

HRA Approval Update - October 2014

The HRA Approval implementation programme began in April 2014 following the funding decision confirmed by DH. Although a great deal of development and testing had gone in to the preparation of the proposals that were presented to DH in a business case in September 2013 the HRA did not have resources available to take forward the implementation phase until the funding was confirmed.

The HRA ambitions to streamline research governance through the HRA Approval programme are closely aligned to the ambitions of the original AMS review. HRA Approval will address issues raised with research governance in the review and as suggested by the review will build on the experience of transforming research ethics in the UK and success of IRAS as an IS platform UK wide.

This funding was awarded as part of the annual budget setting processes on 31st March 2014. The first stage in the implementation programme has therefore largely been about recruitment, planning and procurement. It is worth noting that the Approval Programme in practical terms will see the HRA recruit almost half as many staff again from the initial HRA headcount so the organisational impact and scale of the programme for the HRA should not be underestimated.

That said the HRA is pleased to announce that the early set up phases have proceeded extremely well and it is able to move now to a detailed planning phase for the roll out of HRA Approval. The HRA has listened that care is required to not create an impression of 'turmoil' within the UK. The HRA has deliberately not set dates for implementation whilst the dependencies of risks in the planning phases were not reasonably mitigated – specifically with respect to staff recruitment and IS procurement for further development on IRAS. There has though been significant progress in developing the components that will come together in HRA Approval that are also reported to the AMS. The Gateway review has been completed and the status recorded by the Gateway team was Amber '*Successful delivery appears feasible but issues require management attention. The issues appear resolvable at this stage of the programme/project if addressed promptly.*' The HRA accepts that this is an accurate reflection on current status where detailed planning and milestone setting have not been yet been possible, and that it has the resources to address the issues raised by the review team (they were not surprises) and is therefore in the position to proceed with some confidence on delivery.

1. *Planning phases update*

- Janet Messer has been appointed as Director of Systems and Development and has responsibility for the HRA Approval programme.
- Good progress with recruitment of the team for HRA Approval and wider HRA roles, including HRA Programme Management Office has been made
- The IS project to replace the Research Ethics Database (RED) with a new database HARP has been completed on time and within budget and is now in use UK wide.
- Procurement steps for further work on HARP and IRAS now completed and the company that delivered HARP is in place to develop these systems further as the platform for HRA Approval
- Contracting framework in place to enable specialist contractors to be recruited to support IS development

2. *HRA Approval – key messages*

As previously communicated there are a number of key messages and principles that will underpin HRA Approval. Although there is further detail to work up on the operational arrangements, these principles that have been communicated are not expected to change:

- There will be one application, one assessment and one Approval for research in the NHS in England which will include the REC opinion
- HRA Approval is for England, there is a commitment from all countries to maintain UK wide compatibility
- The one application will be provided from IRAS and will be a single IRAS application form (replacing the current separate REC and R&D forms) and this is an IRAS form (not an HRA Approval form) as this enables UK wide compatibility
- IRAS and HARP will be further developed to provide the IS platform for HRA Approval and the UK wide operational equivalents
- The HRA assessment is made up of a set of components: Contract assurance, technical assurance, compliance and delivery, participant interests and research passport assurance
- The HRA Approval Programme is a set of projects and programmes that will come together into the HRA Approval, the components will deliver improvement in specific areas ahead of full roll out
- The roll out of HRA Approval will be on a study type basis, not geography and there will be no more piloting or feasibility stages. It will be phased controlled roll out, with opportunities for learning and refinement during roll out.
- Expertise for technical assurances will be coordinated by the HRA but provided by the NHS e.g. pharmacy and radiation
- Assessors will be recruited in to the HRA as a dedicated HRA resource
- Funders with direct influence across the NHS will be used to support implementation e.g. Cancer Research UK
- The HRA is providing an interim resource via a small team of Application Managers to support applications that are particularly disadvantaged by the current processes e.g. rare diseases and will continue to do so until HRA Approval is rolled out for all studies

