

# HRA Approval in Primary Care Settings: Principles of Study Set-Up



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## Introduction

For sponsors, setting up a study in primary care can often be complex. Many primary care providers are independent contractors who are responsible for making the decision as to whether or not to host any given study. Independent contractors are generally supported by R&D offices with a specific expertise in primary care research. However, because of the different ways in which primary care R&D offices are hosted and the different approaches to the role, there are a multitude of different working practices and communication routes across the sector. For the sponsor/researcher setting up a study across primary care in England, this variance of approach in different geographic regions can become confusing.

Much of the support provided by primary care R&D offices is for studies that have been included on the [NIHR CRN portfolio](#) and some areas do not have a primary care R&D office that supports non portfolio research. The volume of non-portfolio research also differs geographically. In areas where there is non portfolio activity, it is expected that relevant local partners identify appropriate funding to ensure that a suitably trained and resourced function is provided.

The implementation of HRA Approval provides an opportune time to provide further clarity on the set-up of studies in primary care, so that primary care R&D offices can offer consistent advice and a uniform service to sponsors/researchers across England. This document seeks to support this endeavour by providing information and guidance on:

- Who should make the decision as to whether a study can take place in an independent contractor primary care setting (for example, at a general practice).
- How primary care organisations should be listed on the IRAS form.
- Who should be the Principal Investigator or Local Collaborator, where there should be one, within an independent contractor primary care setting.
- For non-commercial studies, who should agree to the [Statement of Activities, and accompanying Schedule of Events](#) for research taking place within an independent contractor primary care setting.
- How the sponsor, primary care R&D office (including the Local CRN as relevant) and independent contractor should work together to set up a study.

This document outlines seven key principles to be followed when setting-up and delivering a study in primary care, followed by two appendices:

- Appendix 1 provides twelve examples to demonstrate the principles in practical terms
- Appendix 2 is a leaflet for primary care R&D offices to use with local independent contractors, sponsors and secondary care Trusts.

This document builds upon “[Local support functions in primary care R&D offices following the implementation of HRA Approval](#)”, released by the NHS R&D Forum Primary Care Working Group in February 2015, as well as on the good work undertaken by primary care R&D offices themselves over the past few years. The document promotes the vision that primary care R&D offices (including the Local CRN as relevant) should support practices in confirming capacity and capability, where those practices would like support.

The HRA recognises that primary care R&D offices have different levels of communication and collaboration with their counterpart Local CRN teams. As such, this document makes no

distinction about when a process should be undertaken by the R&D office, or when it should be undertaken by the Local CRN team. Because of this:

- Hereinafter, the term “primary care research support function” is used to cover the array of set-ups in primary care
- Local primary care R&D offices and the Local CRN teams should work together to discuss how support to both sponsors and practices can be consistently provided and review current working practices to enable a supportive environment in primary care.

**Please note:**

- This document is for studies to be undertaken by independent contractors in primary care. It does not relate to studies undertaken in a Clinical Commissioning Group (CCG – for example interviewing CCG staff). Whilst some primary care research support functions may be hosted by a CCG, the set up and processes required to undertake research in a CCG setting may be different to that in a primary care independent contractor setting.
- This document provides examples for use in general practices, as the majority of research in primary care is undertaken in this setting. However the principles of this document can be applied to other primary care independent contractors, such as dentists or pharmacies.
- This document aligns with the NIHR CRN “[Principles of good practice in assessing, arranging and confirming local capacity and capability for Participating Organisations delivering CRN Portfolio studies](#)” document, and provides additional information to specifically highlight information relevant for primary care.
- This document uses the term ‘applicant’ to refer to the individual(s) delegated by the sponsor to apply to the HRA and liaise with participating organisations and their support functions about study set-up.

## Principles

The following seven statements outline key principles that primary care research support functions, applicants and general practices should work towards when setting up a study in primary care.

- 1. The level at which agreement is given, and appropriately documented, for the study to be undertaken is always at the level of the participating organisation (i.e. at the level of the general practice).**

Ultimately the final decision on whether to proceed with a study, based on considerations of capacity and capability, rests with the practice.

- 2. The role of the primary care research support function is to assist applicants and practices in effectively setting up and delivering studies in primary care.**

Primary care research support functions can [provide expert assistance](#) for practices, in making their decisions on whether or not to host a study, and facilitate the activities required to support effective delivery of a study. They can also provide the expert local link between the applicant and practice to promote fast and effective set up in primary care and are integral to the set-up of studies in primary care.

### **3. Applicants should always ensure that the relevant research support function is promptly informed about any study which will happen in the local area.**

For most studies, applicants will benefit from assistance from primary care research support functions to enable effective set up of their study in the local primary care area and applicants should contact the research support function(s) as early as possible (ideally before application to the HRA). For CRN portfolio studies, the [Study Support Service](#) provides dedicated services, such as early contact and engagement or feasibility, to support a single, national approach for this activity.

For research studies that require limited input from primary care research support functions (for example, the researcher is contacting a member of the practice staff to complete a simple questionnaire), the applicant should still ensure that the research support function is notified about the study for information, as early as possible.

Informing research support functions will enable them to have an overview of all primary care research being undertaken in their area and will ensure that they are able to provide support to practices if any queries or issues arise before or during the running of the study. It will also ensure appropriate support and advice is given to practices and hopefully prevents practices not taking on research because of a 'bad experience' with a previous research study.

