Health Research Authority

Summary of the role and operation of NHS Research Management Offices in England

The purpose of this document is to clearly explain, at the operational level, the activities undertaken by NHS R&D Offices and their staff. The document can be used as part of the induction or professional development of HRA staff, Research Ethics Committee members and others wanting a summary overview. The Introduction section is common to a companion document summarising the role of the National Research Ethics Service.

1. Introduction

Research is vital in providing the new knowledge needed to improve health across the population. The NHS Constitution confirms the commitment of the NHS to "the promotion, conduct and use of research to improve the current and future health and care of the population". All parts of the NHS have a role to play in undertaking and supporting research as well as using research evidence when deciding what services the NHS provides. Additionally NHS based research is a very important part of the UK economy.

Research in the NHS is very varied in terms of disease area and clinical setting. Some examples are the development of a new drug to treat new born babies, a new type of replacement hip, a new type of physiotherapy for stroke patients, the use of an existing therapy for a new condition, a new type of medical device, how frequently a condition occurs, what are the risk factors for a certain condition and how lifestyle impacts health. Research also looks at how services are delivered – in the community, at GP surgeries or at a large specialist centre – and at how people experience health care. Research can be funded in many ways such as through grant awards, by commercial companies and national and local charities.

Research carried out in the NHS must comply with any legislation (such as the Data Protection Act, the Human Tissue Act, the Mental Capacity, etc.) relevant to the activities being undertaken as part of that study and must obtain any necessary regulatory approvals. The regulatory approvals required for any one study depends on the type of research being carried out. For example:

- Clinical trials of investigational medicinal products (CTIMPs) require a clinical trial authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA).
- Medical device studies may require a Notice of No Objection from the Medicines and Healthcare products Regulatory Agency (MHRA).
- Studies that involve ionising radiation or the administration of radioactive substances must have the appropriate approvals or licence in place.

- Occasionally researchers need to be able to access to identifiable patient data without consent. To do so permission is required from the Health Research Authority, decisions are made by the HRA on the advice of the Confidentiality Advisory Group (CAG).

- Studies that involve working with prisoners must be reviewed by the National Offender Management Service (NOMS) and it is advised that they are reviewed by a Research Ethics Committee which is flagged to review this type of research.

- Most studies require a favourable opinion from a NHS Research Ethics Committee although there are exceptions, details of which can be found on the Health Research Authority website.

Research is actively managed in organisations delivering NHS and healthcare services to ensure that the study can be delivered in that place and that there are appropriate indemnity arrangements in place. Researchers must gain permission to undertake the research at the site(s) where they intend to carry out their work.

The Integrated Research Application System (IRAS) allows researchers to coordinate their research applications to regulators and to sites where they intend to carry out the research.

2. The role, function and context of NHS R&D Offices

Research Management staff working within or on behalf of NHS service providers have two key functions:

- To support the growth and delivery of faster, easier quality research within the organisation

- To support set up and delivery of individual research projects within the organisation

3. NHS R&D Office Structures

R&D Offices can vary widely in their size, activity and staff mix depending on how research active the organisation is and whether or not the organisation acts as a research sponsor in addition to hosting research sponsored from elsewhere.

Job titles in R&D offices do not give a reliable indication of the actual activities of an individual or of their level of seniority. In a small NHS organisation one individual might deal with the whole range of research activities for a small number of projects where in large teaching hospitals the R&D Office may have several staff doing more specific specialist roles. In some organisations some of the activities or functions set out below might be carried out by finance or human resources departments or devolved to research teams based in clinical areas. No matter where the activities or functions are undertaken they all form part of how research is managed in the organisation and more generally in the NHS.

Some organisations have their own R&D office. Sometimes one R&D office, a research consortium or a research network undertakes the research management functions on behalf of a group of NHS service providers.

4. R&D Office Functions: To support the growth and delivery of faster, easier quality research within an organisation

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

4.1 Working with senior management and board members to develop and deliver the research strategy of the NHS organisation[1]. This clarifies the organisation's overall commitment to research and helps to support the staff in the R&D office.

