

## Primary Care Research Support Activities

**NB** This paper makes no attempt to specify who undertakes or funds the activities listed below but rather suggests what could be put in place to specifically support primary care research at the local level. **Not all offices will undertake all of these functions** - what actual functions are performed by an individual R&D Office will depend on their individual contractual relationships and funding arrangements.

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

### 1. Host Related Activities

#### 1.1. Managing Office functions / host requirements

Local Activities	Comments
<b>1.1.</b> 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.
<b>1.2.</b> 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.
<b>1.3.</b> 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
<b>1.4.</b> Management of income / budget and sourcing / securing appropriate income streams	
<b>1.5.</b> Supporting FOI requests in relation to research	

## 1.2. Discharging Grant Hosting / Contracting Responsibilities

Local Activities	Comments
1.2.1. Negotiation and execution of contracts and variations with funders and collaborators / sub-contractors	A number of NIHR grants must be held by NHS Partners, where these involve research in Primary Care, the host of the local Primary Care R&D Office, may hold these contracts and grants
1.2.2. Oversight of and management of contractual requirements	To include financial management and reporting; management of Intellectual Property

## 1.3. Discharging Sponsorship Responsibilities

Local Activities	Comments
1.3.1. Development of SOPs / Processes for discharge of Sponsor responsibilities	E.g. Quality Management, safety reporting, data management systems, delegation of activities
1.3.2. 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.
1.3.3. 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
1.3.4. 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.

## 2. Strategic

### 2.1. Promotion / Communication

	Local Activities	Comments
2.1.1.	Promotion of research / Stakeholder Engagement	To act as a champion for research in primary care to all relevant stakeholders
2.1.2.	Development of local website and social media tools to support research / promote local research news and activities	To ensure clarity of who to approach. Provide general advice & guidance on research within the locality. To promote research to patients
2.1.3.	Promoting patient & public engagement in research <ul style="list-style-type: none"> <li>• As participants</li> <li>• In development</li> </ul>	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

### 2.2. Oversight / Relationship Building

	Local Activities	Comments
2.2.1.	Promotion of partnership working with local and national stakeholders including: <ul style="list-style-type: none"> <li>• Academia</li> <li>• NHS England</li> <li>• AHSNs / CLAHRCs / CCGs / Practices</li> <li>• Local Trusts</li> </ul>	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, rapid set-up and delivery of cross-sector projects and to facilitate smooth running of projects that cross geographical and sector boundaries.

Local Activities	Comments
<p>2.2.2. Understanding local architecture &amp; 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</p>	<p>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&amp;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.</p>
<p>2.2.3. Development of a local research strategy</p>	<p>Dependant on local set-up of R&amp;D Office</p>
<p>2.2.4. Being a champion for primary / community care locally / building collaborations / Engaging practitioners &amp; organisations</p>	<p>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”).</p>
<p>2.2.5. Strategic oversight of income streams / stakeholder requirements / maximising funding opportunities</p>	<p>Primary care R&amp;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&amp;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.</p>
<p>2.2.6. Development of a quality research environment within Primary Care</p>	<p>Includes:</p> <ul style="list-style-type: none"> <li>• Development of SOPs / guidelines for research in primary care / host office functions</li> <li>• Training / guidance for employed staff and to support delivery and development of primary care staff</li> <li>• Systems to deal with research incidents / research misconduct &amp; fraud and learning from incidents / complaints / concerns</li> <li>• Auditing against contractual requirements</li> <li>• Preparedness for any regulatory inspections</li> </ul>
<p>2.2.7. Reporting on activity to CCGs / practices / steering groups / other stakeholders</p>	<p>May entail multiple reports tailored to multiple stakeholders (e.g. CCG Boards; steering groups; host organisation; practices)</p>

Local Activities	Comments
2.2.8. 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).
2.2.9. Supporting innovation and maximising intellectual property	Provision of advice / support to practices / researchers / CCGs as required

### 3. CCG specific

#### 3.1. Supporting & engaging CCGs

Local Activities	Comments
3.1.1. 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 / funding and using evidence. Providing support and input to CCG Research Strategy Group, Quality Committee etc
3.1.2. Supporting CCGs on inclusion of research in provider contracts and provider research requirements	E.g. Quality Accounts, Provider Contract Quality Schedules
3.1.3. 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
3.1.4. Supporting use of Research Capability Funding (RCF)	To ensure use is within DH guidelines and reporting requirements are met
3.1.5. Supporting development of ETC policy / processes	Will potentially include monitoring and reporting on ETC spend; facilitating applications to ETCs, co-ordinating approach across a number of local CCGs.

