NHS Wales - R&D Office Functions

Purpose

This document outlines the functions that all NHS R&D offices should undertake in order to efficiently and effectively support the promotion and delivery of research within NHS organisations.

The document splits functions into two sections:

A – Functions intended to provide a supportive and safe environment for research activity;

B – Functions intended to specifically support individual studies.

Note: This document does not specify how each activity should be funded (research cost, Research,Support & Governance funding etc), nor does it clarify the relative time or grade of staff undertaking.

SECTION A

A NHS R&D Office undertakes the following functions intended to **provide a supportive and safe environment for research activity** within that organisation:

	Includes (for example):
1. Working with senior management and board members to develop and deliver the research strategy of the NHS organisation.	• Develop R&D governance infrastructure to facilitate the safe conduct of the NHS Organisation's sponsored and-/-or hosted research programme
2. Promoting participation in and use of high quality research to clinical and other staff within the organisation. This may include helping to identify sources of evidence to support service reform/redesign work being led by other parts of the NHS organisation.	• Developing a research culture within the organisation • Raising awareness across the organisation of the benefits of research and the support available (signposting to services) • Hold conferences • Engaging GPs
3. Promoting patient and public engagement in	

research by	
a. Ensuring that information about research is readily available to patients	
b. Promoting opportunities for patients to participate in research	
c. Overseeing opportunities for patients and the public to get involved with research strategy and the development of research.	
4. Promoting partnership working with external organisations such as life science companies, universities, the NISCHR Academic Health Science Collaboration (AHSC), the NISCHR Clinical Research Centre (CRC) and other NISCHR research infrastructure including Health Research Wales, to promote their NHS organisation as a research provider.	• Development work to support the NISCHR agenda • Signposting • Collating responses to consultations from NISCHR/AHSC • Attending NISCHR events • Develop and maintain national/international links • Lead national developments/projects • Attending conferences, training • Collaborating with All Wales R&D offices (FORWARD) • Working with Health Research Wales
5. Managing research income and expenditure.	• Implementation and interpretation of AccoRD, purpose • Use of NHS R&D allocations • Maybe undertaken by Finance Department and overseen by R&D • Managing research accounts • Invoicing • Cost recovery (commercial)
6. Ensuring that the organisations builds, maintains and effectively manages research capacity and capability by:	
a. Bidding for and managing research income from a wide variety of commercial and non-commercial sources.	
b. Building relationships with the broader NISCHR research infrastructure , e.g. Biomedical Research Centres, Biomedical Research Units, , Clinical Research Facilities, Clinical Trial Units, etc.	
c. Ensuring research delivery staff are in post with clear objectives and lines of accountability; this includes research nurses, data managers, and pharmacy, laboratory	

and radiology staff funded and managed from NISCHR AHSC or CRC or other sources.	
d. Ensuring that clinicians have research recognised in their job plans.	
e. Ensuring staff have access to appropriate training and development to support their research activities.	• Delivery by R&D team/HB and access to external training.
f. Ensuring there are appropriate procedures and space to archive study documentation in line with regulatory requirements.	
7. Creating and maintaining robust Standard Operating Procedures for the conduct of research in that organisation. There will be different requirements for research that is sponsored by that organisation and research hosted by that organisation.	
8. Supporting an audit programme to ensure delivery of hosted research is being undertaken appropriately.	
9. Preparing for, hosting, coordinating and responding to regulatory inspections.	• Quality Management System
10. Maintaining a record of all research being undertaken within the NHS organisation.	• Ongoing record keeping relating to the study •
11. Reporting to Boards, NISCHR, funders, Health Inspectorate Wales, on research activity and money spent.	• NISCHR All-Wales data for R&D Offices (metrics) • Administering, managing and signing off AHSC funding streams
12. Supporting the organisation's Innovation Lead to provide advice and support on Intellectual Property Management – in some organisations the Innovation Lead is based in the R&D Office.	• Knowledge transfer • Checking IP arrangements in contracts
13. Putting in place and maintaining systems to identify and deal with research misconduct and fraud.	• Managing investigations – safety, conduct • Implementing existing HR policies

SECTION B

An NHS R&D Office undertakes the following functions to **specifically support individual studies** taking place within that organisation:

	Includes (for example)
14. Supporting investigators to prepare and submit grant applications including signposting to specialist support for protocol development, facilitating collaborative relationships, undertaking costings, supporting feasibility work, and signing off grant applications.	• Protocol development • Identify portfolio and pathway to portfolio studies • Initial advice – research, audit, service evaluation to ensure project is signposted to correct

	processes • Scientific review • Cost attribution (Accord) • Pricing
15. Providing advice and practical support to internal and external investigators making applications to undertake a specific study at the site; for example advising how to comply with legislation or on how to make research applications.	• Feasibility assessment • Liaise with industry partners re commercial studies • Use of National Commercial Costing template – costings
16. Providing advice and support on research related to higher degrees to both students and supervisors.	• Supporting MSc students to develop research projects that meet the organisation's objectives • Putting together a list of proposed projects suitable for MSc students • In collaboration with HEI partners where appropriate
17. Having delegated responsibility for, or working with, their Human Resources Department to operate the Research Passport Scheme to issue Honorary Research Contracts and Letters of Access for research staff not employed by that NHS organisation.	
18. For research studies that the NHS organisation sponsors, ensure that the NHS organisation meets its sponsorship responsibilities to initiate, finance and appropriately manage the studies throughout their lifecycle from funding to dissemination of findings. These responsibilities will be different for Clinical Trials of Investigational Medicinal Products (CTIMPs) and non CTIMPs but will include supporting submissions to regulatory bodies.	• Clearly defined accountability • Pharmacovigilance • Safety reporting • Monitoring • Source data verification /ensuring data integrity
19. For each research study that the NHS organisation hosts	
a. Ensuring that the NHS organisation has both the capability and capacity to undertake the study – that is, bearing in mind the inclusion and exclusion criteria and the resources required, will it be possible to recruit the required number of participants within the timescale of the study delivery period?	
b. Managing the resources required to deliver the study both at study set up and throughout the study life cycle.	• Excess treatment costs • Liaise with NISCHR CRC to gain support for portfolio studies
c. Undertaking an early assessment of operational risks to the delivery of the study and to the organisation and ensuring there are proportionate systems in place to manage those risks in order to effectively deliver the study through its life cycle.	

d. Negotiating contracts/agreements and costs for the delivery of the study (sometimes with support from the Finance or Legal Departments within the NHS organisation, or with support from NISCHR AHSC contracts colleagues).	
e. Gaining assurance that research applications comply with the relevant legislation, information governance requirements, complies with local policies and, where required, that there is sufficient insurance in place.	
f. Formally giving NHS permission, or not, for the study to take place within the organisation, within 40 calendar days (to include global and local governance review), within the national streamlined permissions process (NISCHR PCP).	• Liaising with PCU • Operating a proportionate review
g. Ensuring that the study is delivered "to time and to target" – i.e. the site recruits the number of participants stated in the original application (or a revised target) within the time line agreed with the sponsor to the study protocol.	• Monitoring and auditing • Ensuring the study recruits its first patient within 30 calendar days of NHS permissions / site initiation
h. Processes amendment information and makes any necessary arrangements to continue NHS permission or, very occasionally, withdraws NHS permission if the amendment adversely affects the capacity and capability of the organisation to deliver the research to the new protocol.	• Safety reporting
i. Supporting Dissemination - Encourage/promote publications and output/impact	