Health Research Authority

HRA Approval: Question and Answers

This document is divided into sections to help you find the answer to your question more easily. This version has been comprehensively revised and updated.

If you have any questions not addressed, please contact hra.approvalprogramme@nhs.net. We will endeavour to answer your query and update this document.

Questions

1 Background and implementation

1.1 What is HRA Approval?

HRA Approval is the new process for the NHS in England that brings together an assessment of governance and legal compliance, undertaken by dedicated HRA staff, with an independent REC opinion provided through the UK Health Departments' research ethics service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

Although HRA Approval includes a study-wide review in line with UK wide agreed standards, the assessment goes beyond this to include new standards and assurances (for example, assessment will in due course include the coordination of clinical support assurances for pharmacy and medical exposure).

HRA Approval replaces the process of NHS Permission (also known as R&D Approval) from each participating organisation in England. Instead, the sponsor and local research team work together, supported by the R&D team and Local Clinical Research Network, to put the practical arrangements in place to deliver the study. The participating organisation can then confirm that the study can start.

1.2 What does HRA Approval include?

HRA Approval includes the REC review (where required) and an assessment. The assessment considers the following components:

- Compliance with legislation and HRA Assessment standards
- Contract assurance
- Study Delivery arrangements
- Clinical support technical assurances for pharmacy and radiation (to follow in 2016)
- HR Good Practice expectations
- The need for Principal Investigators, Local Collaborators or neither

HRA Approval provides a proportionate approach. Depending on the nature of the study and the activities at the participating NHS organisations, HRA Approval can provide assurances that mean that the organisation does not need to undertake any assessments or issue a confirmation, and will simply need to be aware of the study. For other study types, HRA Approval provides assurances about legal and regulatory compliance that means that the participating organisations can focus on assessing its ability to undertake the study, putting arrangements in place and formally confirming that the study can start in accordance with the sponsor's timetable.

The HRA assessment will confirm compliance with standard contracts, agreements and templates to improve consistency and avoid delays resulting from negotiation of sponsor-specific or site-specific preferences.

HRA assessment builds on the study-wide review previously undertaken as part of the Co-ordinated system for gaining NHS Permission (CSP). By creating a single team employed by the same

organisation that manages the Research Ethics Service in England, HRA Approval provides a consistent, holistic system that streamlines the application process and removes duplication.

1.3 Why is HRA Approval needed?

The HRA undertook a root cause analysis of reported issues and delays in current research approval systems and reviewed the areas regarded as performing well. We identified that individual components may perform well and that a number of improvement programmes had been successfully implemented through NIHR CSP, REC and MHRA. It was clear, however, that inconsistency across the NHS remains and that even across those components of the system that are functioning well there can be unnecessary repetition.

Although arrangements for coordination between regulators are in place, issues remain at the interfaces between regulatory and NHS systems. HRA Approval builds on the strengths of existing individual components but addresses itself to the whole journey of a research study, to radically streamline and simplify how studies are set up in the NHS in England.

HRA Approval addresses the concerns raised by the Academy of Medical Sciences in 2011 that led to the creation of the HRA, and the Select Committee Report on Clinical Trials in 2013. HRA Approval will make it easier to do good quality research in the NHS in England.

1.4 What are the strengths and weaknesses of the permissions process in the NHS in England?

The NHS Permissions process in England places responsibilities and accountabilities across a number of organisations. Many individual elements meet target timelines following improvements. Many local R&D staff accept assurances from the study-wide review and ethics opinion. There are, however, stages that are not currently measured where there is significant anecdotal evidence of variations, such as the time taken to submit local SSI applications.

Different parts of the system suspend timelines for different reasons, so measured timelines may meet targets but elapsed timelines across the whole journey can be lengthy. The need to coordinate parallel or sequential processes can cause delay. Even where timelines are short, there is considerable duplication of effort by applicants in providing the same information to multiple systems and responding to multiple requests for information, so there is considerable investment involved to get sites set up. Sponsors report having to adopt phased approaches to site set-up due to the work involved.

HRA has built a detailed understanding of strengths and weaknesses to inform the implementation of a new streamlined process that will radically improve the ability to deliver high quality research in the NHS in England in an efficient manner.

Back to Contents

1.5 How is this approach consistent with the Research Governance Framework that expects NHS organisations to give permission for research they host?

The Research Governance Framework recognises the importance of good management and oversight of research by organisations hosting research activity. The Research Governance Framework is written for a context in which ethical review and legal review have been undertaken entirely separately. This has resulted in NHS organisations repeating local legal and compliance reviews. For some studies, systems that coordinate permissions through a single study-wide review have addressed these issues to some extent. HRA Approval is a further radical step, which provides an integrated system of both legal and ethical review by an authoritative body, so that NHS organisations can fully rely on the assurances from the HRA.

In December 2015, The HRA and devolved administrations published for consultation a new UK Policy Framework for Health and Social Care. This provides a high level set of principles for good research management and conduct that is consistent with HRA Approval.

1.6 How and when was HRA Approval implemented? (revised 31 March 2016)

In Summer 2014, the HRA established a programme team to plan and manage the development. HRA Approval was rolled out in a controlled phased approach by study type that completed on 31 March 2016. The implementation approach meant that the process could be reviewed and revised through the implementation.

The HRA started with studies that have minimal impact on patient care and clinical services. Roll out then moved to studies in primary care where, increasingly, support for research is being offered through large geographical clusters. The next phase was introduced on 30 November 2015 to include research projects taking place within the NHS that are not a clinical trial or clinical investigation and that may have sites across the UK. From the end of January 2016, clinical trials or investigations and single site studies hosted by a sponsor were accepted to test processes in advance of full roll out for all studies in the NHS in England from the end of March 2016.

Work continues on standardising the standards and processes for technical assurances for pharmacy and radiation. These are not necessary for the initial roll out of HRA Approval, so will be rolled out separately in a controlled way across the NHS.

1.7 Am I able to submit my study for HRA Approval? (revised 26 April 2016)

From 31 March 2016, HRA Approval is the process for applying for approvals for all project-based research in the NHS led from England. This means that:

- Research described by any of IRAS filter question 2 categories (except those for “Research Tissue Bank” and “Research Database”) can apply for HRA Approval if the lead NHS R&D Office is in England.
- HRA Approval should be used wherever the project involves NHS organisations in England, where the NHS organisation has a duty of care to participants, either as service users or NHS staff/volunteers, or when the resource required for the study (i.e. data or tissue) are under the responsibility of the NHS organisation as a healthcare provider.

Back to Contents

- For any new studies that are led from outside England but have English NHS sites, the national R&D coordinating function of the lead nation will share information with the HRA Assessment team, who can issue HRA Approval for English sites and thereby retain existing compatibility arrangements.

Please refer to the applicant guidance for further information on submitting applications for HRA Approval.

Please refer to the HRA website for guidance for the review of applications for Non-NHS sites.

1.8 Will HRA Approval include studies undertaken for solely educational purposes? (revised 31 March 2016)

Yes, from 31 March 2016 HRA Approval should be sought for:

- Any educational study led from England which requires review by an NHS REC as described by GAfREC.
- Any educational study outside of GAfREC led from England taking place across more than one NHS organisation.
- Any educational study led from England that is applying for support from the NIHR Clinical Research Network (CRN)

For educational studies that are taking place at a single NHS site in England AND which do not require review by an NHS REC, it is usually the case that the NHS organisation and the University sponsoring the research will have an existing partnership and understanding about how these types of studies are handled. For these studies, there are two options depending on existing local arrangements:

- Where Universities and NHS organisations currently do not require an NHS R&D form to be submitted to the NHS R&D office but have alternative arrangements in place these may continue.
- Where Universities and NHS organisations currently do require an IRAS NHS R&D form to be submitted to the R&D office, then an application for HRA Approval should be made. A template Statement of Activities and template Schedule of Events will not be needed as there is not likely to be the need to attribute funding. Such student studies will be reviewed against the same HRA assessment standards and criteria as other studies. It is expected that the sponsor will provide any advice and support to students using this process.

NHS organisations should confirm the required approach with their partner Higher Educational Institutions.

The HRA will review this approach following the outcome of the consultation on the UK wide policy framework. The HRA has been working for some time to provide guidance on how educational studies can be undertaken to provide a good learning experience for students without impact on NHS resources.

