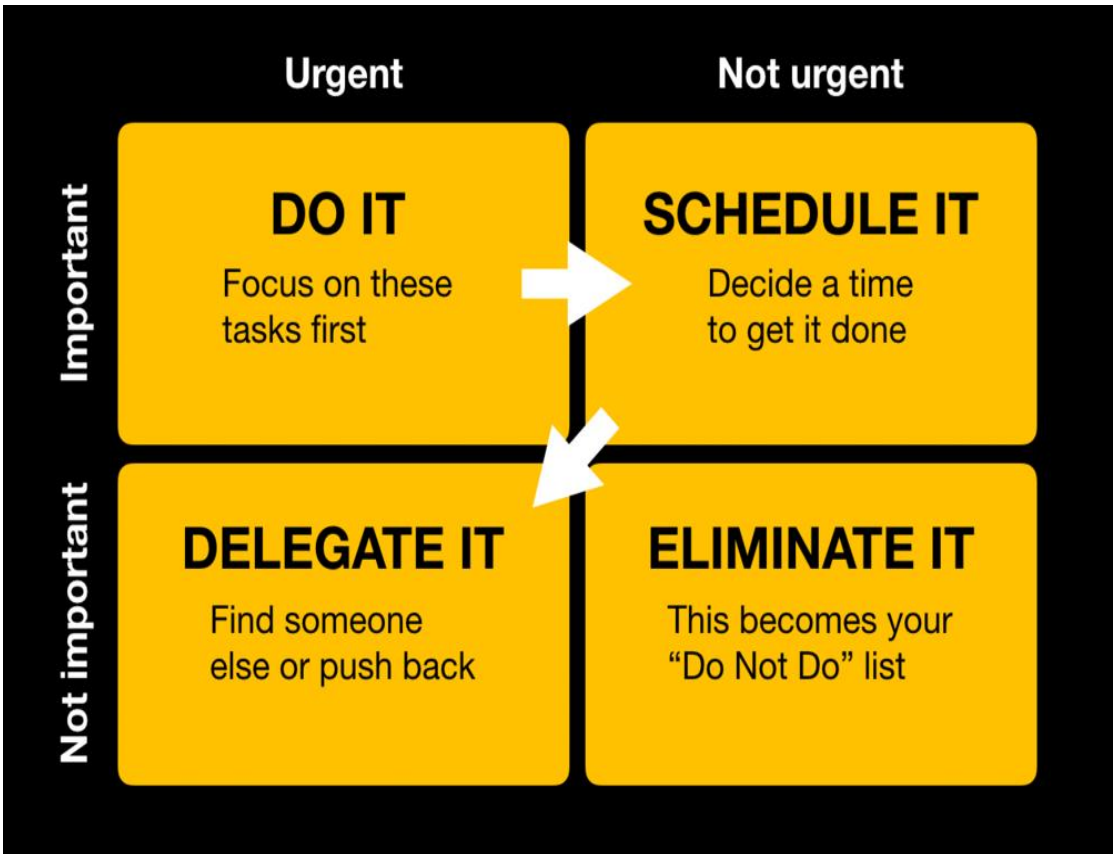
The following workload management tools are recommended for use (see section 6) to facilitate prioritisation and management of own and the team's administrative case-load.

5 Related SOPs and Documents

R&D/F125	Delegation and Signature Log - Delegation of tasks to a named person for CTAs

6 Appendix A

Prioritising Workload - Time Management Matrix



Appendix B

Mastering Workflow