



## Research Management and Governance Functions of Comprehensive Local Research Networks

### Guidance from UKCRN Coordinating Centre

#### 1. Purpose of Report

1.1 Establishment of the Comprehensive Clinical Research Network (CCRN) involves a radical change in the way that NHS Research Management and Governance (RM & G) will be delivered. The purpose of this report is to describe the RM & G functions that will be undertaken by CLRNs for NIHR Portfolio studies based on knowledge of the existing functions performed by Trust R & D Departments.

1.2 For the purpose of this report it should be assumed that CLRN Research Management will comprise a small core team (within a host organisation) supported by a distributed RM & G function across constituent CLRN Trusts. The way in which RM & G is delivered will reflect the need for greater standardisation through the implementation of national systems but will also be shaped by local needs.

1.3 This report focuses on specific functions rather than general responsibilities (e.g. 'comply with the Research Governance Framework') in order to provide as much detail as possible. However, it should be noted that whilst functions may transfer to CLRNs, Trusts will retain the same legal responsibilities for the studies that they host and sponsor.

#### 2. CLRN Research Management and Governance

2.1 A first step in determining the functions that CLRNs will undertake is to list the RM & G functions currently undertaken by Trust R & D Departments (see Table 1). The extent to which individual Trusts currently carry out these functions will vary depending on the types of study they host and the different approaches they take to Research Management. Therefore, Table 1 includes functions that some smaller Trust R & D Departments may not undertake.

2.2 A primary responsibility of CLRNs will be to provide support for RM & G for clinical trials and other well-designed studies included (or intended for inclusion) to the NIHR Portfolio (and, by definition, Research Management and Governance of non-portfolio studies remains the responsibility of Trusts). Table 2 highlights functions that CLRNs will undertake in support of Portfolio studies and some specific areas that fall outside their remit (and which, therefore, Trusts may continue to provide).

#### 3. Next Steps

3.1 CLRNs will develop local plans for the configuration of RM & G in order to deliver the functions described in this paper. This process will be supported by the UKCRN National Coordinating Centre, will involve dialogue with local stakeholders and be discussed at CLRN Boards.

3.2 CLRNs and Trusts may also consider the possibility of integrating the RM & G of portfolio and non-portfolio studies on the basis that CLRNs are reimbursed the costs of providing RM & G for non-portfolio studies.

#### 4. Further Information

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**Table 1 : Typical Trust R & D Department Functions**

Area	Related Functions
<b>Trust permission for research to proceed</b>	<p>Approval of proposed studies in which the Trust may participate. Trusts have different processes but commonly check that all applicable regulatory and governance approvals have been gained, undertake risk assessment, assess local feasibility (e.g. support department capacity) and service user involvement.</p> <p>Approval of protocol amendments for ongoing studies.</p>
<b>Policy development</b>	<p>Developing and implementing written policies and procedures to be followed by Trust staff and non-Trust staff undertaking research at the Trust. Policies and procedures will be designed to ensure regulatory and governance compliance.</p>
<b>Regulatory Inspections</b>	<p>Preparing for and hosting inspections by the MHRA and Healthcare Commission. Selected Trusts are inspected according to a programme of inspections developed by regulators or because there is a particular reason to inspect.</p>
<b>Sponsorship</b>	<p>Trusts may act as Sponsor or be delegated Sponsor responsibilities for a variety of different study types. R &amp; D Departments have a role in deciding which studies the Trust should sponsor and carry out sponsorship duties.</p>
<b>Supporting researchers</b>	<p>R &amp; D Departments will usually run and/or commission training (e.g. GCP). In addition, R &amp; D staff will provide regulatory and governance advice directly or through websites and newsletters.</p>
<b>Financial Management and Contracting</b>	<p>Financial Management and accounting may be a dedicated function with the R &amp; D Department or be provided through the main Trust Finance Department. Typically, functions include managing research accounts, costing individual studies, allocating support funding within the Trust, assisting in the review of grant applications, contributing to the Trust Annual Report and costing prospective industry studies.</p> <p>There are a variety of contracts handled by R &amp; D Departments including contracts with industry sponsors</p>

	(CTAs or CDAs), non-commercial agreements and consultancy agreements.
<b>Reporting</b>	Mandatory reports to the Department of Health, NRR and regulatory bodies (e.g. reports to the MHRA prior to or following a GCP Inspection)
<b>Intellectual Property (IP) Management</b>	R & D Department functions might include awareness raising amongst staff, identification of IP, supporting staff in the exploitation of IP, providing/commissioning training and liaison with NHS Innovation Hubs or other Technology Transfer Organisations.
<b>Honorary Research Contracts (HRCs)</b>	Procedures for allowing honorary staff to work within Trusts (including issuing HRCs) may be managed by the R & D Department, Human Resources or a combination of both.
<b>Promoting a quality research culture within Trust</b>	Includes a wide variety of activities designed to promote research within the Trust, increase research activity and improve governance.
<b>Monitoring and audit</b>	Under the Research Governance Framework Trusts are required to monitor and audit their studies. Trusts adopt different approaches to meeting this requirement and identifying which studies to audit.

