Health Research Authority

HRA Latest, Volume 10

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HRA Approval Programme update

Following confirmation of funding to develop HRA Approval on 31 March, HRA have been actively recruiting to the HRA Approval Programme team. There are other posts to be filled across the HRA to support wider HRA functions and these are advertised on NHS jobs as they become available.
A summary of the HRA Approval Programme team members in post so far is available on the HRA website.

The HRA Approval Programme is working collaboratively with a wide range of stakeholders to refine the elements of the assessment HRA will undertake. We plan to phase in some components as they are developed before incorporating all the elements together within HRA Approval. Progress on some of the elements is set out below, and details of other areas will follow in subsequent newsletters. Our ambition is to start implementing HRA Approval for all studies by the end of 2015.

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Pharmacy and radiation

Working in collaboration with Cancer Research UK we have begun a controlled roll out of a streamlined pharmacy process across the Experimental Cancer Medicine Centres in the UK. Over the next few months we will assess the impact on study set up before progressing to national roll out.

Plans for a streamlined process for research involving ionising radiation are progressing with support from the relevant professional communities, and Cancer Research UK will again be supporting a controlled roll out with the Experimental Cancer Medicine Centres.

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Model contracts and agreements

As a result of implementation of the Care Act 2014, the Health Research Authority will acquire legal responsibilities for providing guidance on the principles of good practice in the management and conduct of health and social care research, and for facilitating the conduct of research that is safe and ethical. This is due to take place early in 2015. As part of these responsibilities, HRA will oversee the ongoing review of model contracts and agreements, ensuring that they continue to facilitate efficient and effective study set-up and conduct.

HRA acknowledges the extensive input on commercial contracts from Mark Lewis, in his capacity as an advisor to DH and subsequently NIHR, over many years. A managed handover from NIHR to HRA is underway and arrangements will be communicated, but Mark Lewis is leading the current review of the mCTA and completion of other model contracts for commercial research, and continues to be available in the meantime to provide advice on contractual issues, either directly for non-portfolio studies or via the CRN industry team.

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Information governance

We have started work on reviewing the issues relating to information governance that researchers are encountering in the NHS. HRA is able to draw on expertise from within its Confidentiality Advisory Group and will be working with NHS Caldicott Guardians and the NHS Information Governance Toolkit team.

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Supporting the NHS to prepare for the implementation of HRA Approval

The HRA is committed to supporting the NHS in preparing for the implementation of HRA Approval. In some areas of England, regional Change Leads will be seconded on a part time basis to HRA from 1 October 2014, each covering two or more Local NIHR Clinical Research Networks. In other regions we will be working with local NHS leaders to support the change and the main point of contact will be Jen Harrison, the HRA Approval Change Manager. Contact details for the team are available on the HRA website.

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HRA Approval questions and answers

From time to time HRA publishes answers to questions that have been raised with us about the HRA Approval programme. Edition 3 will be published soon and will be announced via Twitter. As the HRA Approval Programme is still in development stage we do not yet have the answers to all questions, so please return to the website regularly for updates.

If you would like to raise a question please email us at hra.approvalprogramme@nhs.net

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Research support functions following implementation of HRA Approval

HRA Approval will provide a single approval for research in the NHS that will incorporate assessments by NHS staff employed by the HRA alongside the independent Research Ethics Committee opinion.

This will allow decisions at local sites about participation to be made on local capacity and capability

alone.

In order to provide clarity about what activities the HRA will not be responsible for when HRA Approval is implemented, HRA has prepared a paper based on input from a range of stakeholders on "Research support functions following implementation of HRA Approval". The paper describes the arrangements that organisations may put in place locally to support effective research set up and delivery. The paper is now available on the HRA website [link].

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 will work 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 conducted by NHS Trusts.

We are also working with the Primary Care Working Group of the NHS R&D Forum to define the aspects that are particular to research in primary care settings.

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New HRA Board

The Care Act 2014 will establish the HRA as a non-Departmental Public Body, due on 1 January 2015. As part of this transition, we will formally become a new organisation with a new Board. Jonathan Montgomery will remain the HRA's Chair and the Department of Health will be recruiting to the four Non-Executive Director posts. The posts are due to be advertised on the Cabinet Office website at the end of September 2014. We will alert stakeholders via our website.

