Local support functions in primary care R&D offices following the implementation of HRA Approval

Paper prepared by NHS R&D Forum Primary Care Working Group, February 2015

Introduction

HRA Approval will provide a single approval for research in the NHS that will incorporate assessments by NHS staff employed by the HRA alongside the independent Research Ethics Committee opinion and will provide authoritative assurance to NHS organisations about the suitability, compliance and quality of research proposals, allowing local organisations to concentrate on capacity and capability. HRA has an ambition to implement HRA Approval by December 2015.

In September 2014 HRA issued a paper on research support functions that are expected to continue to be provided locally following implementation of HRA[1]. It is recognised however that there are elements of support that are specific to primary care research and this paper has been drawn up by the NHS R&D Forum Primary Care Working Group to set out the activities that are currently being undertaken locally, and are expected to continue to be undertaken locally following the implementation of HRA Approval, by Primary Care R&D Offices to support the delivery of research in primary care settings.

Context

For the purposes of this paper the term Primary Care R&D Office is taken to mean any R&D Office providing support for research in primary care, whether hosted by a CCG, commissioning support unit, NHS Trust, academic or other partner.

Research within the primary care setting is complex:

- Primary Care R&D Offices support a multiplicity of hosts including GP practices, community pharmacies, other independent contractors, CCGs as well as non-NHS providers of NHS services. These organisations have differing responsibilities with respect to research and hence the support activities will vary.

- R&D offices that support primary care typically have no contractual relationship with, and are external to, the organisations they support (specifically GP practices, other independent contractors, CCGs). In addition, primary care providers typically have no contractual requirement to undertake research, unlike other NHS Providers and therefore the incentives to participate (or not) are different.

- Primary Care R&D Offices are hosted by a wide range of organisations including CCGs, Commissioning Support Units, NHS Trusts and HEIs and operate under a wide range of governance arrangements, hence the level of autonomy they operate under, and the support provided for Primary Care varies greatly, not only in the specific activities being undertaken but

[1] Research support functions following HRA Approval implementation – version 1.0 19/09/2014, Health Research Authority (http://www.hra.nhs.uk/documents/2014/09/research-support-functions-following-hra-approval-implementation.pdf)

also in the parties who undertake these functions, the parties for whom they are being provided and how these activities are funded.

- Primary Care R&D Offices work at a variety of levels, and information needs are complex – information is held at regional, CCG and provider level dependant on the type of information held, study type and complexity and reporting requirements.

This can make delivery of research challenging.

Primary care is however a rich source of patients and potential participants for research, and undertaking research within the primary care setting provides greater opportunities for participants to access research, enabling them to be seen nearer to home, and in a more local environment. It is essential therefore that despite the challenges, support continues to be provided at a local level to maximise these opportunities, without this support there is a danger that providers may simply "opt out" of research.

Primary Care R&D Offices have a unique strategic overview of the environment and a key role in understanding the local architecture and patient pathways, supporting primary care providers to get involved in research, and maximising the recruitment potential of studies. They offer a "co-ordinated approach" to primary care research within the sector, and can offer a single point of contact for research support.

It is recognised that many of the functions detailed in this paper are common to many R&D offices based in secondary care and indeed many are detailed in the HRA Research Support Functions paper referred to above. These activities have not only been included for completeness but also to highlight specific primary care considerations.

Primary Care Research Support Activities

NB: some of these activities will be carried out by R&D office based staff and some by staff based within the Local Clinical Research Network structure. This paper makes no attempt to specify who undertakes or funds the activities locally but rather suggests what could be put in place to specifically support primary care research at the local level.

Activities have been split into a number of categories for ease of reference.

1. Advice & Guidance - General

	Local Activities	Comments
1.1.	Is it research?	Guidance to local researchers on whether a proposal is research, and hence what approvals are / are not required
1.2.	Advising and facilitating engagement with other R&D offices / partner organisations	Role in making links and building / maintaining relationships with other R&D offices to facilitate smooth running of projects that cross geographical and sector boundaries. Critical for rapid set up and delivery of cross sector projects
1.3.	Providing support / advice & guidance to local researchers (including students) on primary care considerations and support available (e.g. trial design / suitability for primary care / feasibility / capability)	For example highlighting where primary care may be able to help in the delivery of their study, NIHR systems and support available, maximising engagement with primary care (e.g. method of participant invite / consent). Use of innovations – pop-ups, search strategies. Critical for maximising recruitment / supporting delivery of research in primary care.
1.4.	Providing support / advice & guidance to primary care practitioners	For example advising on access to patient notes, confidentiality considerations, contracts / agreements, good research practice, support for Sponsor audits or regulatory inspections
1.5.	Understanding local architecture & supporting access routes (e.g. Out of Hours (OOH) services, social enterprises etc). Provide Local intelligence / Translation of issues. Understanding the changing culture and models of primary care eg federated models of primary care	With the variety of providers now commissioned to provide NHS services navigating through this complexity can be a challenge. In many cases primary care R&D offices support researchers to navigate through this complexity and to build links across organisations to facilitate the set-up of studies. This can be extremely time consuming as many non-NHS providers have no infrastructure in place to support research or understanding of their responsibilities if they undertake research and can require a great deal of persuasion, championing and support.
1.6.	Feasibility & capability within primary care (patient population + experience / skills)	Source of expertise on capability of practices and level of support that may be required