4.2 Promoting participation in and use of high quality research to clinical and other staff within the organisation, including helping to identify sources of evidence to support service reform/redesign work being led by other parts of the organisation.

4.3 Promoting patient and public engagement in research by:

i. Ensuring that information about research is readily available to patients.

ii. Promoting opportunities for patients to participate in research.

iii. Overseeing opportunities for patients and the public to get involved in developing research strategy and the development of research.

4.4 Promoting partnership working with external organisations such as life science companies, universities, Academic Health Science Networks, NIHR Clinical Research Networks and other NIHR research infrastructure, etc. to promote their NHS organisation as a research provider.

4.5 Managing research income and expenditure.

4.6 Ensuring that the organisations builds, maintains and effectively manages research capacity and capability by:

i. Bidding for and managing research income from a wide variety of commercial and non-commercial sources.

ii. Managing research infrastructure e.g. Biomedical Research Units, Biomedical Research Centres, Clinical Research Facilities, Clinical Trial Units, etc.

iii. 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 NIHR Clinical Research Networks or other sources.

iv. Ensuring that clinicians have research recognised in their job plans.

[1] This will support the organisation's Research & Development Operational Capability Statements available on the NIHR website http://www.nihr.ac.uk/systems/Pages/OperationalCapabilityStatements.aspx.

v. Ensuring staff have access to appropriate training and development to support their research activities. Some R&D offices deliver this themselves and others buy it in.

vi. Ensuring there are appropriate procedures and space to archive study documentation in line with regulatory requirements.

4.7 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. While there are some national examples, Standard Operating Procedures need to be tailored to the specific organisation.

4.8 Supporting an audit programme to ensure delivery of hosted research is being undertaken appropriately in order to meet contractual requirements.

4.9 Preparing for and responding to regulatory inspections.

4.10 Maintaining a record of all research being undertaken with the NHS organisation.

4.11 Reporting to Trust Boards, NIHR, funders, Care Quality Commission, and Department of Health on research activity and money spent. This can be time consuming and work is needed to ensure that the data reported on is clean and robust.

4.12 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.

4.13 Putting in place and maintaining systems to identify and deal with research misconduct and fraud.

5. NHS R&D Office Functions: To support set up and delivery of individual research projects within the organisation

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

5.1 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.

5.2 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.

5.3 Providing advice and support on research related to higher degrees to both students and supervisors.

5.4 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.

5.5 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.

5.6 For each research study that the NHS organisation hosts:

i. Ensuring that the NHS organisation has the 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?

ii. Managing the resources required to deliver the study both at study set up and throughout the study life cycle.

iii. 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.

iv. Negotiating contracts/agreements and costs for the delivery of the study (sometimes with support from the Finance or Legal Departments within the NHS organisation).

v. Gaining assurance that research applications comply with the relevant legislation, NHS Information Governance requirements, complies with local policies and, where required, that there is sufficient insurance in place.

vi. Formally giving permission, or not, for the study to take place within the NHS organisation.

vii. Ensuring that the study is delivered “to time and to target” – ie 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.

viii. 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.

6. Context in which NHS research is managed in England

6.1 The National Institute of Health Research (NIHR) is a large, multi-faceted and nationally distributed organisation, funded through the Department of Health to improve the health and wealth of the nation through research.

6.2 The NIHR Research Support Services Framework provides a set of tools and guidelines to support a consistent and streamlined approach to managing health research studies in the NHS http://www.nihr.ac.uk/systems/Pages/Research_Support_Services.aspx.

6.3 The NIHR Clinical Research Network supports the initiation and delivery of research in the NHS by providing staff and funding service support costs for studies that are part of the NIHR Clinical Research Network Portfolio – i.e. the group of studies that fulfil certain eligibility criteria[2]. If a study is not part of the Portfolio it will not receive this support.

