Health Research Authority

HRA Latest, volume 7

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HRA business plan approved, including new funding for HRA Assessment and Approval

We are delighted to announce that, on 31 March 2014, Earl Howe, Parliamentary Under-Secretary of State for Quality, announced additional investment for the HRA Assessment and Approval (full details in the press release).

This will provide a single approval for research in the NHS across all study types that will incorporate assessments by NHS staff 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. The process will be coordinated with those in the devolved administrations and with other regulatory approvals to unify the approval process for research in the UK. HRA Assessment and Approval will be available to both NIHR portfolio studies and non-portfolio studies in England.

It will also give the UK a platform for delivering the EU clinical trials regulations – the UK will not just be ready, Assessment and Approval will provide confidence in that readiness.

Detailed information is provided in a Questions & Answers document.

The HRA Assessment and Approval is supported by a wide range of stakeholders

The new system will simplify the approvals process for research, making it easier for research studies to be set up. It provides approval for the NHS and allows resources to be focussed on successful local delivery. Patients will benefit from research funding being dedicated to the delivery of research rather than being wasted in navigating approval systems. By removing duplication of reviews of research by NHS support teams, the NHS will be freed up to focus on delivering research.

The HRA summary plans for Assessment and Approval give more details on our plans.

The HRA has already started work to plan and implement these proposals; further details will be circulated in due course. The implementation approach will be to roll out on a study type basis. Starting with non-clinical studies, we will then be moving to specific clinical studies (e.g. in primary care and rare diseases) with full implementation by late 2015.

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NHS REC Booking and submission changes, Spring 2014

Changes to booking, submission and authorisation to NHS RECs from Spring 2014

The HRA will be changing the processes for applying to NHS Research Ethics Committees (RECs) in Spring 2014 to improve its service and make the booking and application process more straightforward for researchers. The key changes that will be introduced are as follows:

NEW Central Booking Service (CBS) for applications to NHS RECs

A new national Central Booking Service (CBS), with a single number, will be introduced, to cover all bookings for RECs in the UK. This will replace the existing Central Allocation System (CAS), Proportionate Review Allocation Systems (PRAS) and Local Allocation Systems (LAS). It will result in a more efficient allocation of applications across meetings. Researchers will still be able to book to the REC of their choice for full applications when using CBS.

Phase 1 studies may be booked via CBS or direct with the NHS REC.

Mandatory electronic authorisation for declarations on NHS REC forms

All forms created in IRAS for submission to NHS RECs must be authorised using the electronic authorisation (e-authorisation) functionality in IRAS from 28 April 2014.

To electronically authorise an application, the person authorising must have an IRAS account. Please check whether the people that you ask to authorise your applications have IRAS accounts; if they have not, please set them up as soon as possible to prepare for this change.

Electronic authorisation must be completed in advance of booking a REC.

NEW Introduction of electronic submission to NHS RECs

All forms created in IRAS for submission to NHS RECs, except notices of substantial amendment, which should be submitted by e-mail, will be submitted electronically from IRAS.

The NHS REC form (including GTAC, Social Care REC, Research Tissue Bank and Research Database variants) and non-NHS Site Specific Information (SSI) forms and their

associated supporting documentation will be electronically submitted by the applicant from IRAS to the REC system. This will remove the need to submit hard copies.

Electronic submission must be completed on the same day as the booking is made. So applicants must ensure that their application is ready to submit (i.e. form checked, supporting documents attached and electronic authorisations in place) before phoning to book their application. Any pre-submission advice should continue to be sought from local HRA REC Offices.

Notice of substantial amendment forms will still be created in IRAS when these changes are implemented but they will not be electronically submitted. Submission of these forms will continue to be via email.

Assistance will be available from REC Centres to support researchers with these changes

Preparing for these changes

We strongly recommend that you check as early as possible that anyone you will need to ask to authorise an application has an IRAS account. If they need to set up an account, they should complete the simple form to register.

The webpage, http://www.hra.nhs.uk/research-community/booking-submission-changes-spring-2014/, will be regularly updated in the run-up to these changes.

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New policy framework for research in the UK

When the HRA becomes a Non-Departmental Public Body (NDPB), which is expected in late 2014, it will take responsibility from the Department of Health for issuing guidance for research in England, in place of the Research Governance Framework (RGF). The current version of the RGF will be withdrawn when the new framework is published.

Work is currently ongoing to ensure a set of high level principles is ready for consultation in late 2014 with a number of key areas being explored. Comments are currently being sought on an independent working group's paper concerning 'What research can the NHS support?'

