Research Strategy 2014

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1. Introduction

Research is essential to generate new knowledge for the benefit of patients, the modernisation and promotion of services in the NHS and the development of evidence-based patient care. The first responsibility of the Department of Research and Innovation (R&I) is the provision of an excellent research support service.

In recent years there have been dramatic and systematic changes in the structure and funding of research in the NHS. Best Research for Best Health (2006) established the National Institute of Heath Research (NIHR) to provide and manage a framework for the coordinated investment in new research capacity in the NHS. At the core of this initiative was the creation of a stratified system of research networks, the comprehensive local research networks (CLRNs), to provide infrastructure support for high quality clinical research throughout the NHS. The Cooksey Review of UK Heath Research Funding (2006) identified a translational gap in the national capacity to implement new products and approaches in clinical practice, which led to the Collaborations for Leadership in Applied Health Research and Care (CLAHRC). The 2010 White Paper 'Liberating the NHS' and the 2012 Health and Social Care Act have reaffirmed the commitment of the Government to supporting health research. There is now a duty on the Secretary of State to promote research in the NHS and there is also a duty on the new Clinical Commissioning Groups (CCGs) to demonstrate their commitment to facilitating research.

A new Health Research Authority (HRA) has been formed as a result of the 2012 Act, with a remit to protect and promote the interests of patients and the public in health research. From now onwards, NHS organisations in receipt of NIHR funding will have to demonstrate that they play their part in a national system of research governance requiring timely initiation and delivery of clinical trials. To facilitate this, a Research Support Services Framework has been adopted and guidelines have been issued to all NHS R&D Departments.

Against this background, the Department of R&I has had to adapt rapidly to the new research landscape, and the purpose of this document is to set out a new 5-year Research and Innovation strategy for Sherwood Forest Hospitals NHS Foundation Trust. The Trust must demonstrate increased levels of research activity to justify the continuation of CLRN funding and the continued engagement of Directorate management teams. Maintaining and increasing the research culture benefits the reputation of the Trust in terms of quality and innovation and ensures that the Trust can attract and retain highly qualified and committed healthcare professionals. This strategy encompasses the Trust's commitment to providing first class services by developing and supporting a culture of research excellence through observing the requirements set out in legislation and NHS policy

2. Operational capacity and infrastructure

Our goals for the next five years are:
- Supporting and developing research-active staff
- Exploiting opportunities to attract and retain research funding
- Promoting and increasing engagement in research
- Providing well-managed and effective research facilities, research resource and administrative support

Sherwood Forest Hospitals NHS Foundation Trust will ensure that there is sufficient staff infrastructure in place to allow all the principles of research governance to be implemented and adhered to at all times. Operational duties, including but not limited to governance matters, internal and external collaborations, funding opportunities, research promotion, and patient and public involvement will be the responsibility of a dedicated Research Manager.

The annual CLRN funding allocation provides research nursing staff specifically for the purposes of facilitating and undertaking NIHR portfolio studies within the Trust. One condition of funding these posts is that they work solely on NIHR portfolio studies, and cannot work on other research projects within the Trust. Sherwood Forest Hospitals NHS Foundation Trust will therefore ensure appropriate nursing infrastructure within the Research and Innovation department to allow support to be given to non-NIHR studies.

Sherwood Forest Hospitals NHS Foundation Trust will provide appropriate accommodation, equipment, and facilities to allow the proper conduct of approved research within the Trust.

The Trust is aiming to further develop its culture for innovation, identifying ways in which innovation and innovative practice can be nurtured, supported and facilitated. A Healthcare Science Innovation Forum has been established, led by Richard Scott and Ian Hall.

Proposals for supporting innovation have been developed through the Innovation Forum and included within the draft SFHFT Transformation Strategy, these include:
- Production of a SFHFT innovation report to showcase our innovative practice and convey a positive message to the rest of the organisation about our 'culture for innovation'
- SFHFT library to use the old TIN website to create a local research and innovation portal
- Establish an innovation fund that staff/ teams can apply to for innovative ideas and improvements
- Set up training sessions for staff and teams on innovation using the NHS Institute for Innovation and Improvement's "Thinking Differently" material

- Produce an options paper for testing the concept of innovation scouts, who have set time to scan the external environment and the literature, for research and innovation funding sources and for innovations that could be adopted or adapted by SFHFT teams
- Continue to bid for known research and innovation funds, providing support to teams as required with their bids

3. Governance structures

The Research Governance Framework applies to everyone involved in research in a health and social care setting and includes: clinical research; non clinical research; any research undertaken by NHS staff using NHS resources. All staff, partners and associates have a role to play in the proper conduct of research undertaken by the Trust.

It is a statutory requirement that all research involving NHS patients, staff or resources must be assessed by an appropriate research ethics committee.

To comply with the requirements of the Research Governance Framework the Sherwood Forest Hospitals NHS Foundation Trust, through the R&I department, must formally approve all research activities in which it participates. Accountability for all research activity resides with the Medical Director.