**Table 2 Functions of CLRN RM & G for Portfolio Studies\***

Area	CLRN Functions	UKCRN CC Role	Remaining Functions
<b>NHS permission for research to proceed</b>	<p>Assist in the approval of new studies as part of the Central Sign-Off process.</p> <p>Coordinate assessment of local capacity and undertake Site-specific Assessment (SSA).</p> <p>Liaise with Trusts to expedite final Trust approval and provision of indemnity.</p> <p>Assist in the approval of protocol amendments.</p>	<p>Develop and implement national systems for CSO (including new studies and protocol amendments).</p> <p>Provide overall coordination of CSO via the CSO Unit.</p>	
<b>Policy development</b>	<p>Implement best practice models for compliance with Research Governance and other applicable regulations such that Portfolio studies are conducted according to standard best practice.</p>	<p>Develop best practice models to inform local compliance with Research Governance and other applicable regulations.</p>	
<b>Regulatory Inspections</b>	<p>Provide Trusts with advice about preparing for, hosting and responding to inspections by regulatory bodies.</p>		

<b>Sponsorship</b>			Where a Trust has chosen to act as the Sponsor of a study (within or outside the Portfolio) then the Trust is responsible for carrying out associated Sponsorship duties.
<b>Supporting researchers</b>	<p>Supporting the UKCRN Training and Education Programme</p> <p>Provision of regulatory and governance advice as part of the Regulatory and Governance Advice Service (RGAS). Includes handling specific queries and providing general advice through websites and bulletins.</p>	<p>Coordinate the UKCRN Training and Education Programme</p> <p>Manage and provide support to RGAS via the RGAS Coordinating Team.</p>	
<b>Financial Management and Contracting</b>	<p>Financial management and contracting support as appropriate for individual studies, for annual accounting and facilitating contracting.</p>	<p>Support for the set-up of commercially sponsored studies via the Industry Team.</p> <p>Development of costing templates.</p>	
<b>Reporting</b>	<p>Reports to UKCRN CC as required to permit performance management and for other data returns.</p> <p>Advisory support to</p>		<p>Report to Healthcare Commission re : Research Governance Core Standard as</p>

	Trusts regarding Healthcare Commission's Core Standard return on Research Governance (as part of the Annual Health Check)		part of the Annual Health Check (with support from CLRN as required).
<b>Intellectual Property Management</b>			All aspects of Intellectual Property Management
<b>Honorary Research Contracts</b>	Implementing standard approaches to awarding HRCs and inter-Trust SLAs to facilitate efficient across-Trust working by network staff. This will include adoption of the Research Passport. Adopting these systems will also benefit staff working on non-portfolio studies.	Leading the overall implementation of arrangements which will facilitate cross-site working for both NHS and non-NHS staff.	
<b>Promoting a quality research culture within Trust</b>			All related activities
<b>Monitoring and Audit</b>	Monitoring and audit in accordance with best practice	Recommending best practice in relation to monitoring and audit.	

\* as indicated previously RM & G for non-portfolio studies is the responsibility of NHS Trusts

## **Definitions**

### *Annual Health Check*

The annual health check is the most important of the Healthcare Commission's activities to drive improvements in healthcare for patients. It involves assessing and rating the performance of each NHS trust in England including Core Standard C12 (Research Governance).

### *Central Sign-off*

The process for ensuring that a clinical trial or other well-designed study has all necessary regulatory, ethics and Trust approvals prior to entry into the Portfolio and recruitment.

### *Clinical Trial of an Investigational Medicinal Product (CTIMP)*

Means any investigation in human subjects, other than a non-interventional trial, intended

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,

(b) to identify any adverse reactions to one or more such products, or

(c) to study absorption, distribution, metabolism and excretion of one or more such products,

with the object of ascertaining the safety or efficacy of those products;

### *Good Clinical Practice (GCP)*

Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

### *Honorary Research Contract (HRC)*

Where an individual is conducting activities which will have an impact on the care of patients, the individual will be accountable to the NHS organisation for this work. Accountability means clear statements about who an individual staff member reports to, and about the procedures, codes of practice and other rules and regulations that apply to the work in question.

### *Intellectual Property*

Intellectual Property (IP) can be described as the novel or previously undescribed tangible output of any intellectual activity. It has an owner and can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written works, designs and images.

*Portfolio Study*

A clinical trial or other well designed study that has been adopted into the NIHR Portfolio.

*Regulatory and Governance Advice Service*

The UKCRC R&G Advice Service provides support for local advice providers and a route for handling more complex queries such as those involving more than one regulatory issue. It also provides access to a range of web-based resources including tool kits and Frequently Asked Questions.

*Site-specific Assessment (SSA)*

SSA informs the single review of the ethics of the proposed research. In undertaking an SSA, the principal issues to be considered are the suitability of the Principal Investigator and the site for the conduct of the research.

*Sponsor (Research Governance Framework for Health and Social Care 2<sup>nd</sup> Edition)*

The sponsor is the individual, or organisation (or group of individuals or organisations) that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study.

*Sponsor (The Medicines for Human Use – Clinical Trials – Regulations 2004)*

"sponsor" means, in relation to a clinical trial, the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.