

University of Hertfordshire

EXITING STAFF PROCEDURE

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for Planned or Unplanned Staff Exits

SOP Number: gSOP-35-01	Effective Date: 05 June 2018
Version Number: 1.0	Review Date: 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire standard operating procedure. University of Hertfordshire (UH) acknowledges West Hertfordshire Hospitals NHS Trust (WHHT) Research & Development (R&D) which has allowed UH to use the SOPs developed by WHHT where possible, modified for local implementation.

In order to maintain continued participant 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. PURPOSE

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

3. APPLICABLE TO

This applies to any UH employee involved with clinical research sponsored/co-sponsored by UH, including: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Coordinators, Clinical Studies Officers, Data Managers, Research Assistants and Students.

4. RESPONSIBILITIES

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 countersigned. If it is the CI/PI that is leaving, the CTSN will liaise with the Sponsor and identify a suitable replacement if possible. The Data Manager is responsible for disabling exiting staffs' access to the research database

Unplanned Staff Exit –

The CTSN will work with CI/PI/Sponsor to ensure continued safety of research participants and identify replacements. The Data Manager is responsible for disabling unplanned exiting staff from the research database

5. PROCEDURE

5.1 Planned Staff Exit

When a member of staff plans to discontinue working on a research study because they are leaving UH or the project they should complete the following tasks in an appropriate timeframe;

- Handover any research studies to a Delegated Individual (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 UH the PI should inform the CTSN as soon as practicable suggesting a suitable replacement, the CTSN will then liaise with the proposed PI, trial centre and Comprehensive Research Network as appropriate, to change the PI.

The PI, with the Site-Coordinator, 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 CTSN 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.

The Data Manager will temporarily disable the exiting staff member's access to the research database.

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 CTSN staff will liaise with the trial centre, R&D dept and CRN as appropriate to discuss long-term arrangements.

The PI with the Site-Coordinator will ensure that anyone taking over this role has sufficient training to undertake the role and is delegated to do so.

5.3 Change in staff 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. RELATED DOCUMENTS

- gSOP-07 - Research Staff Training
- gSOP-09 - Amendments

7. APPENDICES

- Appendix 1 - Definitions

8. VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

9. AUTHORSHIP & APPROVAL

Author

Signature

Date

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature

Date

10. AGREEMENT (MOVE ON TO SEPARATE SHEET BEFORE PRINTING)

Please detach and retain within your training files

I have read and understood the contents and requirements of this SOP (ref gSOP-035-01) and accept to follow University policies implementing it.

<p>Recipient</p> <p>Signature:Date:</p> <p>Name & Position:</p>
--

Please retain copy of the signed form for your reference in your training file

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.