All governance matters arising will be reviewed by the Research Governance Committee, or if a more urgent response is required, by its operational sub-committee (R&I Director, R&I Manager, Research Nurse Team Leader).

To facilitate the research governance agenda, all research project proposals must be registered with the Research and Innovation Department and undergo rigorous governance review. A database recording all research and development projects is maintained in order to: ensure all appropriate documentation is completed prior to submission for governance review; to prevent duplication of studies; to log the progress of projects for the provision of updated information to the Research Governance Committee.

Departments and individuals who receive funding for research activity through the CLRN or directly from the Trust will be required to agree to and adhere to a number of key performance indicators against which they will be assessed in order to determine whether they are receiving an appropriate level of funding. These include, but are not limited to, satisfactory recruitment to trials against recruitment targets; active promotion of research within departments and/or divisions; appropriate engagement with the R&D department; adherence to the highest standards of research governance. Exact details of individual and departmental KPIs can be requested through the Research Governance Committee.

4. Delivery systems

The challenges are to continue to develop the culture of research activity within the Trust whilst ensuring that robust governance arrangements remain in place to protect patients and assist researchers. The Trust must demonstrate increased levels of research activity to justify the continuation of CLRN funding and the continued engagement of Directorate management teams. Maintaining and increasing the research culture benefits the reputation of the Trust and ensures that the Trust can attract and retain highly qualified and committed healthcare professionals.

The Sherwood Forest Hospitals NHS Foundation Trust Research and Innovation Department will have systems in place to ensure that Trust staff understand and follow the standards and good practice set out in this policy document and the Research Governance Framework (Department of Health, 2003).

As a research sponsor, the Sherwood Forest Hospitals NHS Foundation Trust Research and Innovation Department will have systems in place to undertake expert independent review to satisfy itself on the scientific and ethical standing of the work, its strategic relevance and value for money. The Sherwood Forest Hospitals NHS Foundation Trust Research and Innovation Department will also ensure that systems are in place to ensure that all of the research it sponsors is conducted according to the agreed protocol, to monitor its general progress and to discuss and agree modifications to the protocol if the need arises.

The Sherwood Forest Hospitals NHS Foundation Trust Research and Innovation Department will have systems in place to ensure that it is aware of, and has given permission for, all research being conducted in or through the Sherwood Forest Hospitals NHS Foundation Trust, whether or not it is externally funded. The Director of Research and Innovation will only give permission for research which has a sponsor (external or Sherwood Forest Hospitals NHS Foundation Trust). Systems will be in place, either within the Sherwood Forest Hospitals NHS Foundation Trust or elsewhere, to ensure that all research conducted in or through the Sherwood Forest Hospitals NHS Foundation Trust conforms to appropriate scientific and ethical standards, and offers value for public money.

All delivery systems will be designed to detect failures to adhere to requirements, regardless of whether such failures arise by intent or oversight. Such systems will involve routine and random monitoring and audit. Additionally, other systems (such as IR1 forms) will require, facilitate and support reporting of critical incidents, near misses, systems failures and misconduct either by self-reporting or whistle-blowing.

5. Collaborations

The R&I department has focused over recent years on NIHR CLRN activity, building a portfolio of studies that has attracted direct infrastructure, staffing, and capacity

building funding from the NIHR. To grow the department further, and to maximise research opportunities and income, Sherwood Forest Hospitals NHS Foundation Trust will now actively seek collaborations with external bodies, including but not limited to commercial sponsors, Universities, other NHS Trusts, the Collaboration for Leadership in Applied Health Research and Care (CLARHC), and the East Midlands Academic Health Science Network.

East Midlands Academic Health Science Network
NHS England confirmed the designation of 15 new Academic Health Science Networks (AHSNs) on 23rd May 2013. AHSNs have the potential to transform health and healthcare by putting innovation at the heart of the NHS, improving patient outcomes as well as contributing to economic growth. AHSNs present a unique opportunity to pull together the adoption and spread of innovation with clinical research and trials, informatics, education, and healthcare delivery. They aim to develop solutions to healthcare problems and get existing solutions spread more quickly by building strong relationships with their regional scientific and academic communities and industry.

Sherwood Forest Hospitals NHS Foundation Trust R&I Department will, in collaboration with the Trust's Innovation Forum, seek to maximise engagement with the new East Midlands AHSN, promoting the Trust through innovation.

Commercial strategy
Commercial research (both NIHR portfolio and non-NIHR activity) is important to the wider research agenda, NHS Trusts (access to latest treatments, financial gain, reputation), and to the wider UK health economy.

Sherwood Forest Hospitals NHS Foundation Trust will have a policy of engagement with and active pursuit of industry-led trials, with responsibility for industry study performance delegated to the Research Manager, with a target of 10% year-on-year growth in income from such studies.

