Document Title: Signing off Clinical Competencies by Clinical Trial Coordinators

Document Number: R&D SOP094

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version Number	Modification:
1.0	**Document created**
2.0	**Amendments made throughout**

Key Points of this Document

This document sets out the procedures which all Clinical Trial Coordinators (CTCs) who sign off clinical competencies should follow.

It provides guidance on the requirements for CTCs to sign off clinical competencies to R&D staff at Royal Papworth Hospital.

1 Purpose and Contents

a. This document defines the Trust's procedure for suitably trained Clinical Trial Coordinators to be able to sign off competencies.

b. The document details the requirements for Clinical Trial Coordinators to assess competencies.

2 Roles & Responsibilities

a. This policy applies to clinical competencies that are conducted within the scope of practice of CTCs at the Trust.

b. Staff involved in signing off competencies must comply with the requirements set out in Section 4.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

a. The Trust's position is that singing off of competencies can be performed by trained and experienced members of the research team.

b. Trust competency documents are used to assess and sign off competencies.

c. For some competencies, staff whose clinical training included the competency i.e physiologist training, phlebotomists and those who can demonstrate and evidence they have these competencies, do not need additional training and may be trainers.

d. All training must be recorded/filed in the individual staff member's training folder on EDGE in accordance with SOP002.

e. In line with Trust policy, the individual staff member maintains accountability for their own competence and knowledge. It will be the individual's responsibility to highlight and arrange further training for any shortfall in training and competence. The individual will be expected to assess and arrange their own updates for the skill; any stipulated timelines for refreshers are set as a maximum timescale and do not preclude more frequent training as required.

4.1 Who can sign off clinical competencies?

f. Assessment of competence can be carried out by a Band 5 and above CTC, who has the relevant experience and has been trained and certified competent.

g. The R&D competency document lists the competencies and how the associated training may be accessed and assessed.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

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What key element(s) need(s) monitoring as per local approved policy/ procedure or guidance?	Who will lead on this aspect of monitoring? Name the lead and what is the role of the multidisciplinary team or others.	What tool will be used to monitor/check/ observe/assess/ inspect/ authenticate that everything is working according to this key element from the approved policy/ procedure?	How often is the need to monitor each element? How often is the need complete a report? How often is the need to share the report?	Who or what committee will the completed report goes to. How will each report be interrogated to identify the required actions and how thoroughly should this be documented in e.g. meeting minutes.	Which committee, department or lead will undertake subsequent recommendations and action planning for any or all deficiencies and recommendations within reasonable timeframes?	How will system or practice changes be implemented the lessons learned and how will these be shared?
Element to be monitored	**Lead**	**Tool**	**Frequency**	**Reporting arrangements**	**Acting on recommendations and Lead(s)**	**Change in practice and lessons to be shared**

			**Individualise the timeframe(s)*	**The lead or committee is expected to read and interrogate the report to identify deficiencies in the system and act upon them.*	**Required actions will be identified and completed in a specified timeframe.*	**Required changes to practice will be identified & actioned within a specific time frame. A lead member of the team will be identified to take each change forward. Lessons will be shared with all the relevant stakeholders.*

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Approval – this is required for all documents. Approval should be by the relevant committee(s)*. State the name(s) of the committee(s) and the full date(s) of the relevant meeting(s): *In exceptional circumstances only, approval can be by Chair's Action or by appropriate ED or NED – state full date of approval	
Approval date (*this version*) (Day, month, year):	Dd/mm/yyyy
Approval by Board of Directors or Committee of the Board **(required for Strategies and Policies only):**	
Date (Day, month, year):	Dd/mm/yyyy

This document supports: *standards and legislation – include exact details of any CQC.*	
Key associated documents:	
Counter Fraud In creating/revising this document, the contributors have considered and minimised any risks which might arise from it of fraud, theft, corruption or other illegal acts, and ensured that the document is robust enough to withstand evidential scrutiny in the event of a criminal investigation. Where appropriate, they have sought advice from the Trust's Local Counter Fraud Specialist (LCFS).	

Further Document Information

R&D SOP094 Signing off Clinical Competencies by CTCs

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018)
Key related documents:	Trust Research Policy Trust Policy DN1 Document Control Procedures

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	DATE

I certify the contents of this SOP has been reviewed and ratified

19-Jul-2023 DocuSigned by: Patrick Calvert 81A52758BFFF421...

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Signed by Dr Ian Smith, Clinical Director of R&D Date

SOP Release Date: …….