



Sheffield Teaching Hospitals NHS Foundation Trust

Research Nurse Framework Strategy Document 2019-2022

June 2019

**PROUD
TO MAKE A
DIFFERENCE**
SHEFFIELD TEACHING HOSPITALS
NHS FOUNDATION TRUST



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1. Introduction

Clinical research is essential to the development of new and improved treatments and involves a wide range of research delivery staff. For the purpose of this document, 'Research Nurse' will relate to all **non-medical, clinical research delivery staff**, including research nurses, clinical trials assistants and midwives. STH NHS FT is currently ranked within the top 10 large teaching hospitals for research performance [1]; the Trust undertook over 450 studies in 2017/18, recruiting over 14,000 participants and the trend suggests these figures will continue to increase (Fig. 1).



Fig.1 - The number of research studies (top) and respective study participants (bottom) at STH NHS FT through 2014 - 2018 [1].

Clinical research has been one of the **fastest growing specialisms** in healthcare delivery; it was estimated that the number of Research Professional posts in the UK was approximately 10,000 in 2014 [2] and has continued to increase since. STH NHS FT is proud to host both the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Yorkshire and Humber (one of 15 CRNs across the UK) and the Sheffield Biomedical Research Centre (BRC) for Neurological Disorders (one of 20 National NIHR BRCs).

The BRC is based at the Royal Hallamshire Hospital (RHH) and BRC clinical activity is supported within the RHH NIHR Clinical Research Facility (CRF) for Experimental Medicine (EM). There are two other CRF's within STH NHS FT; the second site of the Sheffield NIHR CRF for EM is based at the Northern General Hospital (NGH) campus and the Cancer Clinical Trials Centre (CCTC), the third CRF, is based at Western Park Hospital. The CCTC is a member of the Experimental Cancer Medicine Network, funded by both the NIHR and Cancer Research UK.

An estimated 1500 - 2000 new patients are taking part in trials through the clinical research facilities at STH NHS FT each year, meaning the role of the Research Nurse in identifying, recruiting and retaining participants for clinical trials as well as conducting research activities has been key to the success of studies in Sheffield. Consequently, numerous opportunities are available for nurses to get involved in research [3].

2. Purpose

The Research Nurse Framework (RNF) was initially implemented in 2006, in conjunction with changes in research legislation and governance. This provided a framework for the management, training and education of the growing Research Professional workforce. The RNF is a model through which research can be embedded alongside routine clinical care through strategic collaborations within the clinical workforce across STH NHS FT and the wider NHS community.

In 2015, owing to the increase in research activity, the Clinical Research Office (CRO) was established. CRO was set up to provide a unified service for the stimulation, involvement, support, training, governance and costing of clinical and applied health research strategies across both the Trust and Faculty of Medicine, Dentistry and Health at the University of Sheffield (UoS). In 2017 the Clinical Research Office extended its remit to include Innovation to become the Clinical Research & Innovation Office (CRIO).

The RNF has been largely successful to date and has been responsible for the development of **5 core principles**:

1. Training and Education
2. Awareness of Research Activity
3. Roles and Responsibilities of Research Professionals
4. Governance
5. Performance (Metrics)

This framework provides an excellent foundation to build upon, allowing STH NHS FT to work with the NIHR to meet objectives including increasing the opportunities for patients and the public to participate in, and benefit from, research to accomplish their mission:

“To provide a health research system in which the NHS supports outstanding individuals working in world class facilities, conducting leading edge research focused on the needs of patients and the public”

- NIHR (2018)

In addition, the RNF aims to work with the ‘Keep Making a Difference’ campaign in association with the ‘Clinical Research Nurse Strategy 2017-2020’ to:

- Improve awareness and understanding of the specialty of clinical research nursing
- Develop leaders to share best clinical research nursing practice
- Promote innovation in research delivery practice
- Create a patient and public focussed clinical research culture

3. Core Principles

a. Training and Education

Gaining experience within research can not only be an academically stimulating career choice but can also provide opportunities to work in different clinical settings, to make a real difference to future patient care, to undertake local research specific training programmes and to obtain nationally recognised qualifications such as a Master’s degree or PhD through the ‘ICA HEE/NIHR Integrated Clinical Academic (ICA) Programme for non-medical healthcare professions’.