Sherwood Forest Hospitals NHS Foundation Trust will ensure that appropriate resources exist to carry out robust feasibility assessments of potential trials, and that the necessary staff, equipment, accommodation, and are in place to deliver these often complex studies.

6.   <u>Policies and practices</u>

The Research and Innovation Department has a set of standard operating procedures (SOPs), available on the Trust intranet, and subject to 3-yearly review through the Research Governance Committee. A list of all SOPs can be found in appendix 1 of this document.

Sherwood Forest Hospitals NHS Foundation Trust has Data Quality and Information Security policies which apply to all activity within the Trust, including research. These policies can be accessed via the Trust intranet.

7. Equality and diversity

Sherwood Forest Hospitals NHS Foundation Trust is fully committed to the principle of equality, inclusivity and diversity in employment and opposes all forms of unlawful or unfair discrimination on the grounds of race, ethnic or national origin, gender, age, sexual orientation, marital status, family responsibilities, disability, religion, beliefs, political affiliation, trade union membership and social and employment status. The Trust has undertaken a full equality impact assessment, taking fully into account the provisions of the Equality Act of 2010, and a separate Trust-wide policy is available.

8. Patient and public involvement

Patients and other members of the public are important to the design and delivery of research. Sherwood Forest Hospitals NHS Foundation Trust strives to be a leader in patient and public involvement (PPI) in research. Through its R&I department, the Trust will work to change the perception patients and the public may have of research, to actively engage them in study design and delivery, and to ensure that research within the Trust has a focus on the local population.

The Research and Innovation Department will work with the Trust's Communication team to maximise PPI exposure opportunities by using different communication media to broadcast its message, such as local newspapers, screens in the main reception of the hospital, and promotional literature. The Trust will use those media to promote good news stories and successful research projects, as well as to communicate the benefits and importance of research alongside optimum medical care.

Overall responsibility for the delivery of the PPI programme will be delegated to the Research Manager.

9. Implementation strategy

Responsibility for implementing this strategy lies with the Trust's Research Manager. They will be responsible for the development of a research culture throughout the Trust, by engaging with all staff groups to promote the values and benefits of research. The new research finance structure allows incentives for participation in research to individual researchers and departments, and these arrangements will be reviewed annually through the Research Governance Committee.

10. Monitoring, inspections, and sanctions

- The Sherwood Forest Hospitals NHS Foundation Trust's Research and Innovation Department, researchers and care staff will be able to demonstrate adherence to this policy document and the Research Governance Framework on which it is based, in order to reassure patients, service users and care professionals of the quality of their services and to assure their reputation in high quality research and care.

- There are powerful incentives to adhere to many of the principles and standards set out in this policy document and the Research Governance Framework. These include the law, the duties of care in the NHS and social care and the high professional and ethical standards upheld by the majority of care professionals and researchers. Mechanisms, which monitor the quality of clinical work, such as audit, risk management and staff appraisal will be used to assist in the monitoring of research governance.

- If the Sherwood Forest Hospitals NHS Foundation Trust fails to meet the expected standards, it will produce recovery plans for agreement and implementation.

- Clinical trials of medicinal products and medical devices on patients will continue to be notified to the MHRA.

- The Director of Counter Fraud Services has overall responsibility for all work to counter fraud and corruption within the NHS. In addition, the Sherwood Forest Hospitals NHS Foundation Trust Research and Innovation Department will ensure that universities and any other organisations with which they develop local partnerships have appropriate systems for detecting, investigating and addressing fraud by their employees.

- In the case of misconduct, some professional groups will be subject to disciplinary action by their professional bodies. Doctors are responsible to the General Medical Council for their professional conduct as researchers. Similarly, nurses, health visitors and midwives are responsible to the Nursing and Midwifery Council and state registered practitioners are responsible to the individual board of the Council for Professions Supplementary to Medicine for their professional conduct as researchers. Misconduct by social care professionals will be one of the responsibilities of the General Social Care Council.

11. Appendix 1 - List of Standard Operating Procedures

1. Purpose and scope of Standard Operating Procedures (SOPs) – The Research Governance Framework

2. How to write a Standard Operating Procedure (SOP)

3. Study registration

4. Investigator research responsibilities

5. Research and Development study file set up

6. Investigator's Trial Master File (TMF) set up

7. Completion of case report forms/data collection tools

8. Recording of research information in patient medical notes

9. Adverse event reporting in research

10. Creating study related information for clinical study staff

11. Release of pathology specimens and reports to external organisations for clinical research purposes

12. Sample packing for postage via Royal Mail

13. Reimbursement of car parking fees

14. SSI approval by Radiology Department

15. Non-Standard Care Samples / Tests / Investigations

16. Safe Handling of Dry Ice

17. Contracts management

18. Setting up PAS research alerts

19. Request copy for PACS Images on CD for Clinical Trials

20. Request for data for clinical trials

21. Monitoring of research trials conducted with Sherwood Forest Hospitals NHS Foundation Trust