### **4. Primary care research support functions should not agree or reject a study on behalf of practices.**

There should be an interaction between primary care support functions and general practices before the practice decides whether or not to participate. In line with principles (1) and (2) above, the research support function should facilitate information flow to the practice to support them in making a decision, not act as a gate keeper as to whether or not a study should go ahead in their area.

Where the primary care research support function feels that there are compelling reasons for the study not to go ahead in the area, they should provide relevant information to the sponsor and any practices already contacted. It is then for the sponsor to decide whether or not to pursue practices in that area based on the information provided.

If the sponsor wishes to continue, the primary care research support function should work with the sponsor and practices to assess, arrange and confirm capacity and capability. The research support function can provide advice to practices where particularly careful consideration of capacity and capability are required but, in line with principle (1), it is for the practice to decide whether to undertake the study based on the information provided.

### **5. For non-commercial studies, the Statement of Activities is agreed at the level of the participating organisation (by the practice) and not at a regional, Local CRN level or by the primary care research support function.**

The Statement of Activities, combined with the Schedule of Events, plays an important role in establishing whether an organisation has the capacity and capability to undertake a non-commercial study and provides clarity on resource implications. It can also be used as a form of site agreement in line with HRA criteria and standards. Therefore it is the practice that should agree to the Statement of Activities, with the support of their research support function, where wanted. Similarly, it is the practice that will sign any other form of sponsor agreement.

This does not necessarily mean that the documents have to be individually tailored by the applicant before being provided. The non-commercial applicant will submit one Statement of Activities/Schedule of Events per type of participating organisation to the HRA for review (for example, one for practices which would be undertaking all experimental activities and one for participant identification centres, if both types were in the same study). The version(s) agreed with the HRA will be the one(s) provided to research support functions and to each practice that has positively assessed their capacity and capability. Where a study has more than one type of participating organisation, practices are only provided with the Statement of Activities/Schedule of Events that is relevant to the activities that they are undertaking.

Many primary care research support functions provide practices with a summary of the study and the support available in a simple, easy-to-read format. These summary documents can have an important role in presenting key information about the study to practices to aid site identification, and for practices to assess their capacity and capability to undertake the study. Once practices have been identified, the assessing stage is complete and the arranging phase starts with the provision of the local information package, which includes the Statement of Activities and Schedule of Events (for non-commercial studies only) to facilitate the arranging of capacity and capability. Where it is to be used as the agreement, practices can subsequently confirm capacity and capability by agreeing to the Statement of Activities through email. Regular use of the Statement of Activities and Schedule of Events for non-commercial studies will provide consistency in working for sponsors.

The examples in appendix one set out proportionate arrangements for use of the Statement of Activities and Schedule of Events.

## **6. The HRA will set out important information in the Initial Assessment Letter and Letter of HRA Approval to assist in the set-up of the study.**

Letters issued by the HRA will provide clarification and confirmation about important information regarding the set-up of the study, including:

- Information on the types of participating organisation in the study, including where there are multiple types, and what documents should be shared by the applicant with the research team and research support function. The HRA has provided [guidance](#) on what types of documents should be shared by the applicant and at what time.
- The appropriateness of a Principal Investigator (PI), Local Collaborator (LC) or neither. **Where a PI or LC is appropriate for a site this should always be at the level of the practice, even if one person takes on the role for more than one practice.**
- HR arrangements
- Confirmation of capacity and capability arrangements
- Details on what agreement will be used to confirm capacity and capability

- Pass through information on any support being provided by the central research team.

Applicants and primary care research support functions should note the information provided in these letters. Whilst discussions are likely to have been undertaken between the research support function and the applicant prior to issue, these letters will provide authoritative assurance in line with the [HRA assessment criteria and standards](#).

## **7. The organisational level of primary care listed in the IRAS form should be proportionate to the study.**

In all cases, the organisational level listed on IRAS should either be the practice level or the Local CRN level. It should not be at any other level (for example, CCG level). The use of Local CRN as the regional level allows for clarity of service support (for applicable studies). Researchers should be aware that there may be more than one research support function within one Local CRN and should ensure that they contact all relevant functions as soon as possible, so that the appropriate support can be put in place. Contact details for primary care research support functions and their Local CRN can be found on the [NHS R&D Forum website](#). Further sources of information on who to contact may be found by contacting the appropriate person in the [Local CRN](#).

For applications generated in IRAS from December 2016, it is expected that primary care involvement will be listed on Part C of the IRAS form at either the Local CRN region level or the practice level.

For most applications, it is appropriate to list the Local CRN area on Part C of the IRAS form. However, it is still expected that:

- practices have sight of what they are agreeing to undertake prior to confirming capacity and capability at the practice (for example, sight of the Statement of Activities and Schedule of Events for non-commercial studies)
- Principle 1 is applied – that the level of agreement to confirm capacity and capability is with the practice, as the participating organisation.

In the following instances Part C of the IRAS form should be completed at the practice level:

- where practices are full research sites in a Clinical Trial of an Investigational Medicinal Product (CTIMP);
- where practices are acting as the institutions at which a clinical investigation of a medical device will be conducted.

Applicants are advised to list all intended participating practices in the initial application.