Universities and colleges are expected to accept the role of sponsor for all educational research conducted by their own students, unless the student is employed by a health or social care provider that prefers to do this. Sponsors of educational research should ensure that their supervisors can and do carry out the activities involved in fulfilling this role.

Back to Contents

1.9 What is meant “studies being undertaken solely for educational purposes”? (new 31 March 2016)

This relates to Student studies **led from England.** Student studies are those studies being undertaken primarily for the purpose of obtaining an educational qualification. Studies funded as part of wider grant funding where the main purpose is to undertake the specific research and the educational qualification is secondary do not come into this category.

1.10 How are single NHS sites where the site is also the sponsor handled? (revised 31 March 2016)

During the early phases of the roll out HRA Approval single NHS site studies where that site was also the sponsor were excluded whilst the HRA sought feedback from NHS sponsors about proportionate arrangements for managing these studies. These studies are now included in HRA Approval. There is no requirement for a Statement of Activities or Schedule of Events for these studies as the sponsor is expected to have considered the implications for the organisation hosting the study as part of the study development process.

Where a partner university wishes to sponsor a study taking place solely at a local NHS organisation, and there are agreed joint arrangements in place between the institutions, it will be for the NHS organisation to determine whether it has acquired the relevant information during the funding and protocol development stages of the study, and therefore does not require a Statement of Activities or Schedule of Events. The NHS organisation should provide written confirmation that it does not require these documents for the sponsor to provide as part of the application to the HRA. This would not include those studies with PIC activities at another site (a statement and schedule would be required to cover the PICs)

1.11 Is HRA Approval required for Research Tissue banks and Research Databases? (new 31 March 2016)

No, HRA Approval applies only to specific project based research studies, so Research Tissue Banks and Research Databases are excluded from HRA Approval. These can continue to be set up as they are now.

HRA Approval may apply to any specific studies using tissue from Research Tissue Banks, or data from Research Databases.

1.12 What if my research is using NHS facilities or equipment, but there is no duty of care by the NHS? (new 26 April 2016)

HRA Approval only applies where the NHS has a duty of care to participants, either as service users or NHS staff/volunteers, or when the resource required for the study (i.e. data or tissue) are under the responsibility of the NHS as a healthcare provider. It does not cover studies due solely to the involvement of NHS staff as researchers or use of NHS facilities.

Back to Contents

Where NHS organisations agree to the use of their staff and resources in research scenarios outside their role as an NHS provider, whether these are their own studies or the studies of their partner organisations, it is expected that universities and NHS organisations collaborate appropriately to the nature of the interaction, eg agreement to use a specific piece of NHS equipment. NHS indemnity may not apply.

1.13 Would it be correct to say that HRA Approval is REC and R&D approval rolled into one?

This is true to an extent; those issues that can be looked at once for a study will be brought together into an assessment and an independent ethical review. A number of critical aspects of local R&D activity will however remain the responsibility of the NHS organisation, i.e. working with the sponsor to ensure that the site is suitable for a study and putting the arrangements in place to set up and oversee delivery.

1.14 Will HRA Approval satisfy the REC expectation for NHS Management Permission to be in place?

Under previous arrangements, the favourable ethical opinion has been conditional on obtaining NHS Permission at sites. For clinical trials of investigational medicinal products, the ethics committee is required to consider the suitability of the investigator and supporting staff and the quality of the facilities for the trial. In the UK this consideration, called site-specific assessment, is delegated to the NHS for NHS sites.

HRA Approval provides assurances to participating NHS organisations about the legal and regulatory compliance of the study. NHS organisations in England remain responsible for agreeing with the sponsor that the investigator and supporting staff, and the facilities for the trial are suitable.

The organisation will confirm through exchange of the relevant agreement that it has the capacity and capability to participate in the study, and roles and responsibilities have been agreed, as evidence that the requirements of the clinical trial regulation are met. For other studies, the proportionate arrangements provided through HRA Approval mean that confirmation from the NHS organisation is not expected for certain study types, and the organisation will be assumed to participate in the study unless an objection is raised within a specified time limit.

Each NHS organisation must confirm through the signing of agreements and/or other documents that it has confirmed that the research can proceed (except where explicitly specified otherwise).

1.15 Will HRA Approval be compatible with the implementation of the new EU clinical trials regulations?

Yes, HRA Approval will provide a foundation for the implementation of the new European Clinical Trials Regulation in 2018 and the HRA will continue to work the MHRA and with colleagues in the devolved administrations to support a UK-wide framework for review. The Regulations will require greater integration of decision-making by the Member State Competent Authority (MHRA in the UK) and REC, along with site suitability assessment, with specific timeframes for all elements of the process.

Back to Contents

This will provide UK readiness for the regulatory changes and provide reassurance to industry that the UK is ready to adopt the changes and that they can continue to place trials in the UK with confidence.

1.16 How will the implementation of HRA Approval be coordinated with the NIHR CRN?

NIHR CRN will continue to have the lead role for supporting delivery of research within the CRN portfolio through local NHS organisations. Removing duplication of effort currently seen in local approvals will enable a greater focus for the CRN on delivery. The CRN's Study Support Service is aligned with the arrangements for HRA Approval.

2 Benefits

2.1 How will HRA Approval benefit researchers?

Researchers will benefit from the elimination of duplicate application routes and a reduction of paperwork, shortening the time to complete the overall approvals process. This will enable researchers to set up studies more quickly and efficiently, and work on establishing research sites, recruiting participants and completing studies on time.

2.2 How will the HRA ensure there truly is efficiency and that all duplicate assessment and requests for information will be taken out?

HRA Approval is based on a single application package to the HRA for both HRA assessment and independent REC review, which removes the duplicate upload of documents in IRAS.

HRA Approval incorporates assessments currently undertaken in study-wide review and the multiple local R&D reviews and includes the independent Research Ethics Committee opinion.

Having a central assessment team employed within the HRA alongside the staff who support the REC service in England means that staff can coordinate the review of the application, rather than applicants having to navigate between the different review bodies. This reduces the complexity of the approvals process significantly.

The HRA take accountability for the assessment and approval of the study, including accepting responsibility for regulatory inspection findings relating to HRA Approval. The sponsor is provided with the outcome of both the HRA's initial assessment of the study and the final HRA Approval. The sponsor is expected to share this information with the NHS participating organisations in England, so that they can quickly identify the issues that are being (at initial assessment) or have been (at HRA Approval) resolved by the HRA. NHS organisations also have a route through the HRA for escalation of any concerns about the assessment. This will remove the perceived need of individual NHS organisations to review all aspects of the study to suit their local interpretations of legal compliance.

The Care Act 2014, which established the HRA, sets out an expectation on NHS organisations in England to have regard for the HRA's guidance. This includes the guidance about accepting assurances without unnecessary duplication.

Back to Contents

2.3 How will HRA Approval benefit NHS organisations hosting research?

HRA Approval will allow local research teams to focus on the set up and delivery of studies at NHS organisations. The removal of duplicate checks will free up time for NHS support staff and managers to undertake more front line clinical delivery and support more research studies. NHS R&D and LCRN staff will be released from dealing with checks at a local level, allowing them to concentrate on developing and assessing capacity and capability, enabling the successful delivery of research.

2.4 How will HRA Approval benefit sponsors – commercial and non-commercial?

Both commercial and non-commercial sponsors will benefit from reduced complexity and increased consistency. With less time spent negotiating multiple permissions processes, sponsors should be better placed to focus on ensuring that potential participating organisations have the capacity and capability to deliver the study to time and target.

3 HRA Approval process

3.1 What will applicants need to do differently to work with HRA Approval?

Applicants will need to be ready to submit a complete application package to the HRA ready for proceeding through the whole approvals process. Although there is very little difference between the REC and R&D forms on IRAS, many applicants apply for REC review well before they are ready to set up sites, resulting in protocol amendments when practical details of conducting the study are developed after REC approval. Because of the single application, the overall elapsed time to get all sites set up will be shorter and more predictable.

Applicants should ensure that they are prepared at application for both assessment and REC review. This does not meant that the sponsor must set up sites in parallel to HRA Approval.

However, the full benefit of reduced timelines through the study set-up process will be achieved by engaging with NHS organisations early to ensure the study is fit for assessment.

