


STANDARD OPERATING PROCEDURE

Employment of University of Sheffield Non-Medical Clinical Research Staff

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Date effective	01 July 2019	Author	Gail Mills
Related SOPs	SOP C132 Employment of STH Research Nurse and Non-Medical Research Delivery Staff		

Approved by (name & role)	Prof Simon Heller Director of R&D	Date	11 June 2019
Signature:			

Standard Operating Procedure

Employment of University Non-Medical Clinical Research Staff

This SOP has been produced in accordance with **Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments, and the UK Policy Framework for Health and Social Care Research 2017**. This SOP will outline the procedure for the recruitment and employment of Non-Medical Clinical Research Staff with a patient facing role via the University of Sheffield (the University) with an Honorary Contract with Sheffield Teaching Hospitals NHS Foundation Trust (STHFT).

Background

The UK Policy Framework for Health and Social Care Research 2017 requires all the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks. This includes ensuring that non-NHS staff employed in research posts hold an honorary NHS contract and that there is clear accountability for both research and clinical practice. Wherever possible, non-medical research staff, with a patient facing role should be employed through the STHFT. All proposed appointments to Non-Medical Clinical Research posts with a patient facing role should be discussed and agreed with the CRIO via the Lead Nurse R&D prior to commencing recruitment. In instances when non-medical research staff will be employed by the University of Sheffield to work on studies involving NHS staff, patients or premises, this SOP outlines how the employment of these individuals should be managed to ensure that it meets all relevant legislative requirements and the obligations of the Trust.

Definition

Non-medical research staff includes two groups of staff, these are registered health care professionals; i.e. research nurses, midwives, allied health professionals and non-registered health care professionals; i.e. clinical trials assistants, clinical trials coordinators, study site coordinators clinical support workers. This list is not exhaustive as other job titles may be used.

This SOP applies to all non-medical research staff whose role involves working in a patient facing capacity, full or part time, with investigators on research projects, regardless of funding source or Sponsor, within the Trust or University. Non-medical research staff are not in this case researchers or Principal Investigators.

Procedure

All investigators/directorates wishing to utilise the services of non-medical research staff employed via the University must do the following:

1. The investigator notifies the Trust Lead Nurse Research and Development (R&D) and the Nurse Director of the clinical speciality where non-medical research staff member will practice.
2. The investigator decides on the responsibilities and requirements of the post holder in relation to the study protocols the research programme and other research staff.
3. The investigator discusses the post with the Lead Nurse R&D and the post is matched to one of the Trust core job descriptions for non-medical research staff.
4. The Lead Nurse R&D will review the job description provided by the University of Sheffield HR Department to ensure it incorporates the roles and responsibilities relevant to the grade and requirements of the study.
5. The Investigator and the STH Research Accountant in collaboration with the Clinical Research and Innovation Office (CRIO) will confirm sufficient funding is available or will be secured to fund the post.

CONTROLLED DOCUMENT- DO NOT COPY

The Lead Nurse R&D, Investigator and Group Nurse Director decide whether to employ the non-medical research staff member via the Clinical Research Facilities (CRFs) (CRFs: NIHR Sheffield CRF at Northern General or Royal Hallamshire hospital sites, or Cancer Clinical Trials Centre (CCTC) within Weston Park Hospital.) or the Clinical Directorate.

6. The Lead Nurse R&D makes contact with the Trust Research Matron who will act as line manager for the non-medical research staff member as an Honorary Contract holder if they are not employed via the CRFs.
7. The University of Sheffield HR Department and STH Directorate set the timescale for the recruitment process and arrange the interview panel and venue.
8. The University of Sheffield HR Department will ensure the post is advertised via their usual mechanisms.
9. The Investigator and Lead Nurse R&D ensure the interview panel for the post is made up of the following personnel:
 - 9.1. Lead Nurse R&D or designate
 - 9.2. Principal Investigator
 - 9.3. Matron / Line Manager
 - 9.4. Network / project specific representative (if appropriate)
10. The recruiting team in liaison with the Lead Nurse R&D decide on the format of interview and whether the post warrants an assessment and / or oral presentation.
11. The recruitment team follow the recruitment procedure according to UoS Human Resources Policies.
12. The Trust Research Matron is notified of the new appointees start date.
13. The recruiting team when confirming a successful appointment must ensure that the following are in place:
 - 13.1. A period of induction arranged in the most relevant CRF and confirmed by the CRF Matron / Lead Nurse for CCTC.
 - 13.2. An honorary contract is applied for all non-substantive STH posts.
 - 13.3. Research Department registration form part one and two is completed in full and emailed to ResearchAdministration@sth.nhs.uk or sent to the Research Administrator, Clinical Research and Innovation Office, D floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF.

The Research Administrator updates the Research Department Database on receipt of the completed registration form.

Appendix 1 Documents Associated with the SOP

	Document	S-drive	Website	Database	Author/owner
1	Approval to Recruit form	S:\General\HR\SOPs\01 Recruitment	N/A	N/A	ES
2	Research Passport Application Form	S:\General\Research Governance\Research Passports_Research Passports	N/A	N/A	ZW
3	NHS to NHS Confirmation of Pre-engagement Check	S:\General\Research Governance\Research Passports_Research Passports	https://www.sheffieldclinicalresearch.org/for-researchers/useful-documents/forms-and-guidance/	N/A	ZW
4	Clinical Research Registration Form	S:\General\RNFR\Research Nurses\Registration	https://www.sheffieldclinicalresearch.org/for-researchers/research-nurses/	N/A	AD