6.4 Each NHS organisation must give permission for research involving their patients, biological samples, data, staff and premises. This ensures that the NHS organisation has put the resources in place to deliver the study and that staff are covered by the NHS organisation's indemnity. NHS service providers are legally responsible for their R&D activity and the safety of their staff and patients.

6.5 Where the research site is a primary care GP, dentist or other independent contractor, a regional team delivering research management for primary care issues a letter of assurance which local independent contractors can use as part of their decision whether or not to participate in the research.

6.6 NHS R&D Office contacts are listed on the NHS R&D Forum website http://www.rdforum.nhs.uk/044.asp.

6.7 The Department of Health expects that studies are initiated and delivered efficiently. NHS organisations holding research contracts with NIHR are required to report on benchmarks including an initial benchmark of 70 days or less from the time a provider of NHS services receives a valid research application for a clinical trial to the time when that provider recruits the first patient for that study. Failure to meet these benchmarks may impact on future research income from NIHR.

6.8 The NIHR Clinical Research Network usually funds the research management activities associated with an NHS organisation hosting research for studies that are part of the NIHR Clinical Research Network Portfolio. In some regions the NIHR Clinical Research Network undertakes this function directly and in other regions it funds NHS organisation R&D offices to undertake this work.

[2] For more details about which studies are eligible for the NIHR CRN Portfolio see http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_eligibility/. Researchers use IRAS to apply to be part of the NIHR Clinical Research Network Portfolio.

6.9 For studies that are part of the NIHR Clinical Research Network Portfolio, NHS permission is facilitated through the NIHR Coordinated System for gaining NHS permission (CSP). Electronic applications are made by the investigator via the Integrated Research Application System (IRAS) and go to staff in the relevant R&D office via an IT system called the NIHR CSP Module. For studies that are not part of the NIHR Clinical Research Network Portfolio researchers submit their applications by email to the relevant R&D offices.

6.10 If a study is gaining permission through the NIHR Coordinated System for gaining NHS permission

i. A Lead R&D office undertakes a "study wide review" which is shared between all participating NHS sites. This covers confirmation of regulatory approvals, grant funding, confirmation that a sponsor is in place, confirmation of the use of model agreements, etc.

ii. Each site then reviews the Site Specific Information (SSI) and assesses whether or not the site has the capability and capacity to undertake the study (i.e. the lab space, the radiology capacity, a trained research nurse, contract in place, etc.).

6.11 Reviews are undertaken consistently in accordance with a national operating manual. By sharing the "study wide review" the work required to give permission for a study at each site is reduced.

6.12 If a study is gaining NHS permission outside the NIHR Coordinated System for gaining NHS Permission, each R&D office undertakes both types of review.

6.13 The NIHR Clinical Research Network funds the service support costs to ensure that there are local resources in place to deliver NIHR Clinical Research Network Portfolio studies. This resource is usually managed by the NIHR Clinical Research Network in collaboration with NHS R&D offices.

6.14 Arrangements in Scotland, Wales and Northern Ireland are different.

Glossary of Terms

Term	Explanation
AHSN	Academic Health Science Network – A group of NHS and other organisations whose core purpose is to enable the NHS and academia to work collaboratively with industry to identify, adopt and spread innovation and best practice. There are 15 AHSNs across England funded by Department of Health.
Care Quality Commission	The independent regulator of all health and social care services in England.
Clinical staff	Staff who actively work with patients in a health care situation rather than in a laboratory. For example doctors, nurses, physiotherapists, etc.
Commercial studies	Studies funded by a for profit commercial company.
CTIMP	Clinical Trial of an Investigational Medicinal Product
Honorary Research Contract	Document setting out the terms and conditions under which a person that does not hold an NHS employment contract may conduct research activities that impact on patient care in an NHS organisation. There is a standard template and nationally agreed process for obtaining an Honorary Research Contract in the NHS.
Inclusion and exclusion criteria	The conditions which define what type of person is to be recruited as a participant to a research study. For example, between 18 and 80 years of age.
Independent contractor	Someone who is self-employed and is contracted to deliver NHS services. For example a dentist or GP (General Practitioner).
IRAS	Integrated Research Application System - A web based system used by researchers to prepare (and sometimes submit) applications for the various review bodies in order to carry out research in the NHS.
Letter of Access	Document setting out the terms and conditions under which a person that holds an NHS employment contract, or whose activities will not impact patient care, may conduct research activities that impact on patient care in an NHS organisation. There is a standard template and nationally agreed process for obtaining an Honorary Research Contract in the NHS.
Life Sciences	The fields of science that involve the scientific study of living organisms.