## **Research Support Functions in Primary Care**

, Research support functions working in primary care settings should:

- Ensure the way the research support function interacts with sponsors, the Local CRN and practices provides a supportive, enabling environment to undertake primary care research. Across any one Local CRN area, teams should be working in a cohesive fashion to support consistent processes



- Understand the [HRA assessment criteria and standards](#) document to provide support to applicants prior to HRA Approval
- Review the [mock applications and sharing mock HRA documentation](#) (Statement of Activities, Schedule of Events, Initial Assessment letter and HRA Approval letter) with general practices so that they understand what HRA communications will look like.
- Familiarise general practices (particularly research active ones) with the [Statement of Activities and Schedule of Events](#), so that they understand the purpose of the documents and what processes that should be put in place.

The HRA always appreciates feedback on any aspect of HRA Approval. If you have any feedback or queries, please direct them to [hra.approvalprogramme@nhs.net](mailto:hra.approvalprogramme@nhs.net).

## Appendix 1 - Examples to Demonstrate Principles

The following twelve example scenarios represent situations likely to be encountered in primary care, with details on how research support functions can best support the sponsor and practice to set-up a study with HRA Approval. Examples are intended to demonstrate the principles above and are not exhaustive. Research support functions should take each study on its own merit as to how it can be best supported.

**Example 1: A non-commercial sponsor would like to run a non interventional study in 30 general practices in one Local CRN region. All practices will undertake the same activities, undertaken by practice staff. A modified non-commercial agreement will be used, the study has been included on the NIHR Clinical Research Network portfolio and service support will be required, in the form of Local CRN nurses to undertake some activities at the practice.**

