Papworth Hospital NHS
NHS Foundation Trust

Document Title: Change of Investigator

Document Number: PTUC SOP038

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Administration Manager, Clinical Project Managers
Document author/owner:	R&D Administration Manager
Directorate:	Research and Development
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For use by:	NHS Staff Trust-Wide
Review due:	October 2019

Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
	Minor administrative changes throughout

Key Points of this Document

- This document describes the procedure for changing either Principal or Chief Investigator and the subsequent regulatory approvals that are necessary for studies that are managed by Papworth Trials Unit Collaboration (PTUC), sponsored by Papworth NHS Foundation Trust or hosted by Papworth NHS Foundation Trust.

1 Purpose and Content

a. This document defines the Trust's procedures for changing either the Chief or Principal Investigator involved in research studies and clinical trials managed by Papworth Trials Unit Collaboration (PTUC), sponsored by Papworth NHS Foundation Trust or hosted by Papworth NHS Foundation Trust.

b. The document clarifies the situations when an Investigator may be changed and the regulatory and departmental approvals needed so as to meet the standards described in Good Clinical Practice (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

c. The document outlines the processes involved in changing Investigator including the submissions necessary for ethical, other regulatory agency and Trust approval.

2 Roles & Responsibilities

a. Staff involved in the process of changing the Investigator must comply with the requirements set out in section 4.

b. It is the responsibility of the Investigator to notify the Sponsor of their departure from their role as Chief or Principal Investigator.

c. For CTIMPs which are archived, in the event of a change of Chief Investigator (CI), the departing CI must notify the Sponsor.

d. It is the responsibility of the Sponsor (or their delegated representative) to appoint the incoming Investigator and to seek approval from any relevant third parties.

e. The nominated Investigator will require approval by the study Sponsor, R&D department and Clinical Directorate in which the study is taking place, before commencing their role.

3 Policy

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

4 Procedure

4.1 When to Change Investigators

a. When the Chief Investigator (CI) of a study changes employment, the Sponsor, in conjunction with PTUC (if appropriate), will decide on a study-by-study basis if a new CI needs to be appointed.

b. If the Principal Investigator (PI) leaves the employment of the hosting Trust they will stand down as the PI.

c. If a PI or CI is unable to continue to perform their study commitments due to unforeseen circumstances such as ill health then they will stand down.

d. The hosting Trust (or their delegated representative) may initiate a change of Investigator on a temporary or permanent basis. This change must be agreed by the study sponsors and PTUC informed if appropriate. Please note, PI duties may be assumed temporarily without further action where a Sub- or Co-Investigator has been signed off to do so on the delegation log.

e. A CI or PI must be changed if there is evidence of fraud or misconduct.

f. It is the responsibility of the departing Investigator and Senior R& D Managers (or their delegate) to have an agreement with the relevant Clinical Directorates that the research study falls into the nominated Investigator's area of expertise.

4.2 Process of Changing Investigator

a. The Investigator must notify a Senior R&D Manager and the Sponsor (if not Papworth) that they are leaving their post as soon as is possible so that alternative arrangements can be made.

b. For CTIMPs which are archived, in the event of a change of CI, the departing CI must notify the Sponsors. In this instance a person with responsibility for the archived data, until its scheduled destruction, must be appointed by the CI (and approved by the Sponsor) or, if necessary, be appointed by the Sponsor in conjunction with the R&D department.

c. The departing Investigator may nominate a substitute who will be approached subject to approval by the Sponsor, a Senior R&D manager and members of the relevant Clinical Directorates.

d. If no substitute Investigator is proposed by the departing Investigator then the Sponsor and a Senior R&D manager (in consultation with the relevant Clinical Directorates) will identify possible candidates.

e. The Sponsor will establish whether a substantial or minor amendment (CTIMP or non-CTIMP, respectively) is required, and if third party approval / acknowledgement are needed e.g. Ethics Board, MHRA, other regulatory agency or funding body, before any local approvals can be given (SOP 034: Trust Confirmation of Capability and Capacity to Conduct Research Studies).

f. The new Investigator should not assume any of the Investigator duties for the study until all approvals have been received. If required, sponsor approval can be sought for the duties to be assumed immediately.

g. Once fully approved, the Sponsor and Site file(s) and all other study information/documentation for the study must be updated and copies of the necessary regulatory approvals filed. For Papworth sponsored studies see SOP 010: Investigator File, SOP 013: Sponsor File, SOP 030: Delegation Log.

h. Before the new Investigator begins work on the study, a signed and dated CV and evidence of GCP training, should be provided (SOP 049: GCP Training).

i. The Investigator's readiness and requirement for any relevant training to undertake the study duties must be determined and organised by the study Sponsor. Where possible, a handover to the new Investigator by the departing Investigator should also be completed. A record of this should be filed in the study file e.g. file note.

j. The research governance database will be updated by R&D Governance and Administration with the new Investigator's details against the project together with a copy of the CV and GCP certificate.

k. For non-CTIMP archived studies which require a change in CI, the departing CI must appoint a person with responsibility for the archived data until its scheduled destruction. The Sponsor may take this responsibility if necessary. The appointed person must first be approved by the Sponsor and Trust Senior R&D Manager (or their delegate).

4.3 No suitable substitute Investigator

a. In the event a suitable substitute Investigator cannot be identified, the Senior R&D Manager or their delegate will convene a meeting with relevant parties to decide the appropriate course of action. The study may be suspended or closed out.

b. The decisions made and subsequent actions to be taken will be recorded in the study site file and reported as per section 4.2e.

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.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	[Current active version approved 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. Research Governance Framework for Health and Social Care (2005)
Key related documents:	Trust Research Policy [Insert list of linked or relevant documents to this SOP]

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							

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Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0				
2.0				
3.0				
4.0				

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

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

11th May 2017

Date

SOP release date: 15th May 2017