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Research Governance Framework update

The HRA is progressing a number of projects to inform the development of a new policy framework for research in the UK. A UK wide steering group is overseeing the work which will provide a new UK wide policy framework and enable the existing frameworks to be withdrawn in due course. The projects are being taken forward now to enable all stakeholders to comment on the development of the principles that will underpin the new policy framework. A detailed update on these key areas is available on our website.

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Revised recommendations on educational research released

Revised recommendations from a working group report on supporting educational research have been published.

Following a call for feedback earlier in the year on the report *How we best support research in the NHS – educational research*, the HRA has revised the report's recommendations.

Twenty-eight responses were received from 19 organisations and, though generally supportive and in praise of the report's proportionate and sensible approach, some areas of concern were identified,

such as the degree to which undergraduate students should undertake research which involves direct contact with patients. The report's recommendations were revised to take these into consideration.

The report originally came about to find ways to improve the quality of student research applications submitted to research ethics committees (RECs). An independent working group, chaired by Professor John Saunders, published the first version of the report for comment in March 2014. It is intended the recommendations will help to shape the development of future governance work in the area of student research.

The report's revised recommendations, and a summary of the responses received on the report are now available on the HRA website.

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Guidance on participant information at the end of a study

We have developed draft guidance on how and what information should be supplied to participants (including children and their parents/carers) at the end of a study.

It is aimed at those undertaking clinical trials and other interventional or diagnostic studies.

We welcome comments on these proposals from individual patients, researchers and research staff as well as from partners and stakeholders.

Please email Amanda.Hunn@nhs.net for further information or to submit your comments.

This guidance is open for comment until 30 September 2014.

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Transparency: HRA updates requirements for sponsor registration of clinical trials

The HRA is updating its requirements of sponsors in relation to transparency clinical trials, following comments on the recent HRA paper and feedback received at a workshop with stakeholders on 18 September 2014,

From 30 September 2014, we will require the sponsor to declare that all clinical trials approved by a NHS REC since 30 September 2013 have been registered (or the HRA has granted a deferral that is still valid) in order to comply with the condition of their favourable ethical opinion. This will provide a checkpoint for the HRA to review the records of previous studies to ensure registration details are complete and, where a request to defer registration has been accepted, that the deferral period still applies.

For sponsors who have complied with the previous REC condition on Clinical Trials from September 2013, no further action will be required.

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New IRAS helpline number: 0207 043 0734

From 14 September, the number of the IRAS helpline will change to 0207 043 0734. Please update your records, including internal guidance, to reflect this new number

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It's all in a year's work – HRA training

The HRA offers a wide range of training, with courses available for internal staff, committee members and the wider research community. Our courses range from introductory courses on legislation relating to research, to advanced training for experienced members on specific ethical contexts, as well as training days designed to help researchers prepare to apply for ethical approval. We also offer job-specific training in specialised areas for our staff'

Did you know that last year:

- More than 90 training days were organised by our training team
- Almost all the training was delivered at our own training facilities at the HRA offices in Bristol, Jarrow, London, Manchester and Nottingham.
- Experts from within the HRA and the Research Ethics Community delivered the training
- We collaborated with other organisations to design and deliver training, including the Medical Research Council, National Institute of Clinical Research, and the GCP Ethics Forum
- 93% of our training days last year were evaluated at 80% satisfaction or more; 57% achieved satisfaction levels between 90% and 99%.

"Facilitators were brilliant. All speakers were engaging with excellent delivery. Very informative, useful and highly applicable to daily practice. Lots of hints and tips to take away. The day manages to succinctly deliver what is essentially a huge topic into a one day session".

Researcher training day feedback

To find out more about HRA training, both for members and for the wider research community, go to Training on the HRA website. The training often books up very quickly – put a reminder in your diary to check our website once a month so you don't miss anything of interest!

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Web survey

As part of our programme of continuous improvement, we are conducting a research survey with users of our website. The results of the survey will help us improve our website, and tailor it better to users' needs.

If you would like to complete the survey, simply click on the link below or cut and paste the entire URL into your browser to access the survey:

https://www.surveymonkey.com/s/HRAwebsurvey2014

We estimate that it will take up to 10 minutes to complete the survey, and will close it for responses on Friday 10 October.

All input is very important to us and will be kept strictly confidential (used only for the purposes of research for this project).

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Please circulate this to your colleagues; if you wish to subscribe or unsubscribe to HRA communications, please email hra.comms@nhs.net