Applicants of non-commercially sponsored studies should complete a Statement of Activities and Schedule of Events for each type of site planned for the study. We are testing these documents for use with NHS organisations in England, as ways to improve the clarity provided to sites about funding and study activities in order to address the current difficulties many researchers encounter with multiple queries from participating NHS organisations.

Applicants of commercially sponsored studies should provide the HRA with an NIHR Industry costing template validated by the NIHR CRN.

3.2 What is a valid application to HRA? (revised 31 March 2016)

An application for HRA Approval looks similar to the previous REC and R&D applications. An IRAS form (combined REC and NHS R&D forms) should be submitted electronically in IRAS alongside a checklist of documents for the assessment and REC review.

Back to Contents

The documents include all those currently submitted for REC review plus information on funding, costs and draft agreements. For non-commercially sponsored studies, this includes a Statement of Activities and Schedule of Events for each type of site included in the study. For a commercial study, this includes the template trial agreement, a validated Industry Costing Template and the template delegation log.

The documents submitted to the HRA should be the generic template versions, not the versions with site-specific details.

3.3 How do I book onto REC under HRA Approval? (new 31 March 2016)

Applications for HRA Approval are booked through the Central Booking Service (CBS), just as is the case for booking a submission to REC. When you book an application for HRA Approval via CBS (Central Booking Service), you will be asked if you want your study to be reviewed by REC as part of the review of your application for HRA Approval. You are still free to request review by a specific REC if you wish. Of course, requesting review by a specific REC may delay processing of your application, depending on availability of meeting slots at the REC of your choice. HRA Approval cannot be issued until the REC favourable opinion is in place and any conditions are confirmed as being met.

3.4 How and when will an application be validated?

Once it has been submitted electronically from IRAS to the HRA, the study will be validated for REC review according to the usual UK-wide SOPs, and an initial assessment will be undertaken. You will receive the usual letter when your application is confirmed as valid for REC review. The outcome of the initial assessment, including information to support site set-up, is sent separately. If we have queries during this time that are not responded to promptly, this may lead to delays in the initial assessment. If an application is valid for REC review but has significant issues for assessment, we will inform you and encourage you to withdraw the application for HRA Approval. Although this may mean re-booking your application for REC review, it could avoid the need for amendments and therefore save time later on.

3.5 When do I receive my REC validation letter and when do I receive my Initial Assessment letter? (New 26 April 2016)

HRA Approval is a coordinated process that includes an assessment of compliance with regulations and other standards, alongside an independent Research Ethics Committee opinion (where applicable). Although a single application is made for HRA Approval, this application is first validated for Research Ethics specific purposes, according to agreed UK wide SOPs that, where applicable, ensure compliance with clinical trial legislation. This is in addition to the initial assessment of the application by the HRA assessment team. It is therefore possible that an application may be valid for REC but that insufficient information has been provided for an initial assessment to be completed (e.g. where no Statement of Activities or HRA Schedule of Events has been provided for a non-commercial study, or no Industry Costing Template for a commercially sponsored study).

Back to Contents

Applicants should expect to hear as to the validity of their application for REC within 5 working days (2 working days for studies submitted for proportionate review). This may be confirmation that the submission is valid, invalid, or that further information is being requested. In any case, the applicant should expect to receive an update as to the status of the initial assessment at the same time or shortly thereafter. Where an application is valid for REC purposes and the initial assessment is complete, both notifications will be sent under the same cover within the 5 days. If the application is valid for REC but further information is outstanding for assessment, this will also be ommunicated. An initial assessment letter will not be issued until the complete document set for HRA Approval purposes has been received, even where the application is already valid for REC.

To ensure that the REC validation and Initial Assessment Letter can be issued in a timely fashion and avoid delays, it is important that the applicant, or knowledgeable representative, is available to answer any queries during the initial assessment. The Initial Assessment Letter may therefore be issued at the same time as the REC validation letter or afterwards, depending on when all the necessary information has been provided.

3.6 What happens if the HRA Assessment team make recommendations for changes to documents after the REC meeting is booked? (new 31 March 2016)

The HRA Assessment team may identify that changes are needed to the documents which have been submitted to the REC. The applicant will be informed of these required changes, and may discuss them with the REC at the meeting. This may mean that an opinion that would previously have been provisional could instead be a favourable opinion with conditions.

Where an application raises significant issues in relation to set up and delivery in the NHS, HRA will offer the applicant the opportunity to withdraw and re-submit once the issues have been addressed. This will help the applicant to achieve the maximum benefit from HRA Approval. We know that under current arrangements, studies that complete the REC review process when there are still outstanding issues relating to engagement with the NHS often can require significant amendment after the REC favourable opinion and thus get delayed at site set-up.

In some cases, in order to satisfy the assessment standards the applicant may have to submit amendments to the REC after the favourable opinion has been issued and prior to HRA Approval being issued.

3.7 Does a submission for HRA Approval also cover applications to all other applicable regulators (e.g. the MHRA)?

No. However, when the new EU Clinical Trials Regulations are introduced, separate applications to the HRA and MHRA will be replaced by a single application, so HRA Approval provides a first step in preparing for the Regulation.

HRA Approval provides a single approval for research in the NHS in England that replaces the need for application for an R&D study-wide review and separate applications to individual NHS organisations in England. It also includes the independent Research Ethics Committee opinion. Although the assessment will confirm that all regulatory approvals are in place, there will remain a separate submission via IRAS to the MHRA where their review is required.

Back to Contents

3.8 Will HRA Approval cover non-portfolio research?

Yes, HRA Approval will provide a single approval system for all research for the whole NHS in England. It will therefore apply to non-portfolio research as well as NIHR CRN portfolio research.

3.9 Do studies that wish to apply for support from the NIHR Clinical Research Network apply to NIHR CSP as well as HRA Approval?

No, HRA Approval replaces the current NIHR Coordinated System for Gaining NHS Permission (CSP). If an applicant wishes to apply to have their study included in the NIHR CRN portfolio, they should complete and submit a Portfolio Application Form in IRAS to the NIHR CRN. A decision on portfolio eligibility will be made by NIHR CRN. For studies where the project filter indicates that the applicant is applying for support from the NIHR CRN, the HRA will provide the NIHR CRN with information from the application to the HRA to determine portfolio eligibility.

3.10 How does HRA Approval work for English sites if the study is reviewed by a REC in Scotland, Wales or Northern Ireland? (updated 26 April 2016)

The UK Health Departments' Research Ethics Service is UK-wide and studies for HRA Approval can be reviewed by a REC in any UK nation. The outcome of the REC review will be available to the HRA Assessment team through the information system used by all NHS RECs.

3.11 Do studies led from a devolved nation (Northern Ireland, Scotland or Wales) need HRA Approval? (updated 26 April 2016)

There is no change to how applications are made for studies where the lead NHS/HSC R&D office is based in a Devolved Administration. An NHS/HSC R&D application to the permissions coordinating function in the relevant devolved administration should be made according to their instructions and a REC application should be submitted.

If a study has NHS sites in England, there is no need to separately apply for HRA Approval in IRAS as well as applying to the devolved nation R&D system. We have agreed systems for compatible UK-wide working with Northern Ireland, Scotland and Wales. If a study with English sites is led from one of the devolved administrations, the application and study wide review will be shared with the HRA in line with processes agreed across the UK so that HRA Approval can be issued for England, without duplication of application or review.

On receipt of the application from the permission coordinating centre in the devolved nation, the HRA will undertake assessment of the areas not addressed in the study-wide review (these are termed nation-specific checks). For sponsors in the Devolved Administrations, the HRA will facilitate the completion of any information requirements in England in order to review the study and will confirm with the sponsor that the information is correct.

If NHS organisations in England are added after the initial application, the lead nation will identify this when the amendment is submitted to the lead permissions coordinating function. They will then share the application and outcome of the study-wide review with the HRA at this stage.

Back to Contents

3.12 If my study is led from Northern Ireland, Scotland or Wales, how do I work with sites in England? (revised 26 April 2016)

The HRA are testing new ways of working with NHS sites in England to set up research. Feedback is welcomed to hra.approvalprogramme@nhs.net.

As part of the roll out of HRA Approval in England, operational and policy leads from the 4 Nations have worked closely to ensure compatibility of NHS research approval systems across the UK.

