Exiting Staff Procedure

Research & Development

Standard Operating Procedure for Planned or Unplanned Staff Exits

SOP Number :SOP-35-02	**Effective Date:** October 2021
Version Number: v02	**Review Date:** 2-3 years

1.0 BACKGROUND

This document sets out the procedures to be followed by all West Hertfordshire Hospitals Trust (WHHT) staff involved in a research study at WHHT. In order to maintain continued support for participants and research support for research studies it is important that anyone who changes role, or discontinues working on a research study follows this Standard Operating Procedure (SOP).

2.0 PURPOSE

This SOP outlines the procedure to undertake when a staff member changes role or discontinues working on a research study.

3.0 APPLICABLE TO

Any Trust employee involved with clinical research sponsored by WHHT including, but not limited to, Unit Heads, Chief Investigators (CI), Principal Investigators (PI), Consultants, Co-investigators, Clinical Trial Pharmacists, Research Managers, Statisticians, Research nurses, Allied Health Professionals, Trial Coordinators, R&D Department, the Research & Development Steering Group (RDSG) & Data Managers.

4.0 RESPONSIBILITIES

For WHHT Sponsored Studies staff exits - The R&D office must be contacted and informed of the staff exit. In addition to this the appropriate process below should be followed (planned or unplanned).

Planned Staff Exit - The employee's line manager is responsible for ensuring the handover detailed below is undertaken. The CI/PI is responsible for ensuring the member of staff has been crossed through on the delegation log and it is counter signed. If it is the CI/PI that is leaving, the R&D Department will liaise with the Sponsor and identify a suitable replacement if possible.

Unplanned Staff Exit – The R&D Department will work with CI/PI/Sponsor to ensure continued safety of research participants and identify replacements.

5.0 PROCEDURE

Staff planning to leave the R&D department or Trust must follow the process set out in the Trust Leavers Policy. In addition the R&D process below must be followed.

5.1 Planned Staff Exit

When a member of staff plans to discontinue working on a research study because they are leaving the R&D Department or Trust they should complete the following tasks in an appropriate timeframe;

- Handover any research studies to a DI, providing a detailed schedule of recruitment processes and follow-up of participants
- Ensure they have signed off the delegation log and that the PI has countersigned their exit
- Inform the Data Manager so their research database access can be disabled

In addition if it is the PI planning on leaving the Trust the PI should inform the R&D Department as soon as practicable suggesting a suitable replacement. The R&D Department will then liaise with the proposed PI, trial centre and Clinical Research Network; North Thames (CRN: NT), as appropriate, to change the PI which will require an amendment (see SOP-09).

The PI, with the Lead Research Nurse/Team Leader, will ensure that anyone taking over this role has sufficient training to undertake the role and is delegated to do so.

5.2 Unplanned Staff Exit

Where a member of staff is suddenly unavailable and their expected unavailability is for more than three months (e.g. long term sickness, career break) the PI and the R&D Department may need to take urgent action to ensure the continued safety of research participants and the continued smooth running of the research study.

The PI will ensure the exiting staff member is off the delegation log, this may also require a file note to clarify events.

If it is the PI who is unexpectedly unavailable, a local collaborator will temporarily take on the PI's role to ensure continued safety of the research participants, the R&D Department will liaise with the trial centre and CRN: NT as appropriate to discuss long-term arrangements.

The PI, along with the Lead Research Nurse/Team Leader, will ensure that anyone taking over this role has sufficient training to undertake the role and is delegated to do so. (see SOP-08)

5.3 Change in roles

If a member of staff changes their role then sections 5.1 Planned Staff Exit or 5.2 Unplanned Staff Exit should be followed as appropriate.

6.0 RELATED DOCUMENTS

- SOP-07 - Research Staff Training
- SOP-08 - Role of CI, Pharmacy, Nuclear Medicine and R&D
- SOP-09 - Amendments
- WHHT Leavers Policy

7.0 APPENDICES

Appendix 1 - Definitions

8.0 REVISION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**
SOP-35-02	**October 2021**	1. Change from general Standard Operating Procedures (gSOP) to SOP 2. Removal of the '10.0 Agreement' from the template - all agreement signatures will be collated on a new 'SOP Signature Sheet Document' 3. Other minor amendments and clarification of terms following review
gSOP-35-01	**October 2017**	New SOP

9.0 AUTHORSHIP & APPROVAL

Author

Signature  **Date** 28/10/2021

R&D Steering Group Approval

Signature  **Date** 28/10/2021

Appendix 1: Definitions

Chief Investigator (CI)
A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the trial.

Clinical Trial
Any investigation in human subjects, other than a non-interventional trial intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products or to identify any adverse reactions to one or more such products and to study absorption, distribution metabolism and excretion in one or more such products with the object of ascertaining the safety or efficacy of those products.

Delegated Individual
An individual delegated by the PI to carry out their task(s).

Principal Investigator (PI)
A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.