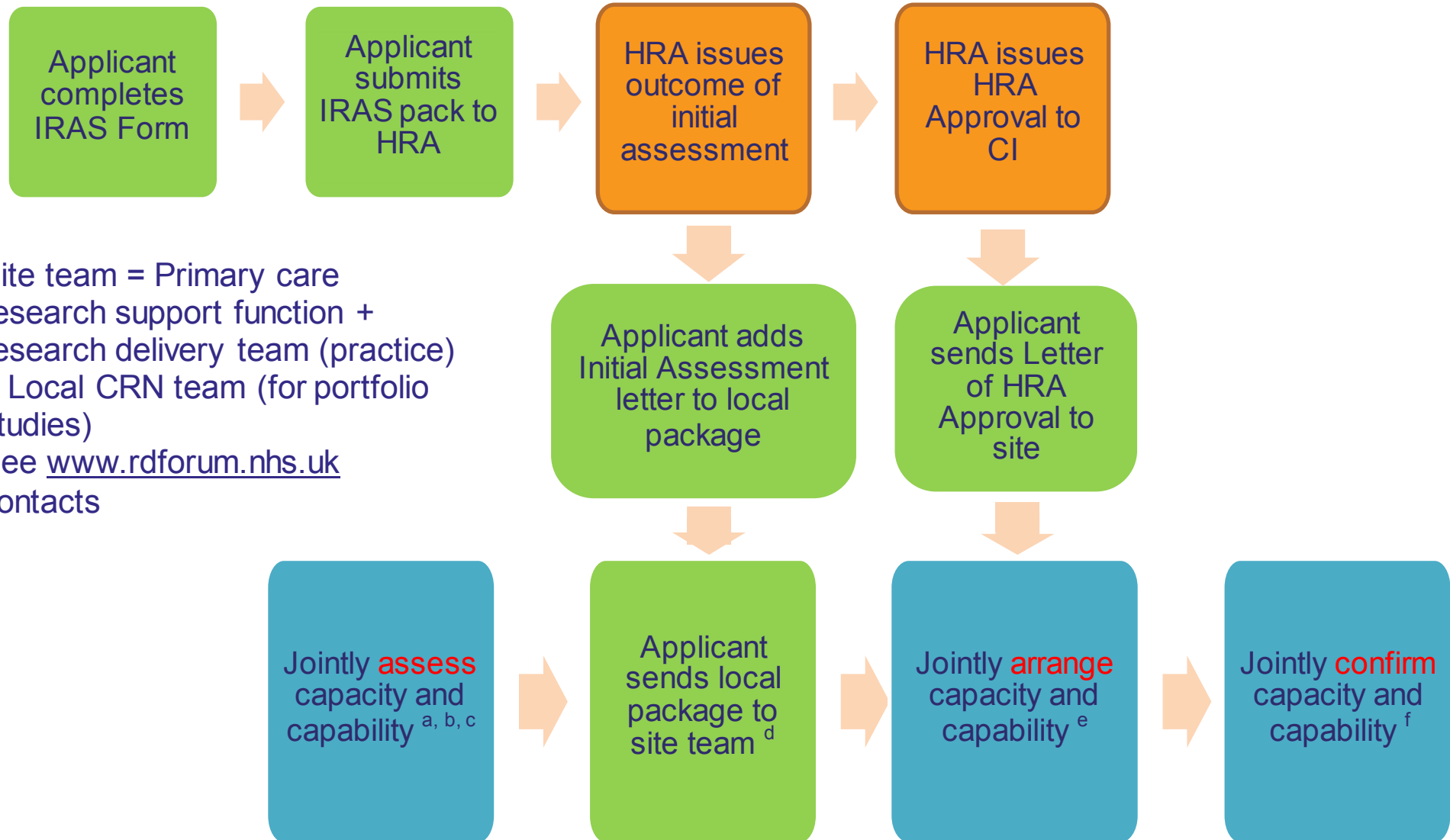
### Key Information

- Part C of the IRAS form should be detailed at the level of the Local CRN area, not the practice. The HRA will provide information on study set-up in the initial assessment letter. A PI should be in place at the level of each practice as local staff will take responsibility for local activities.
- One Statement of Activities and Schedule of Events should be drafted for the study by the applicant, as all practices are undertaking the same activity, and these should be submitted to the HRA as part of the application for HRA approval.
- Supported by the research support function, each practice will make the decision on whether or not to take part, based on the information provided (including the Statement of Activities and Schedule of Events).
- The practice will confirm capacity and capability by signing the modified non-commercial agreement, once all arrangements are in place (e.g. Local CRN nurse support is confirmed).

The flowchart on the next page provides an overview of the processes that should be undertaken. Where indicated, further information is provided thereafter.

Whilst the flowchart outlines the steps that should be undertaken, the timing of them may vary depending on the study and when the initial contact from the sponsor happens. It is for the sponsor/chief investigator to determine the timetable and plan for setting up practices.

# High level primary care processes with HRA Approval



Site team = Primary care research support function + research delivery team (practice) + Local CRN team (for portfolio studies)  
 See [www.rdforum.nhs.uk](http://www.rdforum.nhs.uk) contacts

Further information on the flowchart (lettering relates to the relevant box in the flowchart on the previous page):

- a) It is strongly advised that the applicant approaches the research support function prior to the application for HRA Approval to discuss the potential use of practices in the area (where the geographical area to be approached is known prior to application). At this stage the minimum information that should be provided is the protocol, in line with [HRA guidance](#). Both parties should discuss the study and anticipated set up. Discussions around any specific requirements of practices should also be had to allow for the most effective approach. For example, if the participant population is likely to be in deprived areas this should be discussed so that the research support function can use a targeted approach to practices.
- b) Once the applicant and research support function are clear about the requirements on the practice, the research support function should identify and contact potential practices for them to **assess** capacity and capability. This may involve the use of research summary forms to communicate key information about the study.
- c) Practices that are interested should reply directly to the research support function, who can collate and forward responses to the applicant. This initial reply from the practices indicates that they are *interested* in undertaking the study; it does not constitute agreement to undertake the study.
- d) Upon receiving the initial assessment letter from the HRA, the applicant should provide the research support function and interested practices with the local documentation package, as indicated on the letter and in line with [HRA guidance](#). (**Note**: In instances where the approach to the research support function by the applicant is after issue of the letter of HRA Approval, the HRA Approval letter should be provided in place of the initial assessment letter). For non-commercial studies this includes distribution of the Statement of Activities/Schedule of Events to those practices who have indicated an interest. This does not need to be personalised for the practice – there should be only one per site-type.
- e) All parties should work collaboratively to **arrange** capacity and capability, with practices completing what is required on the Statement of Activities (for example, providing details of who will be PI at the practice). Arranging capacity and capability may include putting in place staff training on the study in line with the HRA initial assessment letter, scheduling staff activities, agreeing costs, etc.
- f) Following HRA Approval, practices should **confirm** capacity and capability by returning the signed non-commercial agreement, or returning the agreed Statement of Activities, as appropriate.

**Example 2: Following HRA Approval, the non-commercial sponsor of the study in example 1 wishes to extend to 10 practices in a second Local CRN. However, as the second Local CRN was not involved in earlier discussions, it is not in a position to reallocate the research nurses to support the study within the timescales that the sponsor has proposed**

#### Key Information

- It is not for a research support function to make a decision on whether or not practices can undertake the study without Local CRN nurse support. However, all parties should work together to explore whether other arrangements may be put in place.
- Practices should be provided with all relevant information so that they can review their capacity and capability to host the study.
- A new Statement of Activities is not required, as the activities to be undertaken are not changing, but it should be clear from the Schedule of Events during initial discussions who will undertake the activities previously conducted by the Local CRN nurse.
- An amendment should be submitted to the HRA to include the second Local CRN area, as this Local CRN area was not listed on the submitted IRAS form

As soon as the applicant wishes to extend the study to practices in the second Local CRN area, they should contact the research support function/s for that area to discuss set up of the study, just as in example 1. However, as HRA Approval has already been issued, the initial assessment letter does not need sharing by the applicant, as the HRA Approval letter will provide final confirmation on all pertinent points related to study set up. As the initial IRAS form did not include the second Local CRN area, the applicant should submit an amendment to the HRA in line with HRA guidance.

When the Local CRN confirms to the applicant and research support function/s that Local CRN nurse support cannot be provided in the timescales proposed by the sponsor, all parties should work together to ascertain whether or not other arrangements may be put in place (for example, provision of service support costs).

It is not for the research support function to make a decision on whether or not practices in the Local CRN can host the study without Local CRN nurse support. The research support function should first discuss with the sponsor whether they wish to pursue practices in the Local CRN, but it is the decision of the sponsor whether or not to proceed.