As part of this, over the next 6 months, the 4 Nations have committed to review the information required for study approval/confirmation of capacity and capability at the local NHS site level. This is with the aspiration of coming to a common UK position, that supports the timely set-up of studies and that meets the needs of sponsors, research sites, NHS patients and service users.

This review will be facilitated through a series of workshops involving operational and policy leads from across the UK. Until further UK-wide guidance on local information can be agreed and issued, the interim position for management of local NHS site information is as follows:

- Site Specific Information (SSI) forms will continue to be used for setting up studies in the devolved administrations (DAs).
- The above includes research studies that are sponsored/led from England with research sites in a DA, where the DA will continue to use SSI forms.
- Where research studies are sponsored/led from a DA with sites in England, the HRA will accept SSI forms.
- For DA-led studies, the HRA Approval team will facilitate the completion of any additional information requirements in England in order to review the study and will confirm with the sponsor that the information is correct.
- Sponsors from a DA (or authorised delegates) are advised to contact the HRA at the earliest opportunity so that the HRA Approval team can facilitate the review of the research study for English sites.

Sponsors from a Devolved Administration (or authorised delegates) setting up research sites in England are advised to contact the HRA hra.approval@nhs.net at the earliest opportunity so that the HRA Approval team can facilitate the review of the research study for English sites.

3.13 How does HRA Approval work if the study is led from England but has sites in Northern Ireland, Scotland or Wales? (revised 26 April 2016)

HRA Approval does not apply to sites in Northern Ireland, Scotland or Wales. We have built on the existing compatibility arrangements, which mean that assurances provided by one country are accepted across the other countries in the UK.

Where England is the lead nation, the applicant should submit the combined IRAS Form by e-submission to the HRA. When booking the application to the HRA, any appropriate REC in the UK may be selected.

Back to Contents

The application and the outcome of HRA assessment will be shared by the HRA with the relevant permissions coordinating centres in line with processes agreed across the UK so that they can undertake any nation-specific checks, without duplication of application or review.

If NHS organisations in Northern Ireland, Scotland or Wales are added after the initial application, the HRA will identify this when the amendment is submitted. The HRA will then share the application and outcome of the assessment with the relevant permissions coordinating function at this stage.

3.14 If my study is led from England, how do I work with local sites in Northern Ireland, Scotland or Wales? (revised 26 April 2016)

There is currently no change to how researchers work with local sites in the Devolved Administrations not matter where the lead NHS/HSC R&D office is based.

The applicant should create and transfer NHS Site Specific Information (SSI) Forms to local research teams for each NHS/HSC site in Northern Ireland, Scotland or Wales. These should then be submitted with accompanying documents for each R&D office in accordance with the instructions from each nation, in addition to the provision of study documents to the local research team as per nation specific guidance.

As part of the roll out of Health Research Authority (HRA) Approval in England, operational and policy leads from the 4 Nations have worked closely to ensure compatibility of NHS research approval systems across the UK.

As part of this, over the next 6 months, the 4 Nations have committed to review the information required for study approval/confirmation of capacity and capability at the local NHS site level. This is with the aspiration of coming to a common UK position, that supports the timely set-up of studies and that meets the needs of sponsors, research sites, NHS patients and service users.

3.15 Will HRA Approval cover non-NHS sites in England?

Initially HRA Approval applies to NHS organisations in England. In due course, we will include arrangements for research involving NHS care delivered through charity or commercial providers. In the meantime, these providers should continue to request site-specific assessment by the REC.

When HRA Approval is running successfully for research within the NHS, we will consider potential solutions for other care related settings. In the meantime, we are undertaking separate work to address some of the complexities faced within specific settings such as care homes and hospices.

3.16 Will the HRA maintain a document store for NHS organisations hosting research to access?

Documents submitted to the HRA will be stored in our internal information system for use during the REC review and HRA assessment. As currently, it will remain a sponsor responsibility to ensure that the local study team is provided with the local information package.

Back to Contents

Study documents should be provided by the applicant simultaneously to: the local research team, research management staff supporting research in the organisation, and, when the study is part of the NIHR CRN Portfolio, the Local Clinical Research Network (LCRN). The sponsor (or their delegate) should provide these documents by email or any secure document transfer system they wish to use.

HRA does not provide a document store or document distribution function for NHS R&D offices, as previously provided through NIHR CSP, because HRA Approval removes the requirement for a separate application to NHS R&D offices in England. It should be noted that CSP was not a mechanism for distribution of documents to local research teams.

The HRA Approval letter will confirm the documents (and versions) reviewed and approved by the HRA. The HRA has provided NHS organisations with access to the HRA Approval Portal. The HRA Approval Portal is a web-based portal, containing details of studies involving the NHS, which enables NHS organisations to check the HRA Approval status of a study in which they are participating. It provides visibility of the HRA Initial Assessment and HRA Approval letters, including the version numbers of approved documents.

3.17 What happens if some sites continue to ask for additional information?

If researchers have any concerns they should, in the first instance, discuss these with the local research management team at the site. If there is no resolution, researchers will be able to address concerns directly to the HRA through hra.approvalprogramme@nhs.net.

3.18 What happens if the HRA make a mistake in their Approval? If a sponsor or site is inspected by MHRA who will be blamed if the site accepted HRA Approval without checking it? (revised 26 April 2016)

The HRA indemnifies NHS research sites accepting assurances from the HRA against any claim covered by NHSLA arising as a result of incorrect assurances.

The MHRA will inspect a sponsor or research site proportionately against relevant information and against the Standard Operating Procedures in place.

Sponsors and sites should ensure that processes and procedures are updated to reflect the fact that the organisation is using the assessment provided within HRA Approval.

The HRA, in issuing HRA Approval, are confirming certain arrangements are in place to allow a study to commence.

We are working with the MHRA (and other regulators) to ensure that HRA Approval is compliant with their respective regulations. In relation to a regulatory inspection, we will accept responsibility for any findings in relation to the HRA Approval itself.

This applies for both for studies where the original application has been for HRA Approval and to studies originally set up in pre-HRA Approval systems which are subsequently issued with HRA Approval.

Back to Contents

3.19 What safeguards will be in place to ensure researchers do not start studies once HRA Approval has been issued, without first having obtained local agreement to do so?

While HRA Approval will be the single approval for research in the NHS in England, there is still an expectation that researchers will engage with sites and that sites will confirm that they have all the arrangements in place in order to participate in the study. Sites confirm all arrangements are in place through execution of a trial agreement or agreement to the Statement of Activities by an appropriately authorised person from the organisation.

HRA Approval provides a proportionate approach to study set-up. There are therefore some study types for which the HRA will advise that there is no obligation for participating organisations to confirm their capacity and capability to participate. The sponsor may assume their confirmation after a set time period if no objection is made. This will apply in situations where the impact of the study on the organisation is minimal or for urgent public health studies where time is of the essence and the NHS is expected to respond. In circumstances where this applies, it will be clearly stated in the HRA Approval Letter and all sites to which it applies will be directly notified by the HRA, ensuring that they have the opportunity to consider opting out of the study if appropriate.

4 HRA assessment

4.1 Do I need to have localised versions of all my documents before I submit to HRA?

No. The applicant should only provide HRA with the template versions of agreements, participant information, Statement of Activities etc. Once the HRA's Initial Assessment letter has been sent to the applicant, it can be added to the local information pack along with any additional local information that the sponsor knows. The sponsor and the participating organisation will then agree any additional local information and arrange practical aspects such as adding local headers to participant information. Please see HRA guidance on site set-up for more details about each step in the process for working with participating organisations.

4.2 Why does the Industry Costing Template need to be validated before submission to HRA?

We anticipate that companies will be contacting CRN early by submitting the Portfolio Application Form in order to receive support for study set up and, in parallel, get the Industry Costing Template validated. The validation process can be undertaken in parallel to completion of the IRAS Form.

The HRA Assessment team would not be able to complete the initial assessment until the Costing Template is validated. This is because the initial assessment letter confirms that sites can start to put local arrangements in place. We feel that the approach of undertaking the validation in parallel to completion of the IRAS Form will therefore make the overall process quicker for sponsors. The CRN have agreed a target of 3 working days for this validation.

Where a non-portfolio commercial study is received for review, the Industry Costing Template will be validated by our Assessment team.