1.7.	Development of local website to support research / promote activities of local R&D offices	To ensure clarity of who to approach. Provide general advice & guidance on research within the locality. To promote research to patients

2. Study specific support – development

	Local Activities	Comments
2.1.	Advising on funding streams / opportunities for researchers and healthcare practitioners working in primary care	To multiple parties including CCGs, Practices, HEIs, includes advice on portfolio eligibility considerations and excess treatment costs
2.2.	Supporting researchers / practitioners in the development of ideas into robust research questions relevant to primary care.	E.g. Provision of expert advice on primary care considerations, maximising opportunities to access patients, cost considerations, global feasibility (do the patients exist)
2.3.	Supporting CCGs in commissioning development of research ideas, research grant applications and research studies relevant to CCG priorities	As part of their duties regarding research and use of evidence. Includes utilisation of NIHR Research Capability Funding to fund development of new NIHR research grant applications and utilisation of CCG funding to commission new research.
2.4.	Supporting / submitting grant applications for funding within primary care	Including costing NHS costs

3. Study specific support – set-up & feasibility

	Local Activities	Comments
3.1.	Support to local CIs on regulatory requirements / Portfolio eligibility / IRAS submissions / supporting documentation etc	Local offices involved in signposting and guidance on IRAS submissions (projects, and amendments). Support across the research lifecycle including signposting and explaining entire NIHR systems and where needed advising on possible approaches for complex or novel scenarios and signposting guidance.
3.2.	Supporting local study set up - how the study is to be delivered locally (who / what / where / when) and supporting risk management	Projects vary in their delivery across localities (e.g. hub & spoke working; using practice nurses / CRN nurses / research team members) so it is essential that how a study is set up is well understood as this can greatly affect the successful delivery of the study. Practical arrangements are not always clear in the paperwork submitted so can require liaison with the research team / CRN local team. There should be clarity about the arrangements in place to deliver the study to the protocol (e.g. to ensure participants are aware they will be seen for the study at a different practice if hub &

	Local Activities	Comments
		spoke working is being used) as the generic REC approved paperwork does not always reflect the subtleties of local arrangements. Local R&D offices also have local intelligence on practices and can advise on any additional support requirements for certain practices for example. Proactive awareness raising of studies with relevant individuals eg CCG leads.
3.3.	Supporting for determining Capacity / Capability	Includes feasibility including global feasibility (if lead) – do the patients exist in the sector being applied for?; consideration locally of any competing studies, alignment with local practices or clinical pathways (e.g. prescribing practice). All may have an impact on ability to deliver. NB studies do not have to conform with local pathways or prescribing policies as the purpose of research is to test the new but arrangements must be put in place to allow the study to happen.
3.4.	Advice on & Liaison with other R&D teams / providers as necessary to support study set-up & delivery	E.g. MRI scans, turn-around times for blood tests etc, Includes liaison on costs, possibly contracting, clarifying providers See also Sponsorship responsibilities - section 12 below.
3.5.	Working with Primary Care providers and study teams to resolve issues that arise	This includes flagging up potential risks (e.g. to practice / participants) and may involve liaison with individual practices to get a view
3.6.	Support with local training of practices on studies, advice on site file requirements for practices	To manage economies of scale. This can include provision of rooms / facilities. Cascading out via network staff.
3.7.	Ensuring resources come into right part of delivery pathway	Reviewing / advising on costing coming to practices and support / excess treatment cost requirements / considerations. Ensuring recruitment is attributed appropriately.

4. Contracts

	Local Activities	Comments
4.1.	Providing advice and support regarding research contracts and agreements to primary care providers	HRA Approval will provide an assessment of any planned agreements or contracts required in the study but practices may still benefit from local support. This includes provision of advice & guidance, flagging of potential issues and negotiation advice although ultimately the decision to sign and overall negotiation lies with the contractor. If potential issues arise that would affect all practices will advise all participating practices of issues. In future this will be done in the context of the review undertaken as part of HRA assessment on a study by study basis.

5. Study specific support – ongoing study activities

	Local Activities	Comments
5.1.	Supporting implementation of amendments	Arrangements may need to be put in place as a result of protocol amendments as there can be impact on costs, ability to deliver, and risk to participants.. The HRA will be responsible for amendment approval
5.2.	Monitoring & management of local risks	Where risks have been identified, supporting the ongoing monitoring and management and learning taken forward
5.3.	Troubleshooting local issues	Many issues can and are dealt with locally, and should form part of a wider system for quality improvement.
5.4.	Reviewing SAEs / incidents / complaints	Enables identification of practice / practitioners / researcher concerns / training needs. Part of overall safety monitoring across all studies (see 9.8 below)
5.5.	Monitoring recruitment	Required for 1) supporting payment of support costs to practices (some offices only); 2) Monitoring delivery to time & target & PID reporting (assuming this will be required at some point for primary care); 3) Monitoring to support achievement of recruitment related RCF for CCGs and CRN funding; 3) Reporting to CCGs and relevant R&D leads 4) Early identification and resolution of issues with delivery of studies 5) Managing resource requirements 6) Incentivising practices and helping to keep them engaged

6. HR Arrangements

	Local Activities	Comments
6.1.	Facilitation and oversight of HR arrangements in primary care	Facilitating applications, ongoing monitoring, advising researchers and primary care practitioners. Due to the multiplicity of organisations in primary care this can involve unpicking complex scenarios to determine specific need (e.g. freelance / voluntary staff / home visits / non-NHS providers etc)

7. Study specific support – End of Study Arrangements

	Local Activities	Comments
7.1.	Collection of final reports / outcomes / lay summaries / Notification of end of study	This can be very time consuming to collate, however are essential in ensuring oversight of ongoing activity as a whole and maintaining a strategic oversight of the sector locally. This is also important in ensuring learning is taken forward, for recognising practice / practitioner input and promotion of research generally. It would make sense for this to be a central activity as long as this was disseminated out locally, and the reports received were fit for purpose. It would also be useful to know what local dissemination had been undertaken (e.g. has it gone out to participating practices and participants?).
7.2.	Dissemination of results locally	To practices, CCGs, others, as appropriate. Helps with research promotion and engagement
7.3.	Advice / guidance on archiving & end of study requirements / Archiving study / R&D folders as required	To ensure robust systems for archiving and retrieval of essential documents.

8. Study Related Funding / Costing

	Local Activities	Comments
8.1.	Reviewing and clarifying study costs, attribution and payment mechanisms for these	Costs need to take account of local model for delivery of research and local service / care pathways. With the complexity of organisations involved in primary care research, mechanisms for identifying costs and for how these might be paid can be difficult to tease out (e.g. eligibility of non-NHS providers for SSCs). Predictions on spend can be problematic due to the multiple variables including numbers of practices and numbers of patients per practice. Work is also undertaken locally (by some offices) at grant application stage to clarify and support CIs with costings (see section 2 above)
8.2.	Disentangling responsibilities for Excess Treatment Costs relating to primary care and supporting applications to commissioners	Managing and obtaining excess treatment costs, particularly for primary care is getting increasingly complex, and disentangling this to ensure the appropriate commissioner is identified and approached can be challenging.
8.3.	Supporting applications for Service Support Costs	Some offices do this and others don't and this activity will vary depending on CRN requirements. This may also include supporting applications for e.g. pathology labs for primary care studies, non-NHS providers of NHS Services, and will depend on the delivery model for the research locally.

9. Strategic

	Local Activities	Comments
9.1.	Development of a local research strategy for primary care	Dependant on local set-up of R&D Office
9.2.	Promotion of research in primary care to CCGs / practices / local stakeholders	To act as a champion for research in primary care to all relevant stakeholders
9.3.	Being a champion for primary / community care locally / building collaborations / Engaging practitioners & organisations	For example - inspiring practice staff; developing links between practices / pharmacies / local organisations; problem solving / offering solutions; engaging with CCGs / other partners. This is essential in supporting delivery of research in primary care. Collaborations are essential in managing difficulties and agreeing solutions (e.g. agreement of Excess Treatment Costs, hub and spoke working). Practices will be more confident at taking on research if they know they have a support system behind them (to keep research within primary care "safe").
9.4.	Promoting patient & public engagement in research • As participants • In development	Via direct marketing to patients (e.g. promotion of international clinical trials day, patient facing web presence) and support of practice promotion of research (e.g. provision of materials & tools), hosting of patient panels, facilitating links between researchers and patient groups at research grant application stage etc
9.5.	Promotion of partnership working with local and national stakeholders including: • Academia • NHS England • AHSNs / CLAHRCs / CCGs / Practices • Local Trusts	Role in making links and building / maintaining relationships with strategic partners – alignment of priorities and objectives. This is critical in supporting research overall within primary care.
9.6.	Strategic oversight of income streams / stakeholder requirements / maximising funding opportunities	Primary care R&D tends to be funded through a variety of income streams. Without a "host organisation" with direct responsibility for primary care research, primary care R&D offices are required to be self-sufficient and cost neutral to their hosting organisation – this requires negotiation with stakeholders and creative thinking to ensure costs are covered without losing strategic oversight or ability to deliver on agreements.
9.7.	Management of staffing and infrastructure to enable delivery of research objectives	To ensure optimisation of staffing and infrastructure (including recruitment, training, management & funding) to enable effective delivery of research objectives and strategy