Term	Explanation
MHRA	Medicines and Healthcare products Regulatory Agency - the Government agency responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.
NHS	National Health Service
NHS permission	The formal agreement issued to a researcher to allow a specific research study to take place within an individual organisation.
NHS Service Provider	Organisation that has a contract to deliver health services as part of the NHS. Organisations can be NHS Trusts, commercial companies, social enterprises or independent contractors (such as General Practitioners (GPs), Dentists or community pharmacists).
NIHR	National Institute of Health Research - a large, multi-faceted and nationally distributed organisation, funded through the Department of Health to improve the health and wealth of the nation through research
NIHR Clinical Research Network	People and resources which the NIHR has put in place to support the recruitment and participation of patients in research within NHS services. See http://www.crncc.nihr.ac.uk/ for more details.
NIHR Clinical Research Network Portfolio	The group of studies that are supported by the NIHR Clinical Research Network. Studies need to fulfil certain eligibility criteria before they are allowed Clinical Research Network support.
NIHR CSP	NIHR Coordinated System for gaining NHS Permission
NIHR infrastructure	People and resources which the NIHR has put in place to support the delivery of research in the NHS. Examples of NIHR infrastructure include Clinical Research Networks, Biomedical Research Units, Biomedical Research Centres and Collaboration for Leadership in Applied Health Research and Care. See the NIHR website for more examples http://www.nihr.ac.uk .
NOMS	National Offender Management Service - Commission and provide offender services in the community and in custody in England and Wales.
Non-commercial studies	Studies funded through government or charitable not for profit organisations.

Term	Explanation
Primary Care	The first point of consultation for someone with a healthcare problem. In England this is usually a GP (General Practitioner) at a local doctor's surgery, a dentist, a community optometrist or community pharmacist.
Protocol	A detailed description of how the research study will be conducted.
R&D Office	Department within an organisation whose role is to support and manage the research activity undertaken.
Regulatory Inspections	Studies that are required to gain authorisation from a regulator (such as the MHRA – Medicines and Healthcare products Regulatory Agency), and organisations responsible for managing or hosting those studies, are subject to inspections by that regulator to ensure that they are compliant with the necessary regulations. If an organisation fails a regulatory inspection the research carried out within that organisation may be stopped.
Research	The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.
Research Consortium	A group of organisations that work together to collectively manage research often through one office.
Research Ethics Committee	A committee appointed by the Health Research Authority whose role is to review applications for research in the NHS with a view to safeguarding the rights, safety, dignity and well-being of the people that will be participating in the research.
Research Passport Scheme	A national scheme which provides a framework for employers to provide assurance to other organisations where a researcher will be working that the employer has undertaken the appropriate employment checks (e.g. confirmation of identity, criminal record, occupational health checks, etc.). It is designed to prevent delays caused by every organisation in which a researcher may be working repeating all of these employment checks.
Service Support Costs	The additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided. Examples include identifying participants, obtaining informed consent and assessments and tests where the results are required by the patient's care team to ensure patient safety.

Term	Explanation
SSI	Site Specific Information - Information about a study that relates to the place in which it is being carried out rather than about the study in general. For example the names of the people that will be carrying out the work. For studies carried out in a number of different locations the Site Specific Information will be different at each of those places.
Sponsor	The organisation that takes responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a research study. All research in the NHS must have a named sponsor.