Back to Contents

4.3 How will the HRA alleviate current delays with contracting at individual sites?

Universities and NHS sponsors report significant resource investment in contract negotiation with individual sites. The HRA assessment will include confirmation of compliance with standard template agreements. This will mean that for applicants complying with the national standards there will be no delay to wait for local negotiation. In addition, the HRA provides clear standards for the provision of information relating to costing and local resource requirements, avoiding debates about the accuracy of financial information. The HRA will collaborate with Academic Health Science Networks and Clinical Research Networks to facilitate agreement where non-compliance is identified.

The HRA will not negotiate contracts, site agreements or costs on behalf of individual sites. However, a number of Academic Health Science Networks and Clinical Research Networks already offer a single costing and contracting model, and others are developing this service.

The HRA is also supporting the review of the model agreements, to minimise time spent in negotiating variations that have developed over time. The ABPI is working with its members on a revision of the model Clinical Trial Agreement. Views on the draft revision have been sought from NHS organisations to support discussions with the ABPI with the intention of agreeing a new version. Alongside this work, the HRA has also been working with non-commercial stakeholders to update the mNCA.

4.4 What is happening about pharmacy and radiation technical assurances?

We continue to take forward the roll out of the pharmacy and radiation technical assurances. At the moment, HRA Approval for studies involving pharmacy and radiation can proceed using the existing processes. Once we are in a position to make the technical assurances available to all studies, there will be additional advantages in terms of efficiency and removal of duplication.

4.5 The pharmacy manual is never available at the stage when we need to submit to HRA. Can I get a pharmacy assurance without it?

Where a pharmacy manual is available, it should be provided for the pharmacy technical assurance process. Experience so far indicates that information to support pharmacy technical assurance can be gleaned from the protocol and IRAS Form, although it is more likely that additional information may need to be requested from the sponsor if all the relevant information is not yet captured in a pharmacy manual.

4.6 Will HRA Approval cover IRMER and ARSAC issues?

It is the intention that HRA Approval will, in due course, include a single radiation technical assurance building on the current system for lead reviews in IRAS. Local IRMER procedures will still need to be carried out to meet legal requirements, but the technical assurance will reduce local duplication and local queries.

The HRA is working with the radiation professions and with ARSAC to revise guidance, create a coordinated process, and simplify ARSAC arrangements

Back to Contents

4.7 What is the procedure for completion of the radiation section of the IRAS form for studies with radiation exposure? (new 31 March 2016)

We plan to roll out a standard coordinated system for radiation technical assurances. This will not be in place from the end of March, so in the meantime applicants should continue with the existing process.

The new process builds on the existing arrangements for radiation authorisations in IRAS, but will use a panel of trained reviewers and will be coordinated by the HRA. The outcome of the technical review will be that the local IRMER review (required by law) can be undertaken swiftly as duplicate local activity will be removed by the standardised process.

We are working with ARSAC to revise the arrangements for ARSAC licences. In the meantime the ARSAC process remains the same

4.8 Why does HRA Approval include a radiation assurance? Doesn't this duplicate the REC and ARSAC review?

The radiation technical assurance process is designed to improve and coordinate the existing arrangements for obtaining information about radiation to support the REC review of the risks and benefits to participants. It is therefore important that this step takes place prior to REC review to ensure that the REC review is supported by the relevant expert advice. The new arrangements focus on standardising the content of the review, including addressing the factors that currently lead to variation and duplication of local radiation review at site level. The ARSAC process draws on this information as well, but reviews separate issues. Furthermore, the standardisation and informationflows that are being established through the radiation technical assurances will allow significant developments to the ARSAC process to be taken forward, which will further simplify and streamline the arrangements for studies involving the administration of radioactive substances.

4.9 Will sites still need to do a local IRMER review and apply for local ARSAC licences? (new 31 March 2016)

Yes, local IRMER review is required by law. The outcome of the technical review will be shared so that the local review can be undertaken swiftly without duplication, removed by the standardised process.

We are working with ARSAC to revise the arrangements for ARSAC licences. In the meantime the ARSAC process remains the same, and local licences will continue to be required.

4.10 How do I create local ARSAC forms in IRAS? (New 26 April 2016)

ARSAC forms are created for each research site in IRAS through Part C. To create an ARSAC form for each of the sites:

- Add the NHS research site in Part C, using the organisational search field to copy the data for the research site.
- Add in the PI details
- Press the tab "create SSI form".

When you return to the navigation page an ARSAC form will be visible which can then be transferred to the site for completion.

Back to Contents

Whilst this process does create an SSI form, please note SSI forms are no longer required for NHS sites in England and should not be transferred or submitted to sites.

4.11 Will HRA Approval guarantee compliance with Data Protection legislation?

Currently individual NHS organisations and their staff interpret the requirements of data protection legislation and information governance codes of practice in different ways. This results in unacceptable levels of variation in expectations placed upon researchers. We are undertaking work with information governance professionals to ensure that there are clear agreed standards and guidance against which the assessment will be undertaken, allowing an appropriate assurance to be provided to NHS organisations. This will ensure that NHS organisations will be able to accept that HRA Approval addresses data protection compliance and therefore will not need to ask further questions or require completion of additional local forms. The HRA recognises the importance of NHS organisations being aware of the use of patient identifiable information.

4.12 Does HRA Approval require companies to use the Master Indemnity Agreement for equipment?

HRA does not require sign-up to the Master Indemnity Agreement (MIA). We do expect clarity on indemnity arrangements (e.g. MIA or other arrangements). Further discussions on how the HRA can facilitate clarity are ongoing, including with the ABPI group looking to update the mCTA template, and more discussions are planned with the MIA on how the MIA can facilitate clarity of their arrangements and expectations.

4.13 What does it mean if the HRA assessment concludes that 'no confirmation of capacity or capability' is required by NHS sites in England? (new 31 March 2016)

HRA Approval provides a proportionate system across the NHS, by clarifying the processes appropriate to individual studies, based upon the impact of a study on participating NHS organisations. The Initial Assessment letter will formally confirm what level of assessment of capacity and capability is expected by host organisations (by site type), the likely extent of any arrangements and key considerations for confirming capacity and capability. Examples are given in the HRA assessment criteria and standards.

In some instances where there are minimal arrangements to be put in place or, in the case of urgent public health studies there is an assumption that NHS organisations will participate in the study, there will be no requirement for sites to confirm capacity or capability. The HRA will inform NHS participating organisations via the contact listed on the R&D Forum website for studies where this applies. The HRA will provide them with the Initial Assessment letter or HRA Approval letter, statement of activities and schedule of events. Provided HRA Approval is granted, if the sites do not raise an objection within 35 days (or as stated in the letter) the study may commence.

Back to Contents

4.14 What if sites ask for further information for studies not requiring confirmation of capacity and capability? (new 31 March 2016)

The Initial Assessment letter will indicate if any further study documentation is required to be sent by the sponsor to sites. NHS organisations must have regard for the HRA guidance. The sponsor should inform the HRA if sites request further information.

5 Amendments

5.1 If a study is amended in any way during the HRA Approval process, how will sites be made aware of the changes in order to assess if capacity and capability needs to be reconsidered?

The HRA will work with investigators and sponsors to improve the quality of applications before they are submitted for HRA Approval, minimising the need for amendments during the HRA Approval process. Currently applicants are not allowed to make significant changes to a submitted application before the REC has issued an initial opinion; this will remain the case under the HRA Approval process.

However, before HRA Approval is issued, the assessment team may request an amendment to make the study compliant with the HRA assessment criteria and standards. Applicants are expected to inform sites of any amended documents and to send sites the HRA Approval letter listing the approved documents.

5.2 Will the HRA review and categorise amendments and reissue an updated HRA Approval?

Yes, we will review and categorise amendments using the UK-wide amendments process as A (requiring consideration by all participating organisations), B (requiring consideration by some participating organisations), or C (not requiring consideration by participating organisations). Once categorised, we will issue this categorisation to the sponsor. The HRA assessment team will undertake a review of the amendment and a letter of continued HRA Approval will be issued to the sponsor.

This categorisation is distinct from defining whether an amendment is substantial or non-substantial. The categorisation applies to all amendments and is used to determine whether the participating organisation has an opportunity (within 35 days of receipt by the organisation) to raise an objection to implementation of an amendment due to local considerations (category A or B), or whether the sponsor may implement the amendment within their own timescales once any relevant regulatory approvals are in place (category C).