If the sponsor wishes to proceed, the research support function should pass information to the practices about any support that could be provided instead of Local CRN nurses and advise on any other areas which may need particular attention with respect to capacity and capability considerations. It is then the decision of the practice whether or not to take part, based on the information provided and any revised capacity and capability considerations that should be considered.

No new Statement of Activities or Schedule of Events templates should be submitted to the HRA, as the new practices will be undertaking the same procedures. The Statement of

Activities and Schedule of Events provide the starting point for discussions on delivery of the study locally. Where local changes are made to reflect the local method of delivery of the study (e.g. who will undertake particular activities), this can be updated on the Schedule of Events without needing to submit an amendment to the HRA (unless the changes would constitute an amendment to the study anyway). Changes to reflect detail of local delivery do not need to be submitted as an amendment.

**Example 3: A commercial sponsor would like to work with three practices in a Local CRN to undertake a CTIMP and, because of previous working relationships, knows which practices they would like to work with. Instead of contacting the research support function, they approach the practices directly to discuss hosting the study.**

#### **Key Information**

- The research support function should be made aware of any approach to the practices, by the sponsor copying in the research support function to the invitation emails sent to the practices.
- No Statement of Activities or Schedule of Events is required, as it is a commercial sponsor. The Statement of Activities and Schedule of Events is only applicable for non-commercially sponsored studies. Commercially sponsored studies use the primary care Industry Costing Template, which provides equivalent information.
- The IRAS form should name the practices in Part C.

In this scenario, it is expected that the research support function is copied into any direct request from the sponsor to the practice. If this does not happen, the practice should inform the research support function of the request at the earliest opportunity, so that the research support function is aware of the study and can provide any appropriate support to the practice.

It is for the practice to assess, arrange and confirm their capacity and capability to host the study in conversation with the sponsor and supported by the research support function as appropriate. The HRA will issue the initial assessment letter, which can support the arranging of capacity and capability in the practices (unless HRA Approval has already been issued, in which case the letter of HRA Approval will perform the same function).

The research support function can assist the practice in these discussions, for example by helping with any queries from the practice regarding any aspect of the set up or delivery of the study. The research support function should be informed when the practice has confirmed their capacity and capability to the sponsor. Ideally the practice should copy the research support function into this confirmation but, if not, the sponsor should ensure that they are informed as soon as possible.

**Example 4: A non-commercial sponsor is running a non-CTIMP study in practices across multiple Local CRN areas. The study itself is relatively straightforward, with each practice undertaking the same activities, but involves an intervention which incurs an Excess Treatment Cost (ETC).**

#### Key Information

- Part C of the IRAS form should be detailed at the level of the Local CRN.
- The applicant should submit a Statement of Activities and Schedule of Events to the HRA.
- The applicant should make contact with the primary care research support functions as early as possible to discuss Excess Treatment Costs
- Primary care research support functions should maintain an up to date knowledge of which is the correct body to approach to discuss ETCs in primary care, in order to correctly advise sponsors.
- Primary care research support functions should also ensure wider support staff who may be in contact with the researcher are aware of who can provide the necessary support around ETCs to avoid inconsistent or incorrect advice.

The HRA will assess the application and pass through any relevant information in the initial assessment letter, but will not be assessing whether Excess Treatment Costs have been appropriately attributed on the Schedule of Events.

The applicant and primary care research support function should work collaboratively to set up and deliver the study, as described in example 1. Where the study may incur ETCs, it is especially important that the applicant contacts the primary care research support function well in advance of the planned start date so that adequate financial planning can take place.

The primary care research support function should maintain an awareness of local primary care commissioning arrangements to know which commissioning body to contact regarding ETCs and to set up efficient local processes. This is especially important given the [current move to provide more responsibility to Clinical Commissioning Groups](#) over primary care commissioning. The support function should also ensure that other staff who may come into contact with the sponsor are able to direct them to the appropriate person to discuss ETCs. This will ensure that there are no unnecessary delays in discussing ETCs.

The sponsor and primary care research support function should work together with the appropriate commissioning body who will be agreeing ETCs to discuss and agree the provision of ETCs. Each primary care research support function may have local processes agreed with relevant commissioning bodies, but should have regard for the [NHS England guidance on Excess Treatment Costs](#).

Gaining agreement over ETCs is part of arranging capacity and capability, and so confirmation of capacity and capability by the practice for the research to begin cannot take place until arrangements for covering ETCs have been agreed including, where appropriate, access to additional funding from the relevant commissioning body.



**Example 5: A non-commercial sponsor is running a study at a local secondary care Trust. As part of the study, they would like to collect information from GP-held medical notes of participants who consent at the secondary care Trust. Because of the set-up of the study, it will not be known which practices will be approached until the participant consents.**

#### **Key Information**

- Part C of the IRAS form should be detailed at the level of the Local CRN for the primary care aspect of the study, not the practice.
- The applicant should submit two Statements of Activities and Schedules of Events to the HRA, one for the activities to be undertaken at the secondary care Trust, and one for the activities undertaken by general practices.
- No formal confirmation of capacity and capability is required of the practices. They will be expected to provide the information requested, unless they have reason to opt out and notify the applicant of this.
- In accordance with HRA Approval standards, no PI or local collaborator is needed to undertake this data collection.
- The local research support function should be contacted about the study by the applicant so that they can provide support to practices, the applicant and the secondary care Trust as needed. The respective research support functions of the Trust and the practices will wish to communicate directly, following the initial contact from the sponsor, to facilitate the practical arrangements.
- The HRA will determine whether the arrangements for data transfer adhere to the HRA assessment criteria and standards. Research support functions should support the transfer as indicated by the HRA Approval Letter.
- It is not necessary for the applicant to provide *all* study documents to the practice and research support function, only those relevant to providing data from medical notes.