Five levels of the **ICA Programme Award** are available, with each requiring the support of clinical and academic host organisations, which together form a career pathway for aspiring and developing non-medical clinical academics:

- Internships
- Pre-doctoral Clinical Academic Fellowship
- Clinical Doctoral Research Fellowship
- Clinical Lectureship
- Senior Clinical Lectureship

Doctoral and Post-doctoral award holders are also eligible for ICA Programme-funded mentorship support through the ‘ICA Mentorship and Outreach Programme’. The scheme’s

mentors are recognised senior healthcare researchers and professional leaders, able to provide essential and unique sector knowledge and understanding of the leadership challenges that face clinical academic researchers from the non-medical healthcare professions.

Moreover, STH NHS FT and the University of Sheffield collaborate to provide the Clinical Research Academy (CRA). The CRA enables clinical NHS staff from STH NHS FT and Sheffield Health and Social Care Trust with an interest in becoming research leaders in their field to be released from clinical duties for one day per week. This includes a 'ring-fenced' award for nurses and/or professions allied to medicine. The award holders work in the School of Health and Related Research (SchARR) or other university schools to develop research grants with input from Sheffield Clinical Trials Research Unit and Yorkshire & Humber Research Design Service.

In line with the aim of offering a wide range of shadowing opportunities in the NIHR Clinical Research Nurse Strategy 2017-2020, a number of secondments, placements and shadowing opportunities are currently available at STH NHS FT through the CRFs for any nurses considering a career as a Research Professional.

An understanding and recognition of the complexity of a research role is reflected in a robust and thorough induction process that supports new starters to comply with research governance and introduces them to the core themes in research.

Previously, it was proposed that a rolling secondment programme for Band 5 nurses would be developed, whereby nurses can gain research experience over a 6-12 month period by assisting on low risk large observational studies. Although this programme is not yet underway, future plans are to include allied health professionals and appropriate trials delivery staff (e.g. clinical trials assistants) as per the STH Trust Research Strategy 2018-2020.

In addition, various local training opportunities are available for Research Nurses through CRIO, with topics such as:

- Good Clinical Practice (GCP)
- Statistics Advice
- Human Tissue Act
- Informed Consent

CRIO also offer a '**Clinical Research Training Programme for Research Professionals**'. This programme is held every year over 6 days (one day a month) and encompasses all relevant information to a career in research from research governance, funding opportunities, public engagement and different career pathways.

b. Awareness of Research Activity

Public and patient involvement and engagement (PPIE) in research is imperative to the development of novel treatments and understanding of medical conditions through the successful development and completion of clinical trials.

The 'Public Involvement Standards Development Partnership' has developed a group of 10 test bed projects, which will be testing the standards over the course of 12 months, from April 2018 to April 2019. The CRIO at STH NHS FT have been selected to test the '**communications**' standard and aim to achieve:

- Outstanding and meaningful PPIE activities throughout the research cycle across all research activities.
- To ensure there is diversity of representation
- Increased visibility of opportunities to be involved.
- Long lasting relationships between researchers and PPIE panels, where two-way feedback is crucial

STH NHS FT currently holds **18 patient panels** that meet regularly to discuss and inform research proposals [3]. These panels are made up of men and women who have an interest in research within the specific disease areas and thus volunteer to support the work of STH NHS FT and UoS; these panels are often composed of retirees, so STH aim to increase the diversity of representation through recruiting students within the local area.

Research proposals are presented to the PPIE panels to ensure that studies are feasible, as well as suitable and manageable for patients. The PPIE panel then advises researchers on information to give to patients and how to explain complicated research procedures in lay language. As research studies are successfully completed, the PPIE panel can also help write up research studies so findings can be disseminated to patients and the public [4].

Even with over 14,000 people participating in studies at STH NHS FT in 2017/18 [1], the trust aims to continue to enhance recruitment numbers through improving the awareness of available trials and dispelling the misconceptions around clinical research activity.

In order to meet these aims, STH NHS FT developed the role of a **Research Champion** whose roles and responsibilities include:

- Disseminating information regarding active research projects in their clinical area
- Acting as the link between the Research Nurse and clinical area to promote engagement in research and embedding into clinical care.
- Encouraging the discussion of research activity at ward/clinical meetings

- Where appropriate, assisting in identifying patients who may be eligible to take part in a clinical trial
- Attending research cafés to provide an informal environment to discuss research activity

Any individual in a clinical role within the Trust who is willing to dedicate time to clinical research within their area of work can be a research champion. A comprehensive description of the current role and responsibilities of a research champion can be found in Appendix A.

Over 50 % of participants in a recent survey of STH research staff indicated that they were unaware of the research champion role, with over 80 % indicating they did not know what research cafés entailed. This is an indicator that individuals outside of the research remit are likely to know little about the research champion role.