Back to Contents

5.3 What are the arrangements for adding sites to studies that have HRA Approval? (New 26 April 2016)

To add new sites which were not listed in Part C of the original application to studies with HRA Approval, the applicant should submit an amendment to add the site.
For studies led in England:

- For CTIMPs applicants only need to submit a *substantial* amendment adding the new site to the relevant NHS REC. The amendment will be accessed by the HRA Assessment Team for categorisation and the category communicated to the applicant.
- For all other study types, a *non-substantial* new site amendment should be sent to hra.amendments@nhs.net. The amendment will be categorised by the HRA Assessment Team and the category communicated to the applicant.

Prior to the submission of the amendment, applicants should provide the final protocol to sites for them to assess capacity and capability. Once the amendment has been submitted, the local package can be sent to site including the previously issued HRA Approval letter. The site must not confirm their capacity and capability to undertake the study until the amendment has been confirmed and categorised.

5.4 What are the arrangements for adding sites to studies that are going through HRA Approval? (New 26 April 2016)

If your study is currently going through the HRA Approval process you may not make amendments to add new sites not listed in Part C of the original application until the REC review is complete. To enable site processes to be undertaken in parallel, the applicant should send the local document package to the new site once the initial assessment letter has been provided. The new site will need to wait for both the HRA Approval and the appropriate amendment approval and categorisation before the site confirms capacity and capability to undertake the study.

These arrangements apply whether you are applying for HRA approval for a new study, or requesting HRA Approval for a study that was processed through previous systems.

5.5 What are the arrangements for amendments for studies reviewed under previous systems? (new 31 March 2016)

From 31 March, amendments for **all** English-led studies taking place in the NHS will be categorised on behalf of the NHS by the HRA in line with the **UK Process for Handling UK Study Amendments**. This includes HRA Approval and pre-HRA Approval studies. Amendments can no longer be submitted to NIHR CSP. The UK NHS amendment categorisation process provides information to NHS sites about whether the amendment may require consideration prior to implementation, and is in addition to the definition of substantial or non-substantial for regulatory purposes.

For studies led in England:

- Applicants only need to submit *substantial* amendments to the relevant NHS REC (where REC review is required for the study type). They will also be accessed by the HRA Assessment Team for categorisation and the category communicated to the applicant.

Back to Contents

- *Other* amendments which do not need to be submitted to an NHS REC should be sent to hra.amendments@nhs.net. They will be categorised by the HRA Assessment Team and the category communicated to the applicant.

The HRA will categorise the amendment and inform the applicant within 5 days. The applicant can then send the amendment and the categorisation information to participating NHS organisations so that, where necessary, arrangements can be put in place to continue the site's capacity and capability to deliver the study. It is the applicant's responsibility to communicate the categorisation and the amendment to English sites (ie the local research team, the R&D office (and the LCRN, where appropriate)).

For studies where the lead NHS R&D office is in Northern Ireland, Scotland or Wales there is no change to the handling of amendments. Compatibility arrangements are in place across the 4 UK nations and amendments are categorised by the lead nation and shared across participating UK nations.

Amendments for studies set up using pre-HRA Approval processes are submitted in exactly the same way as HRA Approval studies. Where the amendment introduces a new site for a HRA Approval study the HRA Assessment Team will ask for confirmation of the most up to date document set and the template agreements and costing information that will be used when working with the new site.

5.6 How should sites be informed about amendments? (New 26 April 2016)

Once the amendment has been categorised by the HRA, the HRA notifies the applicant who is then responsible for notifying sites of the amendment.

For category A, the applicant should send the categorisation email from HRA together with the amended documentation, to the research management support offices **and** local research teams at your participating NHS organisations in England. The organisation will then make the necessary arrangements to implement the amendment.

For category B, the applicant should send the categorisation email from HRA together with the amended documentation, to the research management support offices **and** local research teams at the relevant participating NHS organisations in England. These organisations will then make the necessary arrangements to implement the amendment.

For category C, the participating organisations do not need to put any arrangements in place for the amendment. However the local research team still need to be aware of the amendment so the applicant should send the categorisation email from HRA together with the amended documentation, to the to the research management support offices **and** local research teams at the participating NHS organisations in England.

The HRA provide a template email for the applicant to use to share the amendment information and categorisation with sites – this explicitly states who should receive the email and be copied in. The applicant is provided with a copy of this template when the categorisation email is issued.

Back to Contents

6 Arrangements for studies underway (pre HRA Approval studies)

6.1 Can I continue to make applications to NIHR CSP? (new 31 March 2016)

No. R&D form and amendment applications to NIHR CSP closed on 23 March 2016. SSI applications closed on 29 March 2016. Any applications submitted before those dates will continue to be processed using NIHR CSP.

For non-portfolio studies, NHS organisations in England ceased accepting applications on 30 March 2016.

6.2 What happens for studies part way through review after 31 March 2016? (new 31 March 2016)

If an SSI form has been submitted prior to the end of March, the R&D team will issue NHS Permission under the previous systems.

After 31 March, if an application for an NHS participating organisation in England has not yet been submitted for review under previous systems, it will be set up in accordance with the HRA Approval site level processes. This means that the HRA will issue HRA Approval for the NHS organisations in England to provide assurance that the study is legally compliant, and the NHS organisation can then assess, arrange and confirm its capacity and capability to take part in the study.

6.3 Is a new application required to bring a study under HRA Approval to add new sites?

From 31 March all studies that have started or completed existing approvals processes but want to set up new NHS sites in England will need to complete the set-up of those sites through HRA Approval systems. This does not mean that the study has to start again and apply for HRA Approval: actions already completed in existing systems will be accepted. New sites should be set up in accordance with the HRA Approval site level processes. This means that the HRA will issue HRA Approval for the NHS organisations in England to provide assurance that the study is legally compliant, and the NHS organisation can then assess, arrange and confirm its capacity and capability to take part in the study.

6.4 Do I need to revalidate an industry costing template if I want to add new sites and bring under HRA Approval? (new 26 April 2016)

No, we are not asking that you update your NIHR Industry Costing Template (ICT), nor that you have this revalidated. Instead, we would ask that you provide to us your originally validated ICT (where one exists – e.g. for NIHR CRN portfolio studies), with your current document set, when you make your request to bring your study under HRA Approval to add new site/s. Where changes to the study mean that the ICT no longer reflects the activities to be undertaken, we would ask that you include a very brief description of these changes as a cover note. We appreciate that, in some instances, local price negotiations will already be at an advanced stage and that provision of the ICT may therefore add little or no value. Where this is the case, we would ask that this is stated in the email requesting that the study is brought under HRA Approval and your HRA assessor will take this into account (including by checking with the NHS organisations concerned, where appropriate).

Back to Contents

If no ICT exists for the study, this should be made clear in the email requesting that the study is brought under HRA Approval, as should whether local price negotiations are already underway, and your HRA assessor will contact you to agree a proportionate approach to supporting your local negotiations.

6.5 How is a site added after 31 March 2016? (revised 26 April 2016)

If a site in England has been listed on the original application but for which an SSI application has not been made applicants should request that their study be brought under HRA Approval.
The process is:

- Send an email to hra.approval@nhs.net with title "IRAS XXXXXX – request for study to come under HRA Approval".
- List and attach the current approved document set, ie the versions approved by REC and any other relevant approvals. This includes template agreements (where applicable) and for, commercial studies, the validated Industry Costing Template. Applicants will have this document set readily to hand and it enables a list to be confirmed in the HRA Approval letter.
- Non-commercial studies should include a template Statement of Activities and Schedule of Events for each site type being added to the study. If your lead NHS R&D office is outside England please email hra.approval@nhs.net for advice.
- Confirm if the study has previously applied to NIHR CSP or to a national coordinating function in Northern Ireland, Scotland or Wales.

The HRA Assessment Team will very briefly review the study to ensure legal compliance (we would not expect there to be any issues but NHS sites will need this assurance) and issue a HRA Approval letter to enable applicants to set up the new site.

If a site was not listed on the original application or approved by a subsequent amendment then this will be handled through the amendments process, either by substantial or non-substantial amendment dependent on study type.

Studies that were approved under pre-HRA Approval systems and running currently in the NHS should not raise any compliance issues, so there should be no need for a separate Initial Assessment, and the HRA will issue the HRA Approval to provide assurance to the NHS participating organisations.