The involvement of general practices should be made clear in the application to the HRA and a Statement of Activities and Schedule of Events should be provided for both the Secondary Care Trust and general practices, it is best practice in these circumstances for the applicant to create a GP Letter, to be submitted to the HRA for approval. This should detail the data to be requested, the patient group, the processes to be followed in providing the data, contact details for the research team and the remuneration available. The HRA will assess the application in line with the HRA assessment criteria and standards, which will include Data Protection Act and any other data security requirements for the transfer of information from the medical notes. Outcomes will be detailed in the Initial Assessment letter and HRA Approval letter, where any information for practices will be specifically highlighted.

The applicant and secondary care Trust should contact the primary care research support function to discuss the study and what support may be required from the research support function, as part of the secondary care Trust assessing their capacity and capability, so that the secondary care Trust can ensure that practices will be able to provide the necessary information.

The applicant and primary care research support function should discuss how best to communicate the study to practices, if not already considered by the applicant. For this

study, it has been agreed that a blanket communication to practices from the applicant, via the research support function, will raise awareness of the study. This communication should provide relevant details about the study, for example: brief synopsis of the study, who the practice will receive a request from, what information the practice will provide, how data should be transferred securely from the practice and funding for the practice, where applicable (this may be a summary of the GP letter, or a copy of the template proposed GP letter itself)..

It is for the applicant and primary care research support function to decide the timing of the communication. However, it is suggested that an initial communication is circulated to practices whilst the secondary care Trust is in the process of arranging capacity and capability, with a follow-up communication once the secondary care Trust has confirmed capacity and capability. This will put the secondary care Trust and applicant in the best possible position to start the study as soon as capacity and capability have been confirmed.

No formal confirmation of capacity and capability is required from general practices, who will be expected to provide the requested information, unless they elect to opt out of the study and inform the applicant of this.

Upon receiving a request the practice should provide the data, so long as all arrangements are in place, and the research support function can assist with any queries that the practice may have. There should be no need for practices to receive or request a copy of the participant's signed consent form prior to release of data. Practices should take assurance from the HRA Approval Letter that the consent and information governance arrangements for how the study should be run are acceptable. It is then for the applicant and secondary care Trust to manage and monitor this process accordingly. It is an information governance risk to have identifiable information of participants (on consent forms) being transferred more than is necessary.

**Example 6: A non-commercial sponsor is conducting a health services research study which involves the practice managers of 100 practices across England each completing a single five minute questionnaire. The practice manager will be invited through publically available information and asked to complete the questionnaire by email.**

#### **Key Information**

- Part C of the IRAS form should be detailed at the level of the Local CRN, not the practice.
- There is no principal investigator or local collaborator at sites.
- Whilst the HRA will inform the research support functions about the study, as this type of study does not require confirmation of capacity and capability, there is limited input needed from research support functions and limited documents will be shared. The HRA Approval Letter will make clear the study arrangements.
- The practice manager, as an invited participant, will make the decision on whether or not to take part by completing, or choosing not to complete, the questionnaire.

The HRA will assess the study against the [HRA assessment criteria and standards](#) and issue HRA Approval when able to do so. As the study will not require formal confirmation of capacity and capability, the HRA will inform primary care research support functions about the study, but limited documents will be shared with the research support functions, and all pertinent information will be contained in the HRA Approval Letter.

Research support functions may circulate the HRA communication to practices, but should not undertake anything further, nor should they request any further documentation from the applicant.

Upon issue of HRA Approval, the applicant will contact the identified practice managers, informing them about the study and asking them to complete the questionnaire. It is the decision of the practice manager, as the invited participant, whether or not to complete the questionnaire.

**Example 7: A commercial sponsor is undertaking a CTIMP study in general practices, and all activities will be undertaken at the practice. The investigational medicinal product is licenced for use, but is not in line with local prescribing policy for the condition to be investigated.**

#### Key Information

- Part C of the IRAS form should be detailed at the level of the practice. In this instance, discussions should be had with the practices prior to an application for HRA Approval. New practices added after this will constitute an amendment.
- A principal investigator should be in place and should be at the level of the practice.
- The research support function should not refuse to take the study to practices on the basis that the use of the investigational medicinal product is not in line with local prescribing policy.

The HRA will assess the study against the [HRA assessment criteria and standards](#). This includes ensuring that the end of study arrangements are clearly detailed in the participant information sheet, are consistent with the protocol and IRAS form, and do not lead to unrealistic expectations by participants that they will have post-trial access to the study treatment. Where arrangements for post-study care are described, the applicant should specifically describe how any post trial access to the study treatment will be funded and managed. These arrangements may need to be agreed locally with those responsible for funding the post study care, where applicable.

The research support functions should support the applicant to identify and set up practices as example 1. It is likely that discussions with some practices will be had prior to application for HRA Approval.