3. *HRA Approval – status updates*

- The single pharmacy technical assurance is now in active roll out through the experimental cancer medicine centre network, studies have now been through this first phase of roll out which is being managed in partnership between HRA and Cancer Research UK
- The single radiation technical assurance is following the same pathway of development as the pharmacy process. This has reached a common understanding with professional representatives to achieve compliance with legal requirements whilst removing vast amounts of duplication. The HRA expects to announce the start of the roll out shortly and if progress goes as currently planned it will be in next couple of months
- The information governance project has just started, Mark Taylor (also Chair of CAG) has been seconded to the HRA to lead this work which will develop standards for HRA assessment of information governance as part of the HRA Approval

- The HRA has issued a document describing what HRA Approval is not, but which outlines the research support activity that others within the Networks and NHS can deliver either side of the HRA Approval process. This has been welcomed to support early planning by the Networks and the NHS. The HRA has seconded a small team of change leads specifically to support the change in the NHS. These are a mix of Network and NHS staff very newly appointed to the HRA who met as a team for the first time last week
- The single validation point by existing REC staff has been tested and is ready to implement as HRA Approval is ready for roll out
- The package that will form the compliance and delivery assessment has been agreed UK wide, further consultation is required on a template through which the output of this assessment will be provided
- HRA is supporting the work on model contracts being led by Mark Lewis and will take responsibility for these in the New Year
- The implementation of a streamlined process for Research passports in primary care is due to take place after completion of preparation activities by NHS England
- Questions and Answers have been published by the HRA, providing specific clarification where it is available and setting out where it is not yet clear
- HRA has issued a call for named contacts in organisations to support communications and engagement, in recognition that existing cascading of messages does not always work well.

4. Application Managers

The service provided by the team is already making a significance difference across the NHS. The HRA has provided this additional interim resource in recognition that:

- Traditionally more resource has been absorbed by the poor quality (and potentially lower impact studies submitted to REC and the NHS)
- Some studies are particularly disadvantaged by current processes e.g. rare diseases
- The full potential of some important initiatives e.g. Participant Identification Centres have not been realised as they take negotiation on the ground
- There are some areas where an early HRA 'stamp of approval' to get the NHS thinking differently where it may be outside established practise now (usually not designed with the new situation in mind) will help prepare the NHS for the new culture and process of HRA Approval
- The controlled roll out of HRA Approval by study type will enable case study applications to be put through the new processes early. The case studies provided through this service will be useful for learning and demonstrating the potential of new thinking and new approaches

One such case study is provided for information below.

For other highlights from the HRA, please see our latest issue of HRA latest:

<http://www.hra.nhs.uk/documents/2014/09/hra-latest-volume-10-2392014.pdf>

and other issues on the website:

<http://www.hra.nhs.uk/about-the-hra/our-publications/#HRA>

Application Manager

'Complex' rare diseases case study:

Summary: RCT affecting pregnant women. Intervention of amnioinfusion vs standard management on pregnancy outcome and child's development. In addition to this there is a wish to collect data from a larger cohort of women to establish the prevalence of the condition.

Condition: Rare Disease affecting pregnancy, very early Preterm Premature Rupture of the Membranes (vPPROM)- can lead to cerebral palsy, blindness, deafness, language and cognition problems in children.

Setting: 150 District General Hospitals (DGH), 15 specialist Fetal Medicine Units (FMU).

Issue: As a rare disease a very large number of sites will need to be set up in order to ensure sample size is recruited. Sites may never see a patient but would need to be opened on the off chance a woman with the condition presenting; this is unduly burdensome.

AM Recommendation: DGHs set up as Patient Identification Centres and FMUs set up as full Research Sites using a hub and spoke model. Patients would be identified at DGH and then referred to FMU for consent, randomisation and intervention. Those in the control arm would receive standard treatment at their local DGH as per their routine clinical care.

This model allows only 15 'R&D approvals' rather than 165. The DGHs would require PIC agreement but this is a far less burdensome route in terms of administration for the research team.

The 'cohort' data collection should be a separate Research Database application as this would not require R&D approval from the data collection sites. This is possible as the data required are routinely collected clinical data.

Outcome: The AMs recommendations were accepted by the trial manager.

Feedback: *"HRA recent initiatives are unblocking barriers to trials and the excellent advice and support provided by the team during this period of change has been invaluable to this study"*

Dr Helen Hill:
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