Therefore, the short term objectives for STH NHS FT are to:

- Increase the recognition and understanding of opportunities for STH staff to get involved in research
- Provide each directorate with relevant national and global awareness events and utilise these to action an impetus for raising research engagement and involvement.
- Provide clinical staff with information regarding current clinical trials, patient eligibility and relevant contacts

c. Roles and Responsibilities of Research Nurses

At STH NHS FT, there are **3 routes of employment** for Research Nurses:

- Directly within the 3 Sheffield NIHR CRFs
- Through the directorates of STH supporting disease specific research
- Through the UoS, primarily based at the Sheffield Institute for Translational Neuroscience (SiTraN)

Currently, there are parallel lines of management for each of these employment routes (see Appendix B). However, all Research Professionals whether employed on NHS contracts or working in the Trust via Research Honorary Contracts or Letters of Access have professional responsibility to the Lead Nurse for Research and Development.

There are a range of roles and responsibilities for those contributing to research delivery and management, from opportunities for Clinical Trials Assistants, Agenda for Change band 5 staff nurses interested in gaining experience in clinical research, through to senior Research

Nurse positions who are responsible for providing clinical leadership for the effective management of ongoing trials and introduction of new initiatives.

A Research Nurses job is complex, varied and interesting. Although the Principal Investigator has ultimate responsibility for any study, it is often the Research Nurse who coordinates its day-to-day management. This means leadership and organisational skills are vital, as well as the ability to be flexible and adaptable. Research Nurses may work alone, particularly if placed within the directorates, meaning that individuals must also be able to prioritise and make decisions [5].

The many duties of a Research Nurse include:

- Preparing trial-related documentation
- Submitting study proposals for regulatory approval
- Co-ordinating the initiation, management and completion of the research
- Ensuring patients give fully informed consent. Facilitating the informed consent process
- Being a patient advocate and ensuring participant well-being and safety throughout the clinical trial
- The randomisation of enrolled patients and collecting/recording research data.
- Prompt reporting of adverse events

For Research Nurses working within the directorates, a Directorate Team Research Forum is held quarterly. This provides an informal environment for best practice sharing and where information about upcoming trials and awareness events can be disseminated, as well as providing the opportunity to ask research related questions or access training.

d. Governance

The Health Research Authority and the UK Health Departments are committed to developing safer, more efficient or more effective treatments, care or other services through ethically and scientifically sound research. To do so, it is imperative that projects are properly registered, all research activities are recorded and that the data collected can be made available for future analysis, with adequate consent and privacy safeguards in place.

As previously mentioned, there are 3 different routes of employment for Research Professionals at STH NHS FT. Nurses who hold a substantive contract at STH NHS FT are automatically eligible to get involved in research, provided GCP and informed consent

training have been completed. For Research Nurses who are employed via a Higher Education Institute such as Sheffield Hallam University (SHU) or UoS, a research passport is required. This consists of either an Honorary Research Contract or Letter of Access, depending on whether there is foreseeable impact on patient care pathways and the requirement for NHS indemnity.

All research delivery staff are required to register with CRIO to be recorded on to a central database to ensure all Research Nurses are adequately trained for their role and have adequate clinical and nursing support with oversight. The information on this database that will be recorded and maintained includes:

- Contract type and date of expiry (where applicable)
- Research passport information such as issue / expiry dates and assigned projects (where applicable)
- CVs
- GCP training certificates and expiry dates
- Supervision and line management arrangements

e. Performance

As of Quarter 1 2018-19, improvement in clinical trial performance and reducing site set up and participant recruitment time will no longer be assessed with a 70 day benchmark. A renewed focus will be placed on transparency, accuracy, and meeting sponsor expectations [6] with more emphasis on Recruitment to Time and Target at site and the study as a whole. The minimum data set required for participants has been updated to reflect this change and can be found at: <https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm>

Research Nurses are often responsible for recording patient data and dates relating to consent and recruitment. At STH NHS FT, there are 2 different methods for recording this information:

- CRF Manager
- EDGE

EDGE is an online trial database, where information such as project approval dates and recruitment are maintained and relayed to the NIHR.

CRF Manager is a bespoke database, for use in CRFs and its use is a requirement of the NIHR CRFs for experimental medicine.

Metrics are used to help monitor and manage performance of both individual NHS providers and of the NIHR CRN as a whole. The CRN reports on initiation and delivery, at network level, of all research within the NIHR portfolio. NHS Trusts with NIHR contracts report their own site-level performance at initiating and delivering clinical trials, whether or not the trials are in the NIHR portfolio.