If the research support function identifies that the investigational medicinal product is not in line with local prescribing policy, they should not refuse the study on behalf of general practices in their area. The research is being undertaken because there is a lack of evidence in the use of the investigational medicinal product and only by research will this gap in evidence be filled to provide better information for commissioners and medical staff on its use.

The research support function should support practices and commissioners to put in place arrangements (where needed) for during the study and for any post-study care that will be in place. As before, it is for the practice to decide whether or not to take part, based on their capacity and capability.

Local medicines management teams may be notified for information only about the study, so that they are aware if a practice will be prescribing outside of local prescribing policy (for example, in case a clinical audit is undertaken).

**Example 8: A CTIMP is to be run in primary care, but requires a local secondary care Trust to undertake an MRI of the participant.**

**Key Information**

- A template Statement of Activities and Schedule of Events will be requested for both the activities at the practices, and the activities at the secondary care Trust.
- Part C of the IRAS form should be listed at the level of the practice .
- The primary care research support function should support the applicant in ensuring that appropriate arrangements with the secondary care Trust are in place .

The applicant should highlight early on in discussions with the research support function that support from the local secondary care Trust will be required, and the local secondary care Trust should be contacted by the applicant in collaboration with the research support function. The primary care research support function can support the applicant in ensuring that the necessary arrangements are put in place at the secondary care Trust in a timely manner, parallel to the set-up of practices.

Where arrangements cannot be put in place (for example, the nearest secondary care Trust does not have an MRI scanner), the research support function and applicant should discuss whether any alternative arrangements can be made (for example, using another secondary care Trust). Where this is not possible, it is for the sponsor to decide not to pursue practices in that area, supported by relevant information provided by the research support function.

**Example 9: A study is already running at practices in one Local CRN and, in that Local CRN, all activities will be undertaken at each practice. The study is extended to another Local CRN, but upon initial discussions it is agreed with the research support function that practices in this Local CRN are a will work in a hub and spoke model, where ‘spoke’ practices will act as a participant identification centre to the ‘hub’ practice, where all participant visits will take place.**

#### **Key Information**

- An amendment should be submitted to put in place the new hub and spoke arrangements, if this was not already detailed in the initial application.
- A new template Statement of Activities and Schedule of Events should be submitted as part of the amendment to describe the activities of the spoke practices, and new versions may also be submitted for hub practices (but only if activities differ from practices in the first Local CRN).
- A principal investigator is likely to be required at the hub practice, but no PI or local collaborator is needed at spoke practices. The PI at each hub practice should be based at the practice (ie it is not for the CI to act as PI for all hub practices).

The decision to use differing arrangements in set up of the study in different areas should be a decision for the sponsor, after discussion with the research support function.

Where this is agreed, the applicant should develop a new Statement of Activities and Schedule of Events for the spoke practices, and potentially new versions for hub practices (if their activities differ from the activities of the original practices in the first Local CRN). This should be submitted as an amendment along with any revised documentation as a result of the change, as there is likely to be a protocol change.

The research support function should work to facilitate the identification and recruitment of practices to act as hubs and spokes in a similar way to example 1 (although HRA Approval will have already been given). They should also support the applicant and practices to ensure that arrangements for hub and spoke working are in place (e.g. coordination of timing of activities between the hub and the spoke).

**Example 10: A secondary care Trust running a non-commercial study wishes to use general practices as Participant Identification Centres (PICs). The study already has HRA Approval and is running at the secondary care Trust.**

**Key Information**

- The processes and communications involved in setting-up general practices acting as participant identification centres in primary care are generally similar to setting up general practices which are undertaking all study activities. There are however significant differences in the activities being undertaken to deliver the study.
- Practices should be provided with the Statement of Activities and Schedule of Events. An amendment should be submitted, to take account of the newly incorporated PIC activities, and new versions of the Statement of Activities and Schedule of Events submitted.
- The level of assessing, arranging and confirming of capacity and capability will depend on the activities required of the practice.
- Similarly, whether a local collaborator should be in place will also depend on the detail of activities to be undertaken (if external staff will be attending the PIC to support the referral process, a local collaborator should be identified to support the practicalities involved in this).

Once the sponsor and secondary care Trust have agreed to use PICs, the sponsor should submit an amendment to the HRA, including revised/additional documentation where appropriate, and a Statement of Activities and Schedule of Events for PIC activities.

In parallel with HRA processes for the amendment, the sponsor should contact the primary care research support function to discuss the use of PICs. The sponsor, research support function and practices should work together in a similar way as described in example 1 to identify, select and set up PICs once the amendment is approved.

The level of assessing, arranging and confirming of capacity and capability undertaken by practices acting as PICs will depend on the activities to be undertaken. For example, if PIC activity is limited to the display of a poster there will be no assessing and arranging needed and no formal confirmation required. However, if the PIC activity will be a significant database search and mail-out, then there will be some level of assessing and arranging, followed by confirmation of capacity and capability (which would be expected to be a simple email agreeing to the statement of activities/schedule of events).

**Example 11: A sponsor would like to run a diabetes study in practices in a Local CRN. The research support function identifies that there are already a number of diabetes studies with similar eligibility criteria running in practices in the area.**

#### **Key Information**

- The research support function should not refuse a study on the basis that there are already a number of studies on the same topic happening in the area.
- Instead, the applicant and practices should be supported to see where alternative arrangements can be made to enable the study to run. It will be for the practices to assess if there is a sufficiently large potential participant pool to support the study.