6.6 What is the process for working with NHS sites in England for studies processed through pre-HRA Approval systems? (New 26 April 2016)

The activities to be undertaken will depend on the stage that site set-up has reached under the previous systems, and it is important that the sponsor and site avoid duplicating activities already undertaken, whilst ensuring that the steps of assessing, arranging and confirming capacity and capability are completed as appropriate to the study.

In order for the HRA to issue HRA Approval for the new NHS sites in England, you will need to request this from the HRA, see 6.5 above.

If the site was listed in the original application to the REC, no amendment is required, and the local information package can be provided once the request for HRA Approval has been made, but the site cannot issue its confirmation of capacity and capability until HRA Approval has been issued.

Back to Contents

If the site was not listed in the original application to the REC, you will need to submit an amendment as well as requesting HRA Approval for the study. The applicant should send the local information package to the new site with the amendment categorisation email, once the request for HRA Approval has been made. The new site will need to wait for HRA Approval and the appropriate amendment categorisation and approval before confirming capacity and capability to undertake the study.

6.7 How is a PIC added for studies processed through pre-HRA Approval systems? (New 26 April 2016)

A PIC is added in the same way as a new site is added. The applicant should request HRA Approval for the study See 6.5 above. A template statement of activities and schedule of events for the PIC activities will be required as part of the application.

If the use of PICs was not previously described in the application this should be submitted as a substantial amendment.

6.8 I have submitted an amendment to the study whilst waiting for HRA Approval for an existing study. Does this HRA Approval letter also provide approval to my submitted amendment? (New June 2016)

No, in most cases the amendment that you submitted will be categorised and assessed in addition to the issuing of HRA Approval for the study, and you should receive notification of this separately. The amendment should not be implemented until the assessment of the amendment has been confirmed.

However, if the amendment you submitted **only** added new sites (hence the study will be brought under HRA Approval), you may provide the local information pack to sites upon receipt of the HRA Approval letter, and do not need confirmation of the assessment of the amendment as well. You only need to provide new NHS sites with the HRA Approval letter.

6.9 I have submitted an amendment to an existing study in order to add new sites and bring the study under HRA Approval. Do I need to wait for confirmation that the amendment has been assessed as well as for the HRA Approval letter before I can provide the local information pack to the sites? (New June 2016)

No, you may provide the local information packs to sites upon receipt of the HRA Approval letter, and do not need confirmation of the assessment of the amendment as well. You only need to provide new NHS sites with the HRA Approval letter.

6.10 I have brought my study under HRA Approval but now need to set up more new sites. Can I just set these up using the HRA Approval letter? (New June 2016)

You can only set up new sites that have been identified through either the initial application to the REC, or through an amendment (substantial amendment for CTIMP, non-substantial amendment for non-CTIMP) processed through a previous system or through the HRA.

Back to Contents

7 HRA Approval for studies which have an existing UK Study Wide Governance review

7.1 Why does HRA need to assess studies that already have a UK study-wide review? (New June 2016)

Where a study has already completed a UK study-wide review, the HRA will undertake a proportionate process to issue HRA Approval. Based on experience of reviewing these studies, the HRA has determined that it would be disproportionate to reassess a study that has already completed a study-wide review. New NHS sites in England can be set up in accordance with the HRA Approval process, and NHS organisations can take assurance from the HRA Approval issued for the study.
Applicants should provide copies of all the current documents when requesting HRA Approval, but the HRA will not provide a list of the version numbers to sites, as it is the sponsor's responsibility to ensure that sites are provided with the current approved documents.
For non-commercial studies, applicants should also provide the template Statement of Activities and Schedule of Events. However, in order to minimise delay in issuing HRA Approval for these studies, the HRA will not review these, because many of the new sites will already have been liaising with sponsors about site set-up prior to 31 March 2016.

7.2 The HRA has not version numbered the Statement of Activities or Schedule of Events for my non-commercial study that has previously had a study-wide review. Should I use them with participating NHS organisations in England? (New June 2016)

Where a study has previously completed a study-wide review, many of the new sites being set up under the new arrangements will have previously started on the previous site set-up processes. In recognition of this historic activity, HRA is taking a proportionate approach to allow site set-up to be completed. These documents provide a starting point for NHS organisations to arrange capacity and capability, and are still the mechanism by which to complete the study set up at any new participating NHS organisations in England. Any changes that are appropriate to the content of the Statement of Activities and HRA Schedule of Events should be agreed in a pragmatic fashion between the sponsor and NHS organisation.

Participating NHS organisations in England should not request version numbered copies of these documents; instead they should work with the sponsor to arrange and confirm capacity and capability on the basis of the Statement of Activities and Schedule of Events provided.

7.3 I am a participating NHS organisation in England and have just received the HRA Approval letter titled Letter of "HRA Approval for a study with an existing UK study-wide review" from the sponsor. How should I handle this study and confirm agreement to host the study? (New June 2016)

These studies should not be handled or agreed any differently from other HRA Approval studies. NHS organisations should still assess, arrange and confirm their capacity and capability. Agreement will be confirmed by either execution of the agreement used by the sponsor or confirming by email the contents of the Statement of Activities. Further information can be found here.

Back to Contents

7.4 This HRA Approval letter for a study with an existing UK study-wide review does not provide any information to aid study set up. How can I set up the study at my NHS organisation in England without this information? (New June 2016)

Generally, studies being issued HRA Approval in this way are quite advanced in study set up at NHS organisations in England. As such, the usual information provided in the HRA Approval letter in this scenario is likely to have already been discussed and agreed between the sponsor and participating NHS organisation in England. The sponsor and NHS organisation should continue to set up the study under HRA processes, as described above.

8 R&D functions

8.1 What will be the role for NHS R&D offices once HRA Approval is implemented, and how can they be "ready for HRA Approval"? (revised 31 March 2016)

The document "Research support functions following HRA Approval implementation" describes the functions that R&D offices in England might undertake in order to support research delivery in their organisation. There is an equivalent document for primary care R&D offices, developed by the R&D Forum Primary Care Working Group called "Local support functions in primary care R&D offices following the implementation of HRA Approval".

R&D offices are encouraged to use these documents to review and revise their systems to ensure they are "ready for HRA Approval".

Through their Study Support Service, the NIHR Clinical Research Network (NIHR CRN) already provides resources for many of these functions for studies that are part of the NIHR CRN Portfolio. We are working in partnership with the NIHR CRN as they define and communicate the local activities that will complement HRA Approval, specifically the tasks funded and performed by the NIHR CRN and those that will be supported by the NHS. The NIHR CRN have produced documents to support a consistent approach to assessing, arranging and confirming local capacity and capability to participate in the study.

HRA seconded regional Change Leads to support NHS organisations in preparing for the implementation of HRA Approval. With full implementation, the change leads have returned to their other roles. HRA will continue to provide training and support with embedding the changes. If you are still working on making change happen within your organisation and require further support please contact HRA Approval Change Manager Jennifer.harrison2@nhs.net.

We will continue to use HRA Approval change contacts in individual NHS organisations in England as a key point for communication.

In addition, we are working with the NIHR Champions for Research Support, CRN RM&G Leads and CRN Study Support Service Leads to facilitate local discussions around HRA Approval.

Back to Contents

8.2 How will this affect the roles of NHS R&D staff and research governance staff in networks?

The HRA's plans have been developed to support the efficient approval of research. HRA Approval will allow CRN funded staff to focus on research delivery and management. Similarly, the new service will be of value to Trusts in enabling resources for research to be focussed on the successful set up, recruitment and delivery of health research. The functions which NHS based R&D staff can offer to support research delivery are described in "Research support functions following HRA Approval implementation".

Although HRA Approval will remove the burden from local organisations of some activities currently involved in local NHS Permission, these activities are only a small part of what CRN and R&D staff currently do. Many R&D and CRN staff are focussed on supporting researchers in assessing site capacity and capability, negotiating arrangements with local staff and overseeing the set up and delivery of studies. In addition, staff may undertake sponsor activities, manage funding for grants, support costs and infrastructure, develop researcher capacity through training and professional development, encourage and enable patient and public involvement and engagement in research, and support the development and implementation of innovation. Freed from the governance burden of NHS permission, local staff will be able to devote more time to these vital activities. Further information around how these activities are supported through NIHR CRN can be found at www.crn.nihr.ac.uk.