To review the paper and comment on the recommendations please follow the link below: http://www.hra.nhs.uk/about-the-hra/consultations-calls/educational-research/.

The full areas of work currently being considered are detailed below along with the timings for the comment periods:

Project	Activity	Timeline
What research can the NHS support?	Comment period	17/3/14 – 11/4/14 **ACTIVE**
Social Care	Scoping report developed	11/04/14
What are the risks to research because of perceived risks of	Comment period	26/5/14 – 20/6/14

research?		
Risk in research: serious breach notifications and safety reporting	Comment period	26/5/14 – 20/6/14
Perception of risk in research by REC members	Comment period	26/5/14 – 20/6/14
Proportionate consent processes	Comment period	1/8/14 – 1/9/14

Formal 40 day consultation will take place once the HRA has become an NDPB.

For more information on this work please see the HRA website: http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/replacing-research-governance-framework/

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Compliance and good clinical practice

The HRA is committed to promoting good quality research managed in accordance with approved protocols by suitably qualified, trained and experienced individuals. To help achieve this aim, we are undertaking a piece of work looking at non-compliance with protocol and standard operating procedures.

Whilst individual protocol deviation, violation, serious breach and instances of non-compliance with the principles of good clinical practice are reviewed by Research Ethics Committees on an individual basis, we are also now looking at the information on a more general level. This work aims to identify common themes and trends which can be translated into key messages and learning outcomes to feedback to the research community and other key stakeholders. The hope is that by undertaking this work, the HRA can highlight common issues, work with stakeholders to develop pragmatic and proportionate ways to improve the regulation of research and therefore promote public confidence in research.

We intend to share the outcome and would also welcome the opportunity to work more closely with stakeholder groups to ensure that key messages are reaching all relevant groups and to allow the opportunity for continued discussion and consultation. If you would like to know more about this piece of work, please contact Catherineblewett@nhs.net.

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Case study: University and NHS Trust benefits from the joint HRA/NRES-HTA scheme for Research Tissue Banks

The HRA's National Research Ethics Service has a long-standing agreement with the Human Tissue Authority (HTA) to provide improved processes for the establishment of Research Tissue Banks (RTBs). Professor Nalin Thakkar, Associate Vice-President of the University of Manchester, and Consultant Histopathologist at Central Manchester University Hospitals NHS Foundation Trust, talks to the HRA about the benefits of this joint approach.

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2014 HRA Stakeholder Forum

Our Stakeholder Forum this year focused on our plans for 2014-15 and beyond, and how these will benefit health research in the UK. Whilst this was by invitation only, we have published the presentations on our website.

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R&D Forum – In association with the HRA

We have worked with the R&D Forum to integrate workshops on sponsorship, study set-up, the use of data, risk in research and an ethical debate, as well as our plans for 2014-15 into this annual event. The result, we hope, is a Forum which will offer more content and therefore better value than ever.

Click here to find out further details and to book

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EU Clinical Trials Regulation pass major hurdle

On 2 April the EU Clinical Trials Regulation was voted through by the European Parliament in Brussels. The next steps are a vote in the EU Council and publication in the Official Journal, but this was one of the last major hurdles for the regulation.

The HRA Assessment and Approval will provide the platform for ensuring the UK is prepared, enabling industry can plan to place studies with continued confidence in UK readiness.

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New HRA website – your feedback needed

The new HRA website has been live for almost six months, and we would like to know what you think. Please complete this survey, which will give you an opportunity to compare it with the previous site (if you had visited it), and to recommend improvements to us.

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New website for The Over-volunteering Prevention System (TOPS)

A new TOPS website will be launched at the end of May/early June 2014 following consultation with the Phase 1 research community. Data currently entered into the existing TOPS database will be migrated onto the new website. There will be some changes to the new system, such as issuing an individual username and password for each TOPS user. The new system will also ensure that the volunteer data will only be retained for the minimum period required. A summary of the changes and an updated user guide will be circulated to all TOPS users once the launch date of the new site has been confirmed.

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New look Social Care Ethics Committee website

The new look website of the Social Care Research Ethics Committee is now live. The site has been redesigned to allow for a more user-friendly experience with easy-to-use navigation and updated content. The national Research Ethics Committee, hosted by the Social Care Institute for Excellence, reviews adult social care research studies from researchers based in England in order to protect the dignity, rights, safety and well-being of research participants and facilitate ethical research.

Visit the new Social Care Research Ethics Committee website here
http://www.scie.org.uk/research/ethics-committee/

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