The research support function should work with the applicant to consider what arrangements can be put in place so as not to impact current diabetes studies and the new study, for example, targeting practices in the area not currently undertaking any diabetes studies.

All relevant information should be passed to practices to consider whether they have the capacity and capability to undertake the study in a similar way to example 1. Where a practice already undertaking a diabetes study agrees to host the new diabetes study, the research support function can provide assistance to the practice to ensure there is no impact to sponsors of both studies and also to the patients at the practice.



**Example 12: A non-commercial sponsor would like to run a study across the country. In many areas the study will be undertaken by individual practices. However, practices in one area would like to run the study across a number of practices centrally through their GP Federation (or equivalent), using a GP Federation administrator to conduct database searches across a number of practices, and a GP Federation nurse to undertake study visits.**

#### Key Information

- The organisational level listed on Part C of the IRAS form will be determined by the information provided in Principle 7.
- Where a study is being run by a GP Federation on behalf of its member practices, the agreement should be between the sponsor and the GP Federation.
- The Schedule of Events and Statement of Activities can be discussed and agreed with the GP Federation, on behalf of its member practices. It should be amended as appropriate during discussions, but no new templates should be submitted to the HRA as the activities undertaken will remain the same.
- Local primary care research support functions can support the GP Federation in making capacity and capability decisions

Where a contractual relationship exists between a practice(s) and a GP Federation (or equivalent organisational structure) to undertake research on behalf of the practice, it is appropriate for that Federation to take the lead in assessing, arranging and confirming capacity and capability, including signing of the agreement to be used in the study. It is however expected that the GP Federation involves its member practices where appropriate to do so (e.g. if arranging room availability at the practice is required).

If the activities to be undertaken are the same as those provided on the statement of activities, but the organisation of how these activities will be undertaken is different when working with the GP Federation, a revised statement of activities and schedule of events does not have to be submitted to the HRA. It is for the sponsor and GP Federation to locally agree who will undertake the activities required by the sponsor.

Where the practice and GP Federation do not have any contractual relationship for the GP Federation to undertake research on behalf of the practice, it remains the decision of the practice whether or not they have the capacity and capability to host the research, based on the information provided by the sponsor and GP Federation.

However, the local primary care research support function should be informed and be in a position to support arranging capacity and capability of the study, regardless of the contractual relationship between the practice and the GP Federation.

As part of HRA assessment, the Assessor will check that the Information Governance arrangements are appropriate, including the involvement of a GP Federation nurse conducting database searches. If necessary, the Assessor may request for the basis in law for such arrangements to be clarified.

## **Appendix 2 – Leaflet for Distribution**

The leaflet on the following page can be used by primary care support functions with local independent contractors, sponsors and secondary care Trusts.

It provides a summary of this document in a simple, short format, with links to this document for further information.

# HRA Approval Studies: Principles of set up of a study in Primary Care

All parties involved in primary care research should be aware of, and take note of, the seven principles below when setting up and delivering HRA Approval research in an independent contractor primary care setting.

## Principle 1

- The level at which agreement is given, and appropriately documented, for the study to be undertaken is always at the level of the participating organisation (e.g. at the level of the general practice).

## Principle 2

- The role of the primary care research support function is to assist sponsors and practices in effectively setting up and delivering studies in primary care.

## Principle 3

- Sponsors should always ensure that the relevant research support function is promptly informed about any study which will happen in the local area.

## Principle 4

- Primary care research support functions should not agree or reject a study on behalf of practices.

## Principle 5

- The Statement of Activities is agreed at the level of the participating organisation (by the practice) and not at a regional, Local CRN level (by the primary care research support function).

## Principle 6

- The HRA will make clear important information to assist in the set-up of the study in the Initial Assessment Letter and Letter of HRA Approval.

## Principle 7

- The organisational level of primary care listed in the IRAS form should be proportionate to the study.

### Further Information

For further information on the principles above with examples, please see the accompanying full length document at [www.hra.nhs.uk](http://www.hra.nhs.uk).

For local information on research in primary care, please contact your local primary care research office or Local CRN [www.rdforum.nhs.uk](http://www.rdforum.nhs.uk).

**HRA Approval** is the regulatory process for the NHS in England. In England, it replaces the need for local checks of legal compliance and related matters, followed by issue of an assurance letter by each primary care R&D Office. This allows primary care R&D offices to now focus their resources to help practices in assessing, arranging and confirming their capacity and capability to deliver the study.

### Contact the HRA

For generic queries relating to HRA Approval please contact [hra.approvalprogramme@nhs.net](mailto:hra.approvalprogramme@nhs.net).

For queries relating to the assessment of a specific study given HRA Approval, please contact [hra.approval@nhs.net](mailto:hra.approval@nhs.net).

## Change History

Version Number	Version Date	Changes
1.0	21 March 2016	Initial Release of Document
2.0	09 March 2017	Changes include: <ul style="list-style-type: none"><li>• Update to Principle 7 to reflect updates to the IRAS organisation search function for primary care organisations in England.</li><li>• Clarifications within examples</li><li>• Update of links</li><li>• Minor textual modifications throughout</li></ul>