Health Research Authority

HRA Latest, volume 8

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News

Annual Review, 2013-14 and Business Plan, 2014-15

We will shortly be publishing our Annual Review for 2013-4, and we will circulate this to you when it is released. This will outline our performance and achievements across our full range of activities during 2013-14.

For details on our plans for 2014-15, please see our Business Plan for 2014-15, which we have also published recently.

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Developing the plans and timetable for implementation of HRA Approval

We were awarded funding on 30 March, so we are now at the start of a recruitment programme to build the team that will develop our plans and timetable. In the meantime, we can share our plans for the approach we will take. There are three key elements to this:

1. Implementing single technical reviews for pharmacy and radiation
2. Developing interim policies to address known difficulties in the approvals system for specific study types (including rare diseases and cell therapy)
3. Phasing the implementation of HRA Approval by study type, starting with health services and primary care research during the course of 2014

The first two components will, in due course, be incorporated into full implementation of HRA Approval for all studies. We are aiming to achieve this by the end of 2015.

We are working collaboratively with the Experimental Cancer Medicine Centres across the UK, supported by Cancer Research UK, to implement a single technical review for pharmacy starting in the summer. This will provide a controlled roll-out at a national level of the coordination of the process through HRA and will also assess the impact on study set-up, following piloting in north London. More details of the other elements will follow in future editions of this newsletter.

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Recruitment for the HRA Approval

We are about to open the second round of applications for new posts that will take forward the development of our plans for the HRA Approval programme. These will be released on 16 June, for application by 27 June and includes a range of IT and change management roles. We are looking for people who are knowledgeable about health research systems and regulation, with excellent change management skills, to be part of this important programme. These will be a combination of fixed-term and secondment posts, and there will be both full- and part-time opportunities.

All posts will be advertised on (and must be applied for through) NHS Jobs, where you can also register for updates on all our vacancies.

Phase 2 roles

Post	Closing date	Interview date
Change Manager (Band 8b [TBC], 2 year fixed term)	27 June	TBC
Project Lead – Systems and Information (Band 8a, Permanent)	27 June	TBC
Business Analyst (Band 8a [TBC], 2 year fixed term)	27 June	28 July
Software Test Manager (Band 8a, Permanent)	27 June	10 July
Finance Manager (Band 7, Permanent)	27 June	9 July
Technical Documentation Specialist (Band 7, Permanent)	27 June	14 July
HRA Public Involvement Coordinator (Band 5, Permanent)	27 June	15 July
Configuration Control Manager (Band 7, 2 year fixed term contract)	27 June	11 July
Change Leads (x10) (Bands 7-8b, 1 year fixed term secondment)	27 June	TBC

To keep up to date with the latest developments on the HRA Approval, please follow us via @HRA_Latest – we will tweet every time we update our website about the HRA Approval, as well as tweeting our vacancies as they are published.

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New policy framework for research in the UK

Upon becoming a Non Departmental Public Body (NDPB), the HRA will take responsibility from the Department of Health for issuing guidance relating to research in England, in place of the Research Governance Framework (RGF). Work is ongoing to ensure that a set of high level principles for good research is ready for consultation in late 2014 with a number of key areas being explored.

We need comments, until **4 July**, on two key projects:

- What are the risks to research because of perceived risks of research?
- Risks in research: serious breach notifications and safety reporting

These can be from individuals or organisations, and it is important we capture as wide a range of views as possible. We will use the feedback on these projects to shape our new draft framework, so the more comprehensive the views we receive now, the more informed this will be.

The comment period for the report considering 'What research can the NHS support?', developed by an independent working group, has now closed. We are currently drafting a response to the recommendations made by the working group, taking into account any comments received, before this response is reviewed by the RGF Steering Group ahead of HRA Board consideration in July.

The range of work currently being undertaken, with the proposed comment periods, in the table below:

Project	Activity	Timeline / Status
What research can the NHS support?	Comment period	Complete
	HRA response to report and comments	July 2014
Social Care	Scoping exercise	Ongoing
What are the risks to research because of perceived risks of research?	Comment period	**Closes on 4 July 2014**
Risk in research: serious breach notifications and safety reporting	Comment period	**Closes on 4 July 2014**

Perception of risk in research by REC members	Comment period	August 2014
Proportionate consent processes	Comment period	June – September 2014

Formal 40 day consultation on the guidance to replace the RGF will take place once the HRA has become an NDPB. For more information on our plans, please see the HRA website.

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Registration of Clinical Trials – we need to hear your experiences

Since the end of September 2013, the registration of clinical trials in a publicly accessible database has been a condition of the favourable REC ethical opinion. For all REC approvals of clinical trials moving forwards, failure to register is therefore a breach of good research practice. In September we stated that we would at a future point seek to understand any difficulties to such registration.

As this requirement has been in place for a few months, the HRA would appreciate feedback on any barriers in the registration of clinical trials that researchers /sponsors have encountered so that developments might be taken forward with Trial Registries over the coming period (and before the introduction of the EU Clinical Trial regulations, expected to be adopted in 2016-17).

Specific examples of issues encountered would be particularly useful, and all responses should be sent to tom.smith2@nhs.net by end of July 2014.

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Registration and reporting – comments period extended to allow further feedback

We are seeking comment on our proposals to use the sponsor declaration to RECs as a mechanism to check:

- Compliance with REC favourable opinion conditions which required clinical trial registration
- The registration of clinical trials in active recruitment in the UK.

Responses can now be submitted to tom.smith2@nhs.net until 28 July 2014

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Submitting applications for ethical review is now more streamlined

On 19 May 2014, we made some important changes to the way that applicants book and submit applications for ethical review. These changes apply to applications to NHS/HSC RECs across the UK, including the Gene Therapy Advisory Committee (GTAC), and to the Social Care REC. They also apply to applications for site specific assessment for non-NHS sites.

There are three key elements to these changes:

- **Booking** - The previous booking allocation systems have been replaced by a single Central Booking Service (CBS) so applicants use the same number to book regardless of the type of study. Note: Phase 1 research may still be booked direct with a local REC and social care researchers should still book their applications direct with the Social Care REC.
- **Submission** – The application form and all supporting documents are now submitted electronically direct from IRAS to the REC. Electronic authorisation is now mandatory for these forms, and they are entirely prepared for submission online in IRAS.
- **Timing of booking and submission** – Applicants must now submit their form and relevant supporting documents on the same day as they book their application for ethical review.

Click here for more information.

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HRA online guidance on Consent and Participant Information Sheets

The updated, final version of the online guidance for consent and participant information sheets was published in April. This updated version has been developed in the light of comments and feedback we received during the consultation-in-use phase and includes further examples and links as well as an option to download content in pdf format. In the coming months, the HRA will be issuing a consultation on proportionate consent processes – please check our Consultations page for more information.

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EU Clinical Trials Regulation published

On 27 May 2014, the European Clinical Trials Regulation was published in the Official Journal of the EU. The Regulation, which streamlines the authorisation process and harmonises requirements for clinical trial in the Europe, will require a single decision per Member State involved in the trial instead of the current, separate approvals given by MHRA and research ethics committees. The MHRA and HRA worked closely together during the negotiation of the Regulation and will continue to do so in preparation for its implementation. Click here for more information.

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