8.3 R&D staff currently deliver training on research regulation. Will this training still be needed?

Yes, HRA Approval does not remove the role of research management and support staff in delivering such training on regulations and other aspects of research. Research management staff supporting NHS organisations have a key role in advising and supporting researchers to help them to make high quality applications and in making sure that research delivery at their organisation remains compliant with the protocol and legislative requirements. It is expected that research sites will ensure that their staff have access to appropriate training, which can be delivered by a range of providers.

8.4 What RM&G funding will NHS organisations receive through the NIHR Clinical Research Network?

Through their Study Support Service, the NIHR Clinical Research Network (NIHR CRN) already provides resources for delivery of studies that are part of the NIHR CRN Portfolio. We are working in partnership with the NIHR CRN as they define and communicate the local activities that complement HRA Approval, specifically the tasks funded and performed by the NIHR CRN and those that will be conducted by the NHS. If NHS organisations have questions or concerns, they should direct them to their LCRN Chief Operating Officer in the first instance. Contact details are available on the Clinical Research Network website.

Back to Contents

8.5 How will research sites and participant identification centres know that they have been listed on an application for HRA Approval? Currently sites are informed through CSP for NIHR CRN Portfolio studies. (revised 31 March 2016)

NIHR CSP was a mechanism to facilitate study-wide and local review processes for issuing NHS permission. Study documents were submitted as part of applications to CSP for review by research governance staff. Sponsors or Chief Investigators were still expected to send documents to local research teams at participating sites. CSP did not provide a mechanism for transferring study documents to local research teams. Once HRA Approval has been fully implemented, CSP will be decommissioned.

As now, the responsibility for working with sites to assess site suitability and open studies will remain with sponsors, or their delegated representatives. Documents sent to study teams should be copied to local research management teams (and LCRN teams if the study is supported by the NIHR CRN Portfolio) so that they can actively support study set up.

Some study types will be able to proceed without special arrangements being put in place and the HRA may advise that confirmation of capacity and capability is not obligatory. Sponsors or their delegated representatives should still send the HRA Approval letter to sites where this applies but, in addition, the HRA will email R&D contacts as listed on the R&D Forum website to inform them of these studies.

8.6 Will NHS sites still need to give permission for a study to begin at their site? (revised 31 March 2016)

NHS organisations in England will not have a formal NHS review and permission process. Instead, research sites will work with sponsors to assess, arrange and confirm local capacity and capability to undertake a study. Once HRA Approval has been issued, research sites will be able to confirm with the sponsor their readiness to recruit and open the study through execution of the contract or agreement of Statement of Activities.

If a study led from England includes NHS sites in the devolved administrations, the existing process of submission of SSI Forms, local review and NHS permission continues to apply to the NHS sites in the devolved administrations.

Where the HRA assessment concludes that there is no requirement for NHS organisations in England to confirm capacity and capability, they can notify the sponsor that they are happy for the study to proceed before the end of 35 days, or wait 35 days. NHS organisations have 35 days to object to the study, after which time the sponsor can proceed once HRA Approval is in place, unless an objection is received. Sites should notify the sponsor and the HRA why the study cannot proceed.

8.7 What information is required to be recorded or held by sites for studies that do not require capacity and capability? (new 31 March 2016)

For certain study types, to provide proportionate arrangements, the HRA will advise that sites do not need to confirm capacity and capability or need to receive a local information package. For these types of studies the HRA expects NHS organisations to simply record basic details about the study, without needing to file a set of study documents.

Back to Contents

8.8 Will there be guidance on what NHS organisations should issue instead of NHS permission letters?

Yes. Participating NHS organisations in England should provide confirmation as outlined in the HRA Approval letter. This will usually be by mutual agreement of the Statement of Activities or by signature of the template agreement – this will be made clear in the HRA Approval letter. The HRA has provided a suggested template email that participating NHS organisations in England may like to use to accompany this agreement. The HRA expect such emails to be short and to the point, use the IRAS number as the study identifier, and have attached the relevant confirmed agreement/Statement of Activities (as described in the HRA Approval Letter).

8.9 Are NHS organisations expected to amend their SOPs to reflect HRA Approval? (revised 31 March 2016)

Yes. HRA have advised Trusts to have interim office processes or Standard Operating Procedures (SOPs), or addenda to existing office processes or SOPs during the phased implementation of HRA Approval.

With full implementation of HRA Approval, NHS organisations are advised to review and update office processes or SOPs.

8.10 What should I do if an organisation is not adhering to HRA guidance either as a sponsor and/or as a host NHS site? (new 26 April 2016)

NHS organisations and research sponsors are in the process of reviewing and updating processes or SOPs to align with the HRA guidance. This is a significant period of change for some organisations dependent on previous set-up of the research function. It will take time for all parties to adjust to the new system and test and refine their SOPs as the first studies come through.

Support is available from the HRA to help organisations understand the changes and embed the changes. If you become aware of an NHS organisation acting as a research site or a sponsor that is not adhering to the guidance you should contact the HRA Approval Change Manager jennifer.harrison2@nhs.net

.

9 Research in Primary Care

9.1 How does HRA Approval apply in a primary care setting? (new 26 April 2016)

The HRA, in collaboration with the RD Forum Primary Care Working Group, has described the key principles of working in Primary Care. The document provides an extensive number of examples to demonstrate the principles.

Back to Contents

10 Staffing

10.1 Who undertakes the HRA assessment? What training have they had? Where are they be based? (revised 26 April 2016)

HRA assessment is undertaken by operational staff employed by the HRA. A dedicated team of HRA Assessors has been recruited and trained in line with the phased implementation of HRA Approval throughout 2015 and early 2016. All staff employed have an agreed job description and possess key competencies and experience. The assessment will be supported by assurances about pharmacy and radiation provided by lead professional reviewers in the NHS.

HRA assessment staff are based within the HRA Centres (Bristol, Jarrow, London, Manchester, and Nottingham).

A suite of Standard Operating Procedures (SOPs) and guidance documents have been produced during the roll out of HRA Approval. These have been revised as necessary throughout the implementation. All HRA staff involved in assessment are trained in these SOPs and their performance is measured against defined standards. Training has been provided for each phase of the roll out and for any revisions made to the SOPs and guidance documents.

11 IT systems

11.1 What changes are being made to IRAS?

IRAS is being developed iteratively to support HRA Approval. The most obvious change is that the REC and NHS R&D forms have been combined into one form. Applicants are strongly recommended to review the information on updates to IRAS whenever they log in to ensure they follow up to date processes.

11.2 Will implementation require changes to other systems that IRAS interfaces with? (revised 31 March 2016)

The NIHR CSP system has been closed to new submissions and in due course will be decommissioned.

11.3 I have started to complete IRAS for a new application, will the changes to IRAS mean I will need to start again? (new 31 March 2016)

No, if you have already started completing separate REC and R&D forms, you can easily convert the forms into a single IRAS form by following the instruction in IRAS.

11.4 What is the HRA Approval Portal? (new 31 March 2016)

The HRA Approval portal is a web-based portal which is provided by the HRA in order that NHS organisations can check the HRA Approval status of a study that they are participating in. The HRA Initial Assessment and HRA Approval letters will be available in the Portal for information. The Portal will not provide a complete set of documents – study documents should be provided to sites by the sponsor. The HRA Approval Portal is not the equivalent to the NIHR CSP Module. The HRA Approval Portal does not list which sites have confirmed capacity or capability, it provides the status of HRA Approval only.

Back to Contents

11.5 Who has access to the portal and how do I request an account?

R&D Offices have been offered the opportunity of requesting up to 2 user accounts per R&D office. We recognise that one R&D office may provide research management support to one or a number of NHS organisations (acute, community or primary care settings in CCG areas) but it is anticipated that use of the Portal will be occasional as for most studies NHS organisations will receive all the information they need from sponsors.

User accounts are granted to individuals and accounts must not be shared and each user will be required to sign up to terms and conditions of use. A user guide for HRA Approval Portal users is available.

Only R&D offices will be granted accounts. If an individual moves role or organization and no longer requires access, they should notify the HRA. The R&D office can make changes or request a new user account if individuals leave their role.

Back to Contents