	Local Activities	Comments
9.8.	Development of a quality research environment within Primary Care	Includes: • Development of SOPs / guidelines for research in primary care / host office functions • Training / guidance for employed staff and to support delivery and development of primary care staff • Systems to deal with research incidents / research misconduct & fraud and learning from incidents / complaints / concerns • Auditing against contractual requirements • Preparedness for any regulatory inspections
9.9.	Reporting on activity to CCGs / practices / steering groups / other stakeholders	May entail multiple reports tailored to multiple stakeholders (e.g. CCG Boards; steering groups; host organisation; practices)
9.10.	Maintaining strategic oversight of activity in primary care	Via maintenance of project database, contracts with practices, monitoring of activity / recruitment, incidents / complaints. This is complex as information tends to be held at a variety of levels (Region, CCG, Practice) depending on the type of information (e.g. study details can be at CCG, Regional/CRN or practice level depending on the project; Details of Letters of Access and Honorary Research Contracts are held at a local/regional/CRN level).
9.11.	Supporting innovation and maximising intellectual property	Provision of advice / support to practices / researchers / CCGs as required

10.Supporting & engaging CCGs

	Local Activities	Comments
10.1.	Supporting CCGs to fulfil requirements for promotion of research and use of evidence	Support CCGs in translation of their duties with respect to research E.g. Development of processes for managing excess treatment costs / dissemination of research / managing grants and Research Capability Funding / reporting on activity / research web presence / use of evidence. Providing support and input to CCG Research Strategy Group, Quality Committee etc
10.2.	Supporting FOI requests in relation to research	
10.3.	Supporting CCGs on inclusion of research in provider contracts and provider research requirements	E.g. Quality Accounts, Provider Contract Quality Schedules

10.4.	Reporting on activity to CCGs	Tailored to individual CCG need – may include activity of member organisations, dissemination etc. May include annual report to the CCG Governing Body
10.5.	Promotion of Partnership working	Acting as link to AHSN, CLAHRC etc

11.Managing Office functions / host requirements

	Local Activities	Comments
11.1.	Arranging relevant agreements with local CCGs / other stakeholders for provision of research support activities and managing delivery against these	E.g. Memorandum of Understandings, Service Level Agreements etc. Will depend on office set-up and funding streams.
11.2.	Hosting primary care delivery staff (e.g. research nurses) and discharging duties as employer	Depending on Office Set-up and hosting arrangements. May include arranging agreements with practices/organisations for deployment of research delivery staff to agree lines of responsibility and indemnity arrangements.
11.3.	Management of income / budget and sourcing / securing appropriate income streams	

12.Discharging Sponsorship Responsibilities

	Local Activities	Comments
12.1.	Development of SOPs / Processes for discharge of Sponsor responsibilities	E.g. Quality Management, safety reporting, data management systems, delegation of activities
12.2.	Advising on implications of being a Sponsor and arrangements for discharge of these duties	Where a CCG or practice wishes to act as Sponsor, R&D offices act as a source of advice / guidance to highlight the implications of Sponsorship and support organisations in the discharge of their duties. Also provision of advice and guidance on who should be Sponsor for different types of research and liaison with other parties as required.
12.3.	Arrangements for delegated responsibility for Sponsorship activities on behalf of partner organisations	R&D offices may take on delegated responsibility for Sponsor activities for other organisations in accordance with SLAs / agreements (e.g. CCGs). This will include making appropriate arrangements / drawing up agreements / reporting activity etc

12.4.	Discharge of duties with respect to Sponsor including management, oversight, audit, storage, archiving etc	Includes implementation of systems for quality management, safety reporting, data management, management of budget & timelines, oversight and reporting etc.
12.5.	Managing grant funding related to Sponsored Studies and reporting to funders	Includes set up and management of sub contracts / agreements with Universities, NHS Trusts, practices and other providers for grant funding; oversight, management and reporting on study budgets