#### 3.2. Supporting Commissioning

Local Activities	Comments
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<p>3.2.1. Supporting CCGs in commissioning development of research ideas, research grant applications and research studies relevant to CCG priorities</p>	<p>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.</p>
<p>3.2.2. Training on use of evidence and evaluation</p>	
<p>3.2.3. Supporting use of evidence in service redesign and commissioning intentions</p>	
<p>3.2.4. Supporting and embedding evaluation of new services</p>	

## 4. Study Related Activities

### 4.1. Advice & Guidance

Local Activities		Comments
4.1.1.	Is it research?	Guidance to local researchers on whether a proposal is research, and hence what approvals are / are not required
4.1.2.	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.
4.1.3.	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, indemnity considerations, information governance related to research
4.1.4.	Feasibility & capability within primary care (patient population + experience / skills)	Source of expertise on capability of practices and level of support that may be required

### 4.2. Research Development

Local Activities		Comments
4.2.1.	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
4.2.2.	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)
4.2.3.	Supporting / submitting grant applications for funding within primary care	Including costing NHS costs

### 4.3. Study Set-up & feasibility

Local Activities	Comments
4.3.1. Support to local CIs on regulatory requirements / Portfolio eligibility / HRA submissions / supporting documentation etc	Local offices involved in signposting and guidance on HRA submissions and supporting documents (projects, and amendments), portfolio adoption and support available. 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.
4.3.2. Supporting local study set up - how the study is to be delivered locally (who / what / where / when)	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 & spoke working is being used) and this should be reflected in the Statement of Activities / Schedule of Events. 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.
4.3.3. Support 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.
4.3.4. 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 1.31.3 above
4.3.5. 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
4.3.6. 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.
4.3.7. Ensuring resources come into right part of delivery pathway	Reviewing / advising on costing coming to practices and support / excess treatment cost requirements / considerations and supporting applications for these where necessary (see also section 8). Ensuring recruitment is attributed appropriately.



Local Activities	Comments
4.3.8. Providing advice and support regarding research contracts and agreements to primary care providers	HRA Approval provides 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 affect all practices will advise all participating practices of issues.

#### 4.4. Ongoing study activities

Local Activities	Comments
4.4.1. Supporting implementation of amendments	Arrangements may need to be put in place as a result of protocol amendments as there can be impacts on costs, ability to deliver, and risk to participants. The HRA will be responsible for amendment approval and will advise on any local consideration needed
4.4.2. Monitoring & management of local risks	Where risks have been identified, supporting the ongoing monitoring and management and learning taken forward
4.4.3. Troubleshooting local issues	Many issues can and are dealt with locally, and should form part of a wider system for quality improvement.
4.4.4. Reviewing SAEs / incidents / complaints	Enables identification of practice / practitioners / researcher concerns / training needs. Part of overall safety monitoring across all studies (see 2.2.6 above)
4.4.5. 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

#### 4.5. HR Arrangements

Local Activities	Comments
4.5.1. 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)

#### 4.6. End of Study Arrangements

Local Activities	Comments
4.6.1. Collection of final reports / outcomes / lay summaries / Notification of end of study	To ensure oversight of ongoing activity as a whole and maintaining a strategic oversight of the sector locally. This is 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?).
4.6.2. Dissemination of results locally	To practices, CCGs, others, as appropriate. Helps with research promotion and engagement
4.6.3. 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.

#### 4.7. Study Related Funding / Costing

Local Activities	Comments
4.7.1. 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 4.2 above)
4.7.2. 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.
4.7.3. 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.