4. Future Targets

In line with the 'Making it personal' Strategy report 2017-2022, STH NHS FT aims to extend current research roles and develop new positions to increase staff, patient and public understanding and involvement of research. This would subsequently encourage a culture that allows research to flourish, and allow rapid improvements and insights into future therapies to benefit the population on the whole.

To do this, several key targets have been developed:

- To strengthen partnerships primarily with SHU and UoS, but also with other NHS trusts and higher education institutes nationally.
- Help staff increase knowledge, training and understanding of different roles and teams at STH NHS FT.
- Design an Internal Development Framework to which staff can easily identify career progression opportunities within the Trust.

5. References

[1] NIHR (2018). NHS Research Activity League Table. <https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/league-tables/>

[2] Royal College of Nursing (2018). Clinical Research Nurses. <https://www.rcn.org.uk/professional-development/research-and-innovation/research-training-and-careers/clinical-research-nurses>

[3] Clinical Research & Innovation Office, STH NHS FT (2018). Research Strategy 2018-2020.

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[4] STH NHS FT (2018). Cardiovascular Research Patient Panel.

<https://www.sheffieldclinicalresearch.org/about/our-directorates/cardiology/patient-panel/>

[5] Pick, A et al. (2010) Getting started in clinical research: the role of the research nurse. *Nursing Times*; 107: online edition, 26 April 2011

[6] NIHR (2018) HRA Approvals and NIHR Metrics. <https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm>

6. Appendices

Appendix A

Clinical Research Champion Role Description and Responsibilities

Purpose

The Clinical Research Champion role is an opportunity for clinical staff with a passion for research to contribute to creating an environment which promotes engagement in research. This role is a key link between the research team, clinical staff and all service users and as such will be a vital support in meeting the overall aim to embed research and innovation alongside clinical care (STH 2012, Department of Health 2012). As an advocate for good practice this role will promote patient choice to be involved in research, working closely with the research team to share knowledge and information pertaining to current studies.

Background

The champion will act as a resource, encouraging staff engagement and increasing the profile of research in their clinical area. This role will make a significant contribution to meeting national, trust and your personal objectives through appraisal and NMC revalidation. Sheffield Teaching Hospitals aims to become one of the top R&D performers in England and Clinical Research is core business for the NHS and is part of the NHS constitution:

“The NHS aspires to the highest standards of excellence and professionalism...and through its commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population.”

- NHS Constitution for England (2015)

Research is identified in the Five Year Forward View (2014) as having a key part in narrowing unwarranted variation with aims of achieving better outcomes, better experiences and better use of resources. The nursing response to this is set out in Leading Change Adding Value (2016) as one of the 10 commitments that **“we will lead and drive research to evidence the impact of what we do”**.

Requirements for the role:

1. Have agreement from line manager to undertake the role
2. Have an interest in gaining knowledge about clinical research
3. Be willing to dedicate time to clinical research within your area of work

4. Have an understanding of the trusts research agenda and the wider context of research for the NHS
5. Have good communication skills and be able to cascade and share information/updates related to clinical research with colleagues
6. Be able to work with Clinical Research Nurses to assist in promoting clinical research within your own area
7. Have a passion for ensuring good practice in being an advocate for patient choice

Responsibilities of the role:

1. Be willing to attend Good Clinical Practice training and keep this up to date
2. Be willing to keep up to date knowledge of current active studies and with changes in clinical research for their area, by meeting regularly with a member of the CRF delivery team. There will be opportunities for shadowing in the CRF (1 shift per year).
3. To help create a clinical research environment by promoting, motivating and encouraging a culture which is research active
4. To support and contribute to Research Cafes in your area
5. To liaise with research staff to aid identification and recruitment of patients into clinical trials
6. To actively promote involvement in research to all service users
7. To act as a resource and be a point of contact for staff queries around active studies in their area
8. Where agreed, participate in clinical research under the supervision of the research nurse/midwife (activities must be outlined in the delegation log)

You are required to liaise with:

- Patients, service users & their families
- Research Nurses/Midwife/AHP
- Clinical Research Champion Representative
- Research Matron and Lead Nurse for R&D
- Principal Investigators
- Colleagues in own clinical work area and speciality

Appendix B

The management structure for research delivery staff at STH NHS FT.

Solid arrows depict direct line management, whereas